U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(szs)
FOLDER:	K103184 - 354 pages
COMPANY:	HOME SKINOVATIONS LTD. (HOMESKIN)
PRODUCT:	LIGHT BASED OVER-THE-COUNTER HAIR REMOVAL (OHT)
SUMMARY:	Product: SILK'N FLASH N GO
DATE REQUESTED:	Apr 19, 2012
DATE PRINTED:	Apr 19, 2012
Note:	Printed

K103184

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Home Skinovations Ltd.

Silk'n Flash N Go

NOV 1 0 2010

This summary of safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

Submitter's information

Name:	Home Skinovations Ltd.
Address:	Apolo building, POB 533, Yokneam 20692, Israel
Contact:	Dr. Amir Waldman VP Regulatory Affairs

Device information

Trade/Proprietary name:	Silk'n Flash N Go
Common/Usual name:	Light based hair removal device
Classification name:	Laser surgical instrument for use in general and plastic surgery and in dermatology (21CRF §878.4810)
Product code:	GEX

Predicate devices

- Flash N Go (K082298), by Home Skinovations Ltd.
- TRIA Laser Hair Removal System (K090820),by Tria Beauty, Inc.
- EpiLight and PhotoDerm HR (K991935), by ESC Medical system Inc.

Intended use:

The Flash N Go device is an over the counter device intended for the removal of unwanted hair. Flash N Go is also intended for permanent reduction in hair regrowth defined as a long-term, stable reduction in hair counts following a treatment regime.

Device Description:

The Flash N Go hair removal system is a pulsed light system composed of a base unit and hand held applicator.

Performance data:

The device complies with the following U.S. Food and Drug Administration performance standards: 21CRF § 1040.10 & 1040.11. Clinical data was collected in a prospective multisite clinical study.

Substantial Equivalence:

The Flash N Go system is substantial equivalent to its predicate devices. The data in this 510k submission demonstrate that the Flash N Go system is identical to the cleared Flash N' Go, and shares the same intended use as other predicate devices. Therefore is substantial equivalent to its predicate devices. Details are provided in Substantial equivalent section of this submission.

Based upon an analysis of the overall performance characteristic for the device, Home Skinovations Ltd. believes that no significant differences exit. Therefore the Silk'n Flash N Go should raise no new issues of safety or effectiveness.

October 21, 2010

Date

Dr. Amir Waldman,
VP Regulatory Affairs
Home Skinovations Ltd.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Home Skinovations Ltd.
% Dr. Amir Waldman
Vice President, Regulatory Affairs
Apolo Building, P.O. Box 533
Yokneam 20692, Israel

NOV 10 2010

Re: K103184
Trade/Device Name: Silk'n Flash N Go
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: OHT
Dated: October 21, 2010
Received: October 29, 2010

Dear Dr. Waldman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K103184

Device Name Flash N Go

Indications For Use: NOV 10 2010

Flash N Go is an over the counter device intended for the removal of unwanted hair.

Flash N Go is also intended for permanent reduction in hair regrowth defined as a long-term, stable reduction in hair counts following a treatment regime.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over The Counter Use_X_
(Per 21 CFR 801.109)

Neil R. Ogden for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

(Optional Format 1-2-96)

510(k) Number K103184

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Home Skinovations Ltd.
% Dr. Amir Waldman
Vice President, Regulatory Affairs
Apolo Building, P.O. Box 533
Yokneam 20692, Israel

NOV 1 0 2010

Re: K103184
Trade/Device Name: Silk'n Flash N Go
Regulation Number: 21 CFR 878.4810
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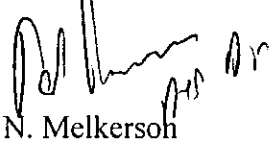
Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K103184

Device Name Flash N Go

Indications For Use:

NOV 10 2010

Flash N Go is an over the counter device intended for the removal of unwanted hair.

Flash N Go is also intended for permanent reduction in hair regrowth defined as a long-term, stable reduction in hair counts following a treatment regime.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over The Counter Use X
(Per 21 CFR 801.109)

Neil R. Ogden for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103184

(Optional Format 1-2-96)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center ¿ WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

November 01, 2010

HOME SKINOVATIONS LTD.
APOLO BUILDING POB 533
YOKNEAM ILLIT
ISRAEL 20692
ATTN: AMIR WALDMAN

510k Number: K103184
Received: 10/29/2010
Product: SILK'N FLASH N GO

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm
for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

HomeSkinovations

Apolo building
POB 533
Yokneam 20692
ISRAEL
Tel: +972(4)9097440
Fax: +972(4)9097471

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

510(k) Submission for Silk'n Flash N Go

Home Skinovations Ltd.
October 21, 2010

K-5

Silk'n Flash N'Go
510(k) Notification

Table of contents

*Appendix 1 contains the Flash N Go (cleared) submission and all communication with the FDA.

Chapter 1

Medical device user fee cover sheet (form FDA 3601)

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: **MD6052074-956733** Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) Home Skinovations Ltd. Apolo Buld POB 533 Yokneam 20692 IL 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)	2. CONTACT NAME Yoram Sadeh 2.1 E-MAIL ADDRESS yorams@silkn.com 2.2 TELEPHONE NUMBER (include Area code) 972-49097476 2.3 FACSIMILE (FAX) NUMBER (include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] Annual Fee for Periodic Reporting (APR)	[ ] Real-Time (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

$4,348.00 06-Oct-2010

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

Chapter 2
CDRH Premarketing Review Submission Cover Sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
October 21, 2010	MD6052074-956733	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Home Skinovations Ltd.	3006948334		
Division Name *(if applicable)*	Phone Number *(including area code)*		
	+972-547404616		
Street Address	FAX Number *(including area code)*		
Apolo building POB 533	+972-49097471		
City	State / Province	ZIP/Postal Code	Country
Yokneam Illit		20692	ISRAEL
Contact Name			
Amir Waldman Ph.D.			
Contact Title	Contact E-mail Address		
VP regulatory affairs	amirw@silkn.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	Phone Number *(including area code)*		
Street Address	FAX Number *(including area code)*		
City	State / Province	ZIP Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

PSC Graphics (301) 443-1090 EF

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*:

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	GEX	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K082298	Flash N Go	Home Skinovations Ltd.
2	K090820	TRIA Laser Hair Removal System	Tria Beauty Inc.
3	K991935	EpiLight and PhotoDerm HR	ESC Medical system Inc.
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Laser Instruments, Surgical powered- general and Plastic Surgery - Class II, 79 GEX

	Trade or Proprietary or Model Name for This Device	Model Number
1	Silk'n Flash N Go	
2		
3		
4		
5		

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
GEX		☐ Class I ☒ Class II
Classification Panel		☐ Class III ☐ Unclassified

Indications *(from labeling)*

The Flash N' Go device is an over the counter device intended for the removal of unwanted hair.
Flash N' Go is also intended for permanent reduction in hair regrowth defined as a long-term, stable reduction in hair counts following a treatment regime.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name: Home Skinovations Ltd.		Establishment Registration Number: 3006948334	
Division Name *(if applicable)*		Phone Number *(including area code)*: +972-547404616	
Street Address: Apolo Buld. POB 533		FAX Number *(including area code)*: +972-49097471	
City: Yokneam Illit	State / Province	ZIP Code: 20692	Country: Israel
Contact Name: Amir Waldman Ph.D.	Contact Title: VP Regulatory affairs	Contact E-mail Address: amirw@silkn.com	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
	Standards No.	Standards Organization	Standards Title	Version	Date
1	IEC 60601-1	International Electrotechnical Commission	Medical Electrical Equipment" Part 1:"General requirements for safety"	2 edition	01/01/1988
	Standards No.	Standards Organization	Standards Title	Version	Date
2	IEC 60601-1-2	International Electrotechnical Commission	Medical Electrical Equipment part 1-2 collateral standard electromagnetic compatibility - requirement and tests	2.1 edition	01/01/2004
	Standards No.	Standards Organization	Standards Title	Version	Date
3					
	Standards No.	Standards Organization	Standards Title	Version	Date
4					
	Standards No.	Standards Organization	Standards Title	Version	Date
5					
	Standards No.	Standards Organization	Standards Title	Version	Date
6					
	Standards No.	Standards Organization	Standards Title	Version	Date
7					

Please include any additional standards to be cited on a separate page.

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Department of Health and Human Services
Food and Drug Administration
Office of the Chief Information Officer (HFA-710)
5600 Fishers Lane
Rockville, Maryland 20857

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Chapter 3

510(k) Cover Letter

HomeSkinovations

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ISRAEL
Tel: +972(4)9097440
Fax: +972(4)9097471

October 21, 2010

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Subject: 510(k) Submission for Flash N Go

Dear Sir/Madam,

Home Skinovations Ltd. is submitting this premarket notification for the purpose of obtaining FDA marketing clearance for its product. A table of contents for this 510(k) application is presented immediately after this cover letter. The following is information required under 21 CFR 807.87:

This is to notify you of the intention of Home Skinovations Ltd. to manufacture and market the following device:

Please send all correspondence by fax (+972-4-9097471), e-mail amirw@silkn.com in addition to mail

Trade/Proprietary name:	Flash N Go
Common name:	Light based hair removal system
Classification name:	The subject of this application is a Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR 878.4810)
Product codes:	GEX
Class of device:	The device should be considered a class II device, as are the predicate devices.
Reason for Application:	New device.

HomeSkinovations

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Name and address of Manufacturer:	Home Skinovations Ltd. Home Skinovations Ltd. Apolo building POB 533 Yokneam 20692 ISRAEL Tel: +972(4)9097440 Fax: +972(4)9097471
Contact person:	Dr. Amir Waldman VP regulatory affairs Tel. +972-547-404616, +972-4-9097440 Fax +972-4-9097471 E-mail - amirw@silkn.com
Applicable standards:	Action taken by the person required to register to comply with the requirements of the Act under section 514 for performance standards or section 513 for special controls: There are no mandatory performance standards applicable to this device. There are voluntary performance standards that the Flash N' Go complies with as discussed in chapter 4.
Labeling/Promotional material:	The labeling and promotional materials for the Flash N' Go, and for the substantially equivalent predicate devices, are presented in later sections of this application.
Substantial equivalence predicate devices:	Flash N' Go is substantially equivalent to the following devices: • Flash N' Go: The Flash N' Go is an over the counter device intended for the removal of unwanted hair. Manufactured by Home Skinovations Ltd. and subject of K082298. • TRIA Laser Hair Removal System: TRIA is an over-the-counter device intended for adjunctive

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use with shaving for hair removal sustained with periodic treatments. TRIA is also intended for permanent reduction in hair regrowth defined as a long-term, stable reduction in hair counts following a treatment regime. Manufactured by Tria Beauty, Inc. and subject of K090820.

- EpiLight and PhotoDerm HR: EpiLight and Photoderm HR are used for removal of unwanted hair. EpiLight and PhotoDerm HR are also intended to effect stable long-term, or permanent hair reduction in skin types I-V through selective targeting of melanin in hair follicule. Permanent hair reduction is definedas a long-term stable reduction in the number of hairs regrowing after a treatment regime. Manufactured by ESC Medical system Inc. and subject of K991935.

Confidentiality:	The material in this application is considered confidential and is not meant for public release.
Truth and Accuracy Statement:	A truthful and accurate statement, according to 21CFR 807.87(k), is presented after a separate page with the indications for use.
SMDA Safety and Effectiveness Summary:	Summary of Safety and is presented following the table of contents.

The Flash N' Go is a pulsed light device (b) (4) cleared Flash N' Go device K082298, and has technological characteristics that are substantially equivalent to other predicate devices. Therefore all safety features are identical to the cleared Flash N' Go device. The indication for use are identical to the other 2 cleared devices, and (b) (4)

(b) (4).

HomeSkinovations

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Tel: +972(4)9097440
Fax: +972(4)9097471

We trust that the information included in this application will be adequate to allow for its prompt review. Please contact me if there are any questions.

Sincerely yours,

Dr. Amir Waldman
VP regulatory affairs
Home Skinovations Ltd.

Chapter 4
Indication For Use Statement

Chapter 5

510(k) Summary of Safety and Effectiveness

510(k) Number (if known)_____.

Device Name Flash N Go

Indications For Use:

Flash N Go is an over the counter device intended for the removal of unwanted hair.

Flash N Go is also intended for permanent reduction in hair regrowth defined as a long-term, stable reduction in hair counts following a treatment regime.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over The Counter Use_X_
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Home Skinovations Ltd.

Silk'n Flash N Go

This summary of safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

Submitter's information

Name:	Home Skinovations Ltd.
Address:	Apolo building, POB 533, Yokneam 20692, Israel
Contact:	Dr. Amir Waldman VP Regulatory Affairs

Device information

Trade/Proprietary name:	Silk'n Flash N Go
Common/Usual name:	Light based hair removal device
Classification name:	Laser surgical instrument for use in general and plastic surgery and in dermatology (21CRF §878.4810)
Product code:	GEX

Predicate devices

- Flash N Go (K082298), by Home Skinovations Ltd.
- TRIA Laser Hair Removal System (K090820),by Tria Beauty, Inc.
- EpiLight and PhotoDerm HR (K991935), by ESC Medical system Inc.

Intended use:

The Flash N Go device is an over the counter device intended for the removal of unwanted hair. Flash N Go is also intended for permanent reduction in hair regrowth defined as a long-term, stable reduction in hair counts following a treatment regime.

Device Description:

The Flash N Go hair removal system is a pulsed light system composed of a base unit and hand held applicator.

Performance data:

The device complies with the following U.S. Food and Drug Administration performance standards: 21CRF § 1040.10 & 1040.11. Clinical data was collected in a prospective multisite clinical study.

Substantial Equivalence:

The Flash N Go system is substantial equivalent to its predicate devices. The data in this 510k submission demonstrate that the Flash N Go system is identical to the cleared Flash N' Go, and shares the same intended use as other predicate devices. Therefore is substantial equivalent to its predicate devices. Details are provided in Substantial equivalent section of this submission.

Based upon an analysis of the overall performance characteristic for the device, Home Skinovations Ltd. believes that no significant differences exit. Therefore the Silk'n Flash N Go should raise no new issues of safety or effectiveness.

October 21, 2010

Date

Dr. Amir Waldman,
VP Regulatory Affairs
Home Skinovations Ltd.

Chapter 6

Premarket Notification Truthful and Accuracy Statement

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

PREMARKET NOTIFICATION TRUTHFUL AND ACCURACY STATMENT

(As required by 21 CFR 807.87(j))

I certify that in my capacity as VP of Regulatory Affairs of Home Skinovations Ltd., I believe, to the best of my knowledge that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

October 21, 2010

Dr. Amir Waldman

Chapter 12
Substantial Equivalent Discussion

Substantial Equivalence Discussion

Flash N' Go indication for use: The Flash N Go device is an over the counter device intended for the removal of unwanted hair. Flash N Go is also intended for permanent reduction in hair regrowth defined as a long-term, stable reduction in hair counts following a treatment regime.

The Flash N Go is substantially equivalent (SE) to the following devices:

- Flash N Go: The Flash N' Go is an over the counter device intended for the removal of unwanted hair. Manufactured by Home Skinovations Ltd. and subject of K082298.
- TRIA Laser Hair Removal System: TRIA is an over-the-counter device intended for adjunctive use with shaving for hair removal sustained with periodic treatments. TRIA is also intended for permanent reduction in hair regrowth defined as a long-term, stable reduction in hair counts following a treatment regime. Manufactured by Tria Beauty, Inc. and subject of K090820.
- EpiLight and PhotoDerm HR: EpiLight and Photoderm HR are used for removal of unwanted hair. EpiLight and PhotoDerm HR are also intended to effect stable long-term, or permanent hair reduction in skin types I-V through selective targeting of melanin in hair follicule. Permanent hair reduction is definedas a long-term stable reduction in the number of hairs regrowing after a treatment regime. Manufactured by ESC Medical system Inc. and subject of K991935.

Labeling and promotional material of the substantially equivalent devices are presented in Appendices 5-1, 5-2, 5-3 of this chapter.

Substantial equivalence is demonstrated according to the criteria outlined in the 510(k) "Substantial Equivalence" Decision Making Process, as published in the FDA 510(k) Guidance (FDA 90-4158).

A comparison table of the subject and predicate devices is included in this discussion.

Technological equivalence

The Flash N Go is a pulsed light device (b) (4) (b) (4) and has technological characteristics that are substantially equivalent to other predicate devices. (b) (4) EpiLight and PhotoDerm HR are intense pulsed light devises. Tria hair removal laser is a laser with wavelength of 810 nm.

A comparison is provided in the table below:

Technological Characteristic	Flash N Go(new)	Flash N Go(cleared)	Tria	EpiLight / PhotoDerm HR	Comments
Nature and Source of Energy Imparted to Patient	Pulsed light via external applicator	Pulsed light via external applicator	Pulsed Diode laser	Pulsed light via external applicator	All devices use optical energy as the energy source for hair removal treatment
Wavelength range (nm)	475-1200	475-1200	810	645-1200	All devices use Visible / Near IR Wavelengths range to achieve reduced hair growth
Maximum Light Energy (J/cm^2)	5	5	20	45	Same output parameters as the cleared Flash N' Go

No new types of safety or effectiveness questions are raised and differences in the technological characteristics between the Flash N Go and the predicate devices can be assessed for their effects on safety and effectiveness.

Intended use equivalence

The Flash N Go device is an over the counter device intended for the removal of unwanted hair. Flash N Go is also intended for permanent reduction in hair regrowth defined as a long-term, stable reduction in hair counts following a treatment regime.

The Flash N Go employs pulses of low energy light to achieve permanent hair reduction. (b) (4)

(b) (4)

The Flash N Go (new) intended use is identical to the Tria, EpiLight and PhotoDerm HR. Both the Flash N Go and the Tria devices are over the counter device: "TRIA is also intended for permanent reduction in hair regrowth defined as a long-term, stable reduction in hair counts following a treatment regime". While the EpiLight and PhotoDerm HR are prescription use, but have the same intended use.

Safety and Effectiveness equivalence

The Flash N Go does not present any new safety and effectiveness issues as compared with the predicate devices.

(b) (4)

As far as effectiveness, since the energy pulse duration as well as spectrum is within similar range to the predicate devices efficacy is expected to be similar. (b) (4)

(b) (4)

In light of the results, we conclude that the Flash N Go device is safe and effective as an over the counter device indicated for the removal of unwanted hair and also for permanent reduction in hair regrowth defined as a long-term, stable reduction in hair counts following a treatment regime.

TRIABEAUTY
PROFESSIONAL RESULTS. AT HOME. AT LAST.

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NOW SHIPPING online activation my account shopping basket (0)

acne & breakouts | see the results | news & events | what is TRIA | quick shop

hair removal

now save $100 — new lower prices ▸

TRIA Laser Hair Removal System

stop shaving. start showing off.

Imagine waking up to silky smooth skin every day and being free forever from endless shaving and painful waxing! The TRIA Laser is the only way to get permanent hair removal at home—guaranteed.

- See results in 3 months; in as little as 6 months, you're done! How to Use
- Get baby soft skin—like the hair was never there
- Created by the same scientists that invented diode laser hair removal for dermatologists
- Get the same results as professional laser hair removal and save thousands of dollars
- FDA-cleared safe, effective, permanent

See what TRIA users say and read the buzz on why *Allure*, *InStyle*, *Women's Wear Daily* and *The Doctor's* have named the TRIA Laser a beauty "must-have".

Find out if the TRIA Laser is right for you.

NOW SHIPPING

TRIA Laser Hair Removal System $495 (was $595) add to basket
new lower price!

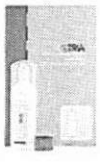
☐ half price today with easypay | $249 down and six payments of $49. details ▸

share: | more

you may also like:

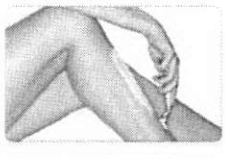
TRIA Skin Clarifying System, $295

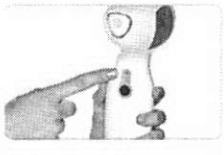
Stay Clear 3-Piece Refill Kit, $80

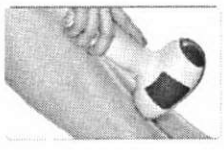


Super Clear 2-Piece Refill Kit, $60

how to use | what to expect | is it right for you? | included







3 simple steps. amazing results.

step 1 : get ready
Cleanse, shave, and towel-dry the skin.

step 2 : get comfortable
Select the highest setting that suits your personal comfort level.

step 3 : treat
Apply the tip of the laser to the skin and listen for the beep. Repeat until you have covered the entire area to be treated. Treat twice a month for the first 3 months, then once per month for the next several months until the hair stops coming back. Bikini line and underarms take 5-10 minutes to treat. Legs may take 20-30 minutes each.

*For detailed instructions check out our step-by-step How To Use Video.

Questions? Contact Us

stay connected:

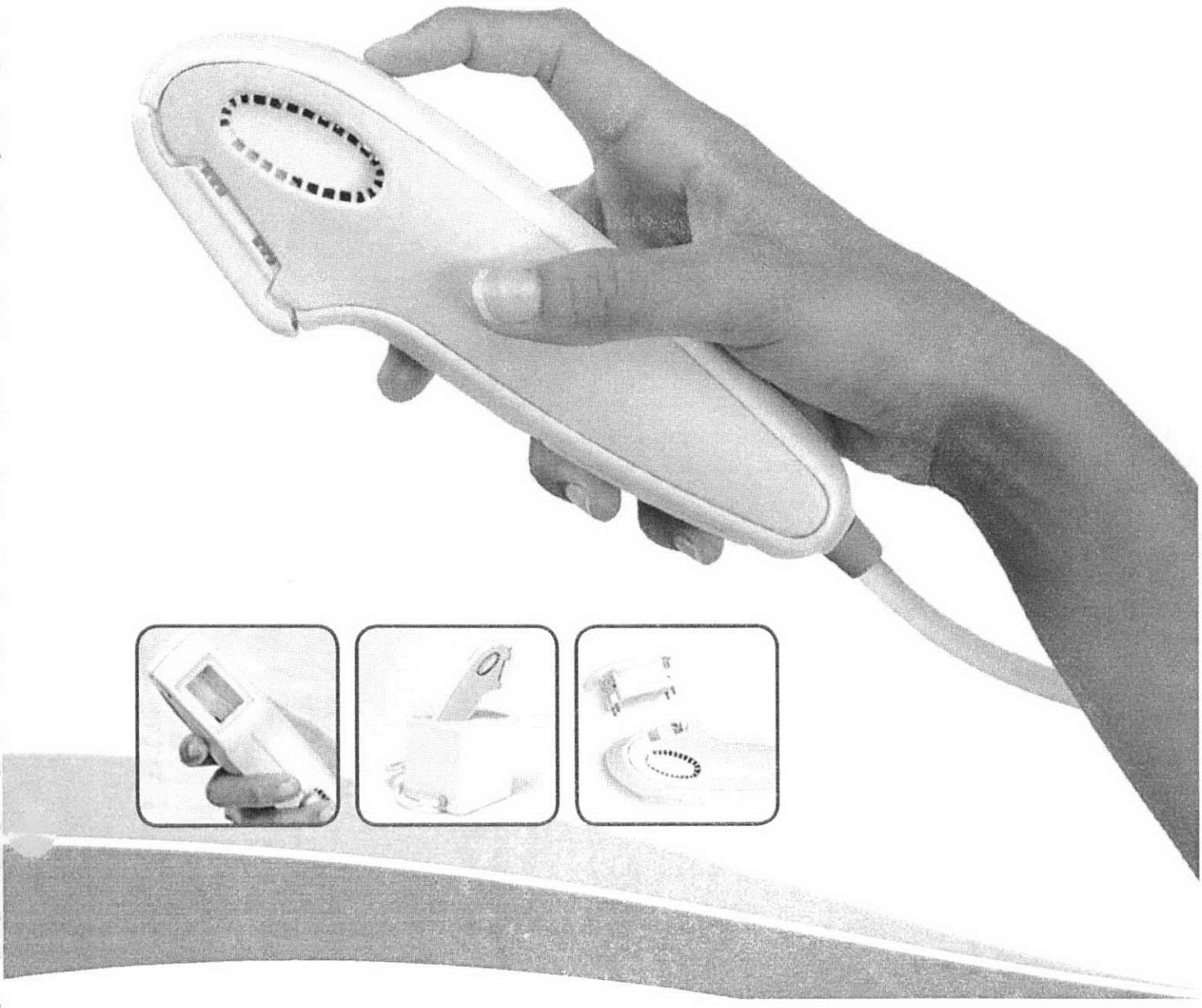
1-877-321-TRIA (8742) | customer care

about us | store locator | contact us | affiliate program | japan | korea

Flash N' Go™

Personal Hair Removal at Home

with Home Pulsed Light™



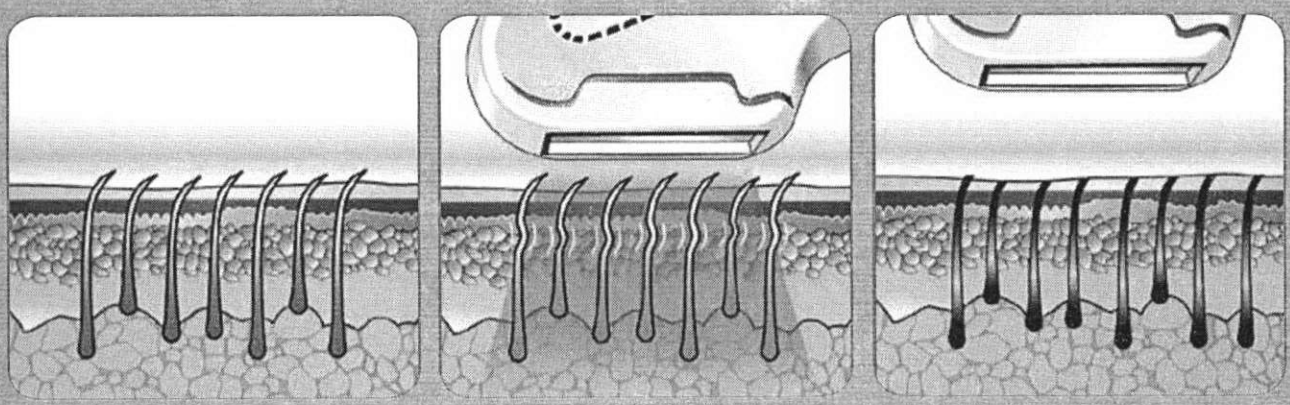
Flash N' Go™ is a physician recommended and innovative light-based device for hair removal in the privacy of your home. Safe, easy to use and cost effective, Flash N' Go™ achieves marked clinical results while offering personal convenience.

THE HPL™ INNOVATION

The Flash N' Go™ device utilizes the highly sophisticated and new **Home Pulsed Light™** (**HPL™**) technology, developed by Home Skinovations Ltd. especially for safe use at home.

HPL™ Epilation is based on the theory of selective photothermolysis in which **optical** energy is used to disable hair growth. Epilation with Home Skinovations' proprietary HPL™ technology is further benefited by a unique **acoustic** effect that enhances the normal process of epilation by photothermolysis.

To safely achieve the desired clinical results the hair shaft needs to selectively absorb HPL™ light energy and transform it into heat. Melanin is the pigment in the hair shaft that is responsible for the absorption of light, which generates the heat at the follicle. Selectivity is achieved when the HPL™ optical energy delivered to the tissue is mostly absorbed by pigment in the hair shaft, while the epidermis and the surrounding tissue remain cool. Additionally HPL™ technology creates an acoustic effect that enhances the overall hair removal result. Together the optical and acoustic effects of HPL™ technology are what enable the Flash N' Go™ device to be safely used by patients for home based hair removal.



● **Before using Flash N' Go™**

● **During Flash N' Go™ pulse**

● **After Flash N' Go™ application**

Flash N' Go™ HAIR REMOVAL CLINICAL STUDY

Flash N' Go™ has been tested in a multi-center clinical study that took place in North America and Israel and involved over 150 female patients.

Treatment Protocol:

Method:	Self treatment at the physician's office
Treatment plan:	3 treatments performed at 2 week intervals
Hair count:	Initial hair count and follow up hair counts 3 and 6 months post last treatment
Investigators:	**Dr. Tina Alster**, Washington DC. **Dr. Stephen Mulholland**, Los Angeles **Dr. James Shaoul**, Tel Aviv

Result

Body site	No. of patients	Average reduction after 3 months	Average reduction after 6 months
Axilla	65	54%	41%
Legs	34	65%	54%
Bikini	56	56%	43%
Arms	20	58%	52%

WHAT EXPERTS ARE SAYING ABOUT Flash N' Go™

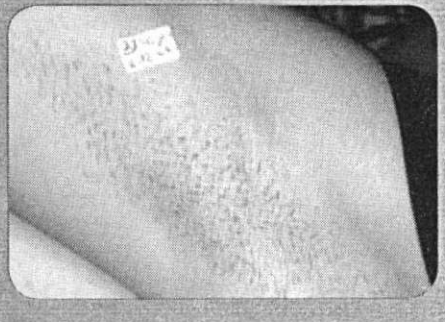
"As a leading investigator in the development of state-of-the-art lasers and IPL systems for hair removal, I was surprised by the marked clinical results that were achieved with Flash N' Go™. Patients who were previously treated with professional hair removal systems used in my clinic had a chance to use Flash N' Go™ in clinical trials. They reported that self-treatment was easy, relatively painless, and resulted in noticeable hair reduction after each treatment."

Tina S. Alster, M.D.
Director, Washington Institute of Dermatologic Laser Surgery
Clinical Professor of Dermatology, Georgetown University Medical Center

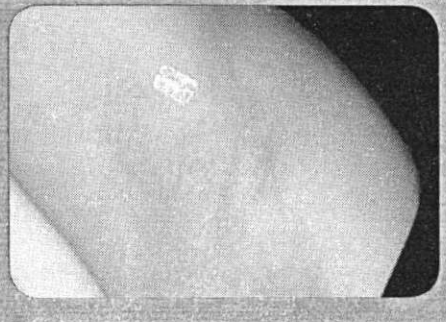
"After supporting the development of leading professional IPL and laser systems for hair removal, and using them in my clinic for many years, I introduced Flash N' Go™ to my patients. After 4 to 6 treatments with the Flash N' Go™ device they were extremely satisfied to see dramatic hair reduction.

R. Stephen Mulholland, MD FRCS(C)
Cosmetic Plastic Surgeon

TYPICAL RESULTS OF Flash N' Go™



Before



After

Flash N' Go™ ADVANTAGES

- **Physician Recommended**

  Tested over 12 months in a multi-center clinical study involving over 150 female patients.

- **Small and Portable**

  Flash N' Go™ is about the size of a hairdryer and it runs off of regular electric power, so treatment can be done anywhere, anytime and non-stop for as long as necessary.

- **Safe**

  When used according to instructions, hair removal with Flash N' Go™ is safe and with minimal discomfort compared to waxing or laser.

- **Easy to Use**

  Flash N' Go™ is easy to set up, and treatments are simple, clean and very quick.

- **Cost Effective**

  Using Flash N' Go™ will save you money when compared to extended use of professional laser treatments, waxing or shaving.

- **Marked clinical Results**

  Although small and portable, the HPL™ technology in Flash N' Go™ captures all the clinical benefits of light-based hair removal.

TECHNICAL SPECIFICATIONS

Spot size	2cm x 3cm [6cm2]
Speed	1 pulse every 3.5 second: 1.7 cm2/sec
Technology	Home Pulsed Light™
Max Energy Level	5 J
Wavelength	475-1200 nm
Charging time / Power source	Continuous operation
Time needed to treat lower legs	30 minutes
Operation and safety	Safety sensor tip enables maximum safety & control. Easy to use.

CONTACT INFORMATION

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Tel. +972-4-9097470, Fax +972-4-9097471

info@silkn.com | www.silkn.com

ISO 13485

CE

IPL® Quantum™

Intense Pulsed Light™ and Laser Technology

Expandable...To Grow With Your Practice

LUMENIS®

Enhancing Life. Advancing Technology.

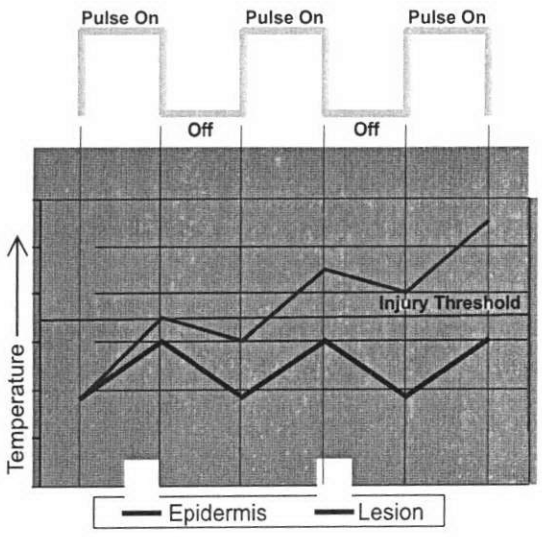
One System: A multitude of applications

Build the system to suit your practice needs—today and into the future

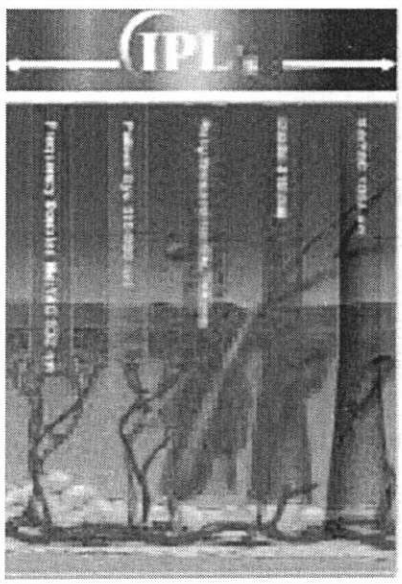
Whether it's a full-time system for skin treatments using photorejuvenation or a single system that can treat a multitude of applications, the IPL Quantum allows you the flexibility to build the system that best meets the needs of your practice today, and will expand to meet your emerging requirements.

Clinical Indication	SR IPL	DL Nd:YAG laser	HR IPL	QS Q-Switched Nd:YAG laser
Rosacea	✔			
Telangiectasia	✔	✔		
Vascular lesions	✔	✔		
Hemangiomas	✔	✔		
Port wine stains	✔	✔		
Leg veins	✔	✔		
Solar lentigines	✔			✔
Epidermal pigmented lesions	✔			✔
Dermal pigmented lesions	✔			✔
Poikiloderma of Civatte	✔			
Skin treatments using photorejuvenation	✔			
Hair removal and permanent hair reduction			✔	
Tattoo removal				✔

A winning combination: Multi-Synchronized Pulsing™ using a broad spectrum of light



High peak-power, Multi-Synchronized Pulsing™ provides optimum treatment of vascular and pigmented lesions while sparing the skin.



Patented advanced technology provides a unique high-powered, broad spectrum of light. The result is the flexibility of IPL with the intensity and optimized results only possible with high peak powers—usually afforded only by lasers.

From the Pioneers...

IPL technology proven in over 10 years of clinical use

Clinically proven in over 10 years of use, Lumenis pioneered and perfected IPL. While some competitive products are similar to our first generation, Lumenis IPL has evolved well beyond these technologies. Lumenis provides the most advanced technology and the confidence of over 10 years of clinical efficacy documented in numerous peer reviewed papers.

True Versatility

"IPL Photorejuvenation using the Lumenis product has provided my patients the lasting results that they are looking for—with a series of treatments, there is minimal to no 'down-time.' The IPL devices simultaneously and consistently reduce unwanted redness and brown spots, and can even improve skin wrinkling."

—Michael Kulick, M.D.

IPL Quantum SR

IPL Skin Treatments Using Photorejuvenation

Our unique IPL photorejuvenation head provides high peak-power, customizable, Multi-Synchronized Pulses. Engineered specifically for the highest level of safety and efficacy, it offers your patients a remarkable treatment for telangiectasias, broken capillaries and benign brown pigmentation from sun damage and photoaging—treatments to restore a youthful texture and complexion to the entire face.

- Fully utilizes advantages of IPL for treating age spots such as sun induced freckles, solar lentigines and telangiectasia—dramatically improving the appearance of photoaged skin
- Provides a smoother appearance in 4–6 treatments over four months
- No downtime—patients can resume normal activities immediately
- Treats the entire face for an even and satisfying effect
- Contact cooling for maximum safety and patient comfort

Three months post 3 IPL treatments
Robert A. Weiss, MD

Three IPL treatments over 10 weeks
Nathan Troolman, MD

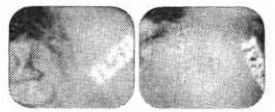
IPL Quantum HR Upgrade

IPL Photoepilation

The IPL Photoepilation head uses lamp configurations for outputs optimized in the red-to-near infrared part of the spectrum. It offers your patients a proven method for achieving permanent hair reduction. You can treat all skin types including the dark skin type VI, and nearly every hair color.

- Adds the versatility of permanent hair reduction to the IPL Quantum system
- Multiwavelength and broad pulsewidths allow safe and effective hair removal on all skin types I-VI and pseudofolliculitis barbae (PFB).
- Treats all body areas, hair depths and a broad spectum of colors
- High speed, large spot-size system supports high patient throughput

One year post 5 IPL treatments
Franklin Johnson, M.D.



Nine months post 6 IPL treatments
Franklin Johnson, M.D.

IPL Quantum DL

1064 nm Nd:YAG Laser to Treat Leg Veins and Benign Cutaneous Vascular Lesions

Three weeks post 1 Laser treatment
Neil Sadick, M.D., F.A.C.P.

Three weeks post 3 IPL and 1 laser treatment
Mark Trosino, M.D.

The 1064 nm laser light has been clinically proven to provide effective treatment of deep and larger telangiectasias, as well as benign cutaneous vascular lesions such as hemangiomas, and melasma.

- Proven, highly effective Nd:YAG technology for the treatment of leg veins up to 4.0 mm
- Integrated contact cooling for maximum safety and comfort
- Multi-Synchronized Pulsing for optimal efficacy while protecting the skin

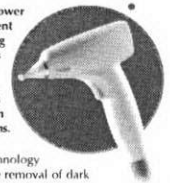
IPL Quantum QS Upgrade

Q-Switched 1064 nm Nd:YAG Laser to Treat Tattoos and Benign Pigmented Lesions

Four weeks post 6 Q-Switched Nd:YAG treatments
M. Lapidot, M.D.

Six weeks post 1 Q-Switched Nd:YAG treatment
M. Lapidot, M.D.

Ultrashort, high peak-power nanosecond pulses fragment pigment particles allowing safe removal by the body's natural healing processes. IPL Quantum QS effectively treats dark tattoos and a wide range of benign pigmented epidermal lesions.



- State-of-the-art laser technology for the safe and effective removal of dark tattoos and benign pigmented lesions
- Added versatility for the growing laser tattoo-removal market

IPL Quantum™

Intense Pulsed Light™ and Laser Technology

Technical Specifications	SR	DL	HR	QS
Light Source	IPL	Nd:YAG laser	IPL	Nd:YAG laser
Standard Spectrum	515–1200 nm	1064 nm	695–1200 nm	1064 nm
Optional Spectra	590–1200 nm 640–1200 nm		645–1200 nm 755–1200 nm	—
Fluence	15–45 J/cm²	90–150 J/cm²	20–45 J/cm²	2–12.7 J/cm²
Pulse Duration	6–26 ms	5–38 ms	6–18 ms	6–8 ns
Pulse Delays	5–60 ms	5–100 ms	10–150 ms	—
Spot Size	34 x 8 mm	6 mm	34 x 8 mm	2, 2.5, 3.5 and 5 mm
Repetition Rate	0.5 Hz	0.5 Hz	0.5 Hz	Up to 5 Hz
Integrated Skin Cooler	Yes	Yes	Yes	No
Electrical Requirements	200–240 VAC +/- 10%, 16A, 50–60 Hz. Dedicated line.			
Physical Dimensions	40 x 40 x 100 cm / 16 in x 16 in x 39 in (WDH)			
Weight	75 kg / 165 lbs			

LUMENIS CUSTOMER CARE

Worry-Free Service and Support

At Lumenis we understand the importance of delivering service and technical support of the highest quality. When you buy a laser or light-based system from Lumenis, you make an investment in the world's most innovative medical technology in its category backed by the most comprehensive service and support organization in the industry. Customer satisfaction is paramount and the ultimate goal of our business.

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ISO 9001 CERTIFIED

CE 93/42/EEC 0473

LUMENIS®
Enhancing Life. Advancing Technology.

Caution: U.S. law restricts this device to sale by or on the order of a physician.

PBP000137 Rev. C

Chapter 13

Proposed labeling

The only change in this labeling compared with the previously cleared Flash N Go is the new indication for use on page 4.

HomeSkinovations

Flash N' Go User manual

Print date: February 2008

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ISRAEL

Website: **www.silkn.com**

e-mail: **info@silkn.com**

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Table of Contents

Before using Flash N' Go™ for the first time, please read this User Manual in its entirety. Pay particular attention to sections on device use procedures, device operation, and after-use procedures.

We recommend you re-familiarize yourself with this User Manual before each use of Flash N' Go™.

Flash N' Go™ is a powerful electrical device. As such, it should be used with special attention to safety.

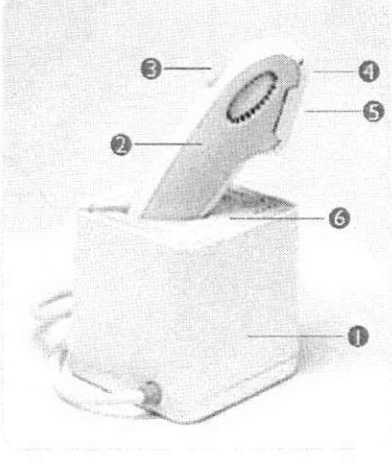
Please read all warnings and safety precautions before use, and strictly follow them when using Flash N' Go™

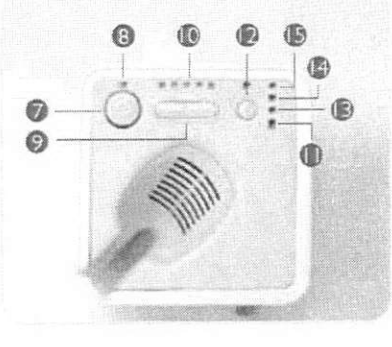
1. What is Flash N' Go™?

Flash N' Go™ is a light-based device for long-term hair removal designed for home-use.

1.1. Flash N' Go™ device description

Flash N' Go consists of a Base Unit, APPLICATOR and Disposable Lamp Cartridges.





1. BASE UNIT
2. APPLICATOR
3. PULSE BUTTON
4. DISPOSABLE LAMP CARTRIDGE
5. *SKIN COLOR SENSOR*
6. CONTROL PANEL
7. POWER ON/OFF SWITCH
8. POWER INDICATOR LIGHT
9. ENERGY LEVEL SETTING BUTTONS
10. ENERGY LEVEL INDICATOR LIGHTS
11. READY INDICATOR LIGHT
12. AUDIO ON/OFF SWITCH
13. CARTRIDGE 90% USAGE INDICATOR LIGHT
14. CARTRIDGE 100% USAGE INDICATOR LIGHT
15. SYSTEM WARNING INDICATOR LIGHT

02

Your Flash N' Go™ consists of a ***BASE UNIT*** and an ***APPLICATOR.***

On the ***BASE UNIT*** you can find the Flash N' Go™ ***CONTROL PANEL*** including ***POWER ON/OFF SWITCH*** and ***POWER INDICATOR LIGHT***, the ***ENERGY LEVEL SETTING BUTTONS*** and ***ENERGY LEVEL INDICATOR LIGHTS***, the ***AUDIO ON/OFF SWITCH***, ***READY INDICATOR***, ***SYSTEM WARNING INDICATOR LIGHT*** and ***CARTRIDGE 90%*** and ***100% USAGE INDICATOR LIGHTS***.

On the Flash N' Go™ ***APPLICATOR*** you can find the ***PULSE BUTTON***. The ***DISPOSABLE LAMP CARTRIDGE*** is located at the ***APPLICATOR TIP.***

1.2. Package contents

Upon opening the Flash N' Go™ package, you will find the following parts:

- Flash N' Go™ *BASE UNIT* and *APPLICATOR*
- An AC cord
- A second *DISPOSABLE LAMP CARTRIDGE*
- This User's Manual and a Quick Start Guide leaflet
- An Instructional DVD

1.3. The Disposable Lamp Cartridge

The Flash N' Go™ *DISPOSABLE LAMP CARTRIDGE* can fire 750 light pulses (regardless of the energy level of these pulses). For average body size 750 light pulses could cover for example:

One treatment sessions of 2 Legs, 2 Arms, 2 Underarms, and Bikini line

Or

Two treatments sessions of 2 legs and 2 Underarms

Or

Ten treatments sessions of 2 Underarms and Bikini line

Depending on the body areas you wish to treat, you will typically need to use from one to seven *DISPOSABLE LAMP CARTRIDGES* during the first year of using Flash N' Go.

2. Flash N' Go™ Intended Use

Flash N' Go™ is intended for removal of unwanted hair. Flash N' Go™ is also intended to effect long term, or permanent hair reduction. Permanent hair reduction is defined as a long-term stable reduction in the number of hairs re-growing after a treatment regime.

Flash N' Go™ may be used to remove unwanted body hair. Ideal body areas for Flash N' Go™ use includes the underarms, bikini line, arms and legs.

3. Safety with Flash N' Go™

3.1. With Flash N' Go™ Safety Comes First

- **HPL™ technology in Flash N' Go™ - Superior safety with lower energy level**

  Home Pulsed Light™ technology is able to achieve long-term hair removal results at a fraction of the energy level used in other light-based hair removal equipment. The low energy used in Flash N' Go™ reduces its potential to cause harm or complications, and contributes to your overall safety.

- **Flash N' Go™ protects your eyes**

  The Flash N' Go™ *APPLICATOR* has a **built-in safety feature** for eye protection. It has been designed so that a light pulse can not be emitted when the *APPLICATOR* is facing open air. The safety switch is activated only when the *APPLICATOR TIP* is in full contact with the tissue and pressed.

- **Flash N' Go™ protects your skin**

  Flash N' Go™ comes with a *SKIN COLOR SENSOR* enabling use only on lighter skin complexions to ensure skin safety.

  Furthermore, the 2X3cm² *OPTICAL LENS* through which pulses of light are delivered is recessed inside the *LAMP CARTRIDGE* at the *APPLICATOR TIP*. This enables Flash N' Go™ to protect your skin by avoiding direct contact between the *OPTICAL LENS* and the skin.

4. Contraindications

Important Safety Information – Read Before Use!

Flash N' Go™ is not designed for everyone. Please read and consider the information in the following section before use. For further information and personalized advice you may also visit www.silkn.com or your local Flash N' Go™ domain.

If you are unsure if Flash N' Go™ is safe for you to use, please ask your doctor or dermatologist!

- **DO NOT USE Flash N' Go™ on naturally dark skin complexion!**

Flash N' Go™ removes unwanted hair by selectively addressing hair pigment. Varied quantities of pigment also exist in the surrounding tissue of skin. The quantity of pigment in a particular person's skin, which is manifested by their skin complexion, determines the degree of risk they are exposed to using Flash N' Go™.

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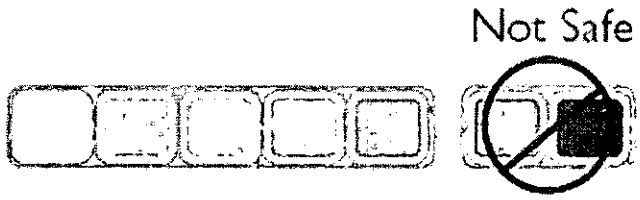
Treating dark skin with Flash N' Go™ can result in adverse effects such as burns, blisters, and skin color changes (hyper- or hypo-pigmentation).



DO NOT USE Flash N' Go™ on naturally dark skin!

A unique *SKIN COLOR SENSOR* is embedded in Flash N' Go™ to measure the treated skin complexion at the beginning of each session and occasionally during the session. *SKIN COLOR SENSOR* ensures that pulse will be emitted on suitable skin tones.

- **DO NOT USE Flash N' Go™ on tanned skin or after recent sun exposure!**

Tanned skin particularly following sun exposure, contains large quantities of the pigment Melanin. This applies to all skin types and complexions, including those which don't seem to tan quickly. The presence of large quantities of Melanin exposes the skin to higher risk when using Flash N' Go™.

Using Flash N' Go™ on skin that has been recently exposed to sunlight can result in adverse effects such as burns, blisters, and skin color changes (hyper- or hypo-pigmentation).

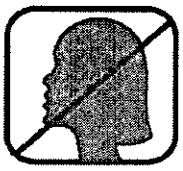
DO NOT USE Flash N' Go™ on tanned skin or after recent sun exposure! Such use can cause serious burns or skin injury. Avoid exposure to the sun for 4 weeks before your Flash N' Go™ treatment!

The unique Flash N' Go™ *SKIN COLOR SENSOR* will also help you avoid treating sun exposed skin.

- **DO NOT USE Flash N' Go™ on the face or neck**

Unlike body hair, most of women's potential facial hair remains inactive and hidden, while only a fraction of it grows and surfaces. Exposing facial hair to the light pulses of Flash N' Go™ may remove apparent hair but simultaneously stimulate unwanted growth of hidden hair.

Using Flash N' Go™ to remove facial hair may cause serious eye injury and may stimulate facial hair growth.



Flash N' Go™ is not recommended for use on the face or neck.

- **NOTE! Flash N' Go™ is not effective on light hair**

The Flash N' Go™ device is not effective on naturally white, grey, blond and red body hair. If your body hair is of these colors, Flash N' Go™ will not work on you.

5. When to avoid using Flash N' Go™?

Certain conditions may prevent the use of Flash N' Go™ temporarily. **DO NOT USE Flash N' Go™** if any of the following currently apply to you:

- If you are pregnant or nursing (lactating).
- If you were exposed to strong sunlight or an artificial tanning machine during the past 28 days.
- If you have a tattoo or permanent makeup on the area to be treated.
- If you have dark brown or black spots, such as large freckles, birth marks, moles or warts on the area to be treated.
- If you have eczema, psoriasis, lesions, open wounds or active infections, such as cold sore in the area to be treated. Wait for the effected area to heal before using Flash N' Go™.
- If you have a history of kelodial scar formation, a known sensitivity to light (photosensitivity) or are taking medication that makes the skin more sensitive to light, including non-steroidal anti-inflammatory agents, (e.g., aspirins, ibuprofens, acetaminophen), tetracyclines, phenothiazines, thiazide, diuretics, sulfonyluraes, sulfonamides, DTIC, fluorouracil, vinblastine, griseofulvin, Alpha-Hydroxi Acids (AHAs), Beta-Hydroxi Acids (BHAs), Retin-A®, Accutane® and/or topical retinoids.
- If you have abnormal skin conditions caused by diabetes, for example, or other systemic or metabolic diseases
- If you are currently or have recently been treated with Alpha-Hydroxi Acids (AHAs), Beta-Hydroxi Acids (BHAs), Retin-A®, topical retinoids or azelaic acid.

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- If you have been treated with Accutane® (isotretinoin) within the past 6 months.
- If you have been on a steroid regimen within the past 3 months.
- If you have a history of herpes outbreaks in the area of treatment, unless you have consulted your physician and received preventative treatment before using Flash N' Go™.
- If you suffer from epilepsy.
- If you have an active implant, such as a pacemaker, incontinence device, insulin pump, etc.
- If you have a disease related to photosensitivity, such as porphyria, polymorphic light eruption, solar urticaria, lupus, etc.
- If you have a history of skin cancer or areas of potential skin malignancies.
- If you have received radiation therapy or chemotherapy treatments within the past 3 months.
- If you have any other condition which in your physician's opinion would make it unsafe for you to be treated.

If you are unsure if Flash N' Go™ is safe for you to use, please consult with your doctor or dermatologist.

6. Precautions – How to use Flash N' Go™ Safely

- **Choose your energy levels CAREFULLY!**
  Energy level refers to the intensity of the light pulse that is projected on your skin during use, from the lowest level (-) to the highest level (+). *INDICATOR LIGHTS* on the *CONTROL PANEL* illustrate the energy level at which the machine is set. As the energy level increases, so do the results of Flash N' Go as well as the risk of side effects (see "Possible Side Effects" below).

  Always begin your first use of Flash N' Go™ at the lowest energy setting (one light at "-")!

  Only if you experience little or no discomfort during and after use of Flash N' Go™ at the lowest energy setting, raise the energy level by one *INDICATOR LIGHT* the next time you use Flash N' Go™, and so on for each subsequent hair removal session.

  For detailed instructions on energy level setting see "Energy Level" box in section 4.4 - "Treating with Flash N' Go™ for the first time".

- **Avoid adverse effects!**
  Do not treat the same area of skin more than once per hair removal session!
  Try to avoid overlapping pulses!
  If your skin blisters or burns, **STOP USE IMMEDIATELY!**

- **Avoid complications after use of Flash N' Go™!**
  Do not expose treated areas of skin to the sun!

Sun exposure includes unprotected exposure to direct sunlight of over 15 minutes constantly, or unprotected exposure to diffuse sunlight of over 1 hour constantly.

To protect recently treated skin when exposed to sunlight, be sure to thoroughly apply sunscreen SPF 30 or higher, for 2 weeks after each hair removal session.

- Always shave the area to be treated and make sure that the skin is clean and dry before using the Flash N' Go™.
- Cover birthmarks and tattoos before Flash N' Go™ application.
- Cover dark brown or black spots, such as large freckles, birth marks, moles or warts before Flash N' Go™ application.
- Never look directly at the light coming from the Flash N' Go™ *APPLICATOR* and *LAMP CARTRIDGE*..
- Do not use Flash N' Go™ on nipples and genitals (male or female).
- Do not use Flash N' Go™ on any body site where you might later want hair.
- Do not use Flash N' Go™ for any purpose other than hair removal.
- Never point the Flash N' Go™ *APPLICATOR* in an attempt to emit a light pulse into open space. Always make sure that the *APPLICATOR* is pointed at, and in full contact with the skin during application.
- Remove the Flash N' Go™ *APPLICATOR* from the skin if either the skin or the *APPLICATOR* is too hot.
- Never use flammable liquids such as alcohol (including perfumes, sanitizers, or other applications containing alcohol) or acetone to clean the skin before using Flash N' Go™.
- Use of Flash N' Go™ may cause temporary pigmentation changes (See "Possible Side Effects" below).
- Keep this device out of the reach of children. Do not use Flash N' Go™ on children or allow children to use it.

7. Reducing the risk of injury

As with any electrical device, certain precautions must be taken in order to ensure your safety when using Flash N' Go™.

- **Keep Flash N' Go™ away from water!**
  Flash N' Go™ is an electrical device. As such it should always be kept away from water.
  Do not place or store Flash N' Go™ where it can fall or be pushed into a tub, sink or any other vessel containing water. Do not place in, or drop into water or any other liquid.
  This may cause severe electrocution.
  Do not use Flash N' Go™ while bathing.
  Do not use Flash N' Go™ if it becomes damp or wet.
  Do not reach for Flash N' Go™ if it has fallen into water.
  Unplug Flash N' Go™ immediately if it has fallen into water.

Keep Flash N' Go™ away from water!

- **Never open Flash N' Go™!**
  Do not attempt to open or repair your Flash N' Go™ device. Opening Flash N' Go™ may expose you to dangerous electrical components and to pulsed light energy, either of which may cause serious bodily damage and/or permanent eye injury.

Do not attempt to open or repair your Flash N' Go™ device. Only authorized Flash N' Go™ repair centers are permitted to perform repairs.

- Trying to open Flash N' Go™ may also damage the device and will void your warranty.
  Please contact Flash N' Go™ Customer Service if you have a broken or damaged device in need of repair.

- Use Flash N' Go™ only for its intended use and as described in its manual.
- Flash N' Go™ should never be left unattended when plugged into an outlet.
- Do not operate Flash N' Go™ if it has a damaged cord or plug and keep the power cord away from heated surfaces.
- Do not use Flash N' Go™ if you see or smell smoke when it is in use.
- Do not use Flash N' Go™ if it is not working properly or if it appears damaged.
- Do not use Flash N' Go™ if the fan vent in its *APPLICATOR* is cracked, coming off or missing.
- Do not use Flash N' Go™ if the *SKIN COLOR SENSOR* in its *APPLICATOR* is cracked, or broken.
- Do not use Flash N' Go™ if the outer shell is cracked or is coming apart.
- Do not use Flash N' Go™ with a damaged *DISPOSABLE LAMP CARTRIDGE*, or if its *OPTICAL LENS* is cracked, chipped or missing
- Always unplug Flash N' Go™ from the electrical outlet immediately after use.
- Unplug Flash N' Go™ before cleaning.
- Do not use Flash N' Go™ with any attachments or accessories not recommended by Home Skinovations Ltd.

8. Risks of using Flash N' Go™

When used according to the instructions, side effects and complications associated with use of Flash N' Go™ are uncommon. However every cosmetic procedure,

including those designed for home use, involves some degree of risk. Therefore it is important that you understand and accept the risks and complications that can occur with pulsed light hair removal systems designed for home use.

Adverse Event	Likelihood of the Adverse Event	Adverse Effect	Likelihood of the Adverse Effect
Stacking or Overlapping of multiple pulses on the same skin spot	Minor	Minor Skin Discomfort	Minor
		Skin Redness	Minor
		Increased Sensitivity of the Skin	Minor
		Skin Wounds and Burns	Rare
		Scarring	Rare
		Pigment Changes	Rare
		Excessive Redness and Swelling	Rare
		Infection	Negligible
		Bruising	Negligible

- **Minor Skin Discomfort**
  Although home pulsed light hair removal is generally very well-tolerated, most users do feel some mild discomfort during use, usually described as being a mild stinging sensation on the treated skin areas. The stinging sensation usually lasts during the time of the application itself or for a few minutes thereafter. Anything beyond this minor discomfort is abnormal and means that either you should not continue to use Flash N' Go™ because you are unable to tolerate the hair removal application, or that the energy level setting is too high.

- **Skin Redness**
  Your skin may become red right after using Flash N' Go™ or within 24 hours of using Flash N' Go™. Redness generally clears up within 24 hours. See your doctor if redness does not go away within 2 to 3 days.

- **Increased Sensitivity of the Skin**
  The skin of the treated area is more sensitive so you may encounter dryness or flaking of the skin.

- **Skin Wounds and Burns**
  Very rarely, burns or wounds to the skin can occur following the application. The burn or wound can require a few weeks to heal and, extremely rarely, may leave a noticeable permanent scar.

- **Scarring**
  Although very rare, permanent scarring may occur. Usually when scarring occurs it is in the form of a flat and white lesion on the skin (hypotrophic). However, it can be large and red (hypertrophic) or large and extend beyond the margins of the injury itself (keloid). Subsequent aesthetic treatments may be required to improve the appearance of the scar.

- **Pigment Changes**
  Flash N' Go™ targets the hair shaft, in particular the pigmented cells in the hair follicle and the hair follicle itself. Nevertheless there is risk of temporary hyperpigmentation (increased pigment or brown discoloration) or hypopigmentation (whitening) to the surrounding skin. This risk of changes in skin pigmentation is higher for people with darker skin tones.

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Usually discoloration or changes to skin pigment are temporary and permanent hyperpigmentation or hypopigmentation rarely occur.

- **Excessive Redness and Swelling**
  In rare cases treated skin may become very red and swollen. This is more common in sensitive areas of the body. The redness and swelling should subside within 2 to 7 days and should be treated with frequent applications of ice. Gentle cleansing is OK, but one should avoid exposure to sun.

- **Infection**
  Infection of the skin is exceedingly rare but is still a possible risk following a skin burn or wound caused by Flash N' Go™.

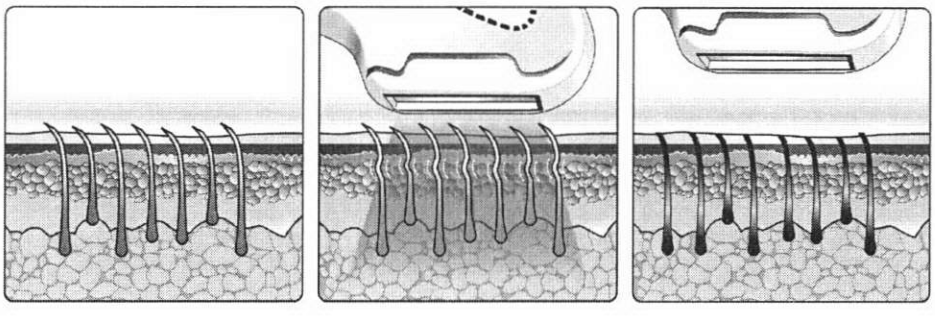
- **Bruising**
  Very rarely, use of Flash N' Go™ may cause blue-purple bruising that can last 5 to 10 days. As the bruising fades, there may be a rust-brown discoloration of the skin (hyperpigmentation) that can be permanent.

9. Long Term Hair Removal the Flash N' Go™ Way

Flash N' Go™ is a personal light-based device for long-term hair removal. The process of laser and light-based hair removal is well known and established. It has been proven in clinical use around the world for over 15 years as a safe and effective way to achieve long-term hair reduction.

9.1. How does light remove hair?

Light-based hair removal is based on the theory of selective photothermolysis in which optical energy is used to disable hair growth. In order to achieve such thermal effect the hair shaft needs to selectively absorb light energy and transform it into heat. This selectivity is achieved when optical energy that is delivered to the tissue is mostly absorbed by hair shaft pigment, while the skin and the surrounding tissue stays cool. Melanin is the pigment in the hair shaft that is responsible for the absorption of the light, which generates the heat that eventually disables hair growth. Therefore the more melanin present in the hair (i.e. the darker the hair) the more light that can be absorbed and the more effective light can be at removing hair.



Before Flash N' Go™ Application **During Flash N' Go™ Pulse** **After Flash N' Go™ Application**

9.2. How does the hair growth cycle impact light-based hair removal?

Every hair in our body goes through the three phases of the hair growth cycle: Anagen, Catagen and Telogen. These phases have an important impact on how the process of light-based hair removal works.

Anagen is the hair growth phase while Catagen and Telogen, both are resting phases.

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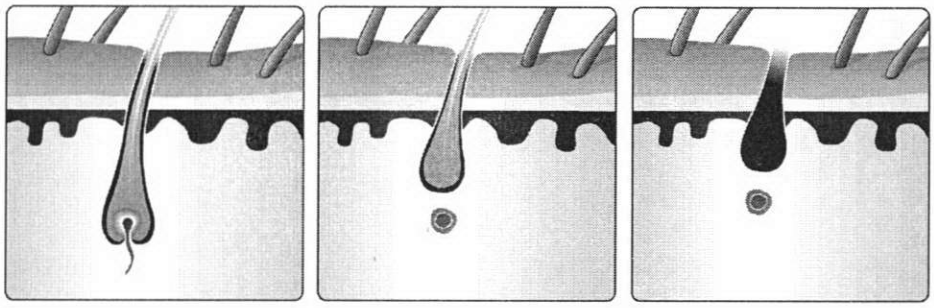
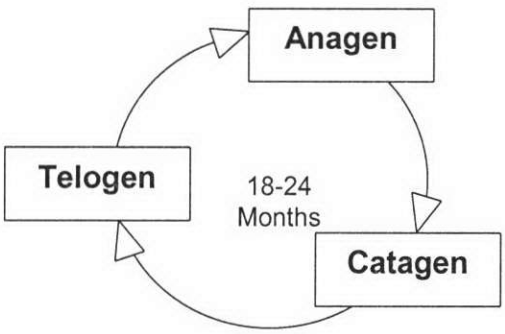


Anagen–Growth phase **Catagen–Resting phase** **Telogen–Resting phase**

The time it takes to complete a full hair growth cycle varies from person to person and the location of the hair on the body, but is typically 18-24 months. At any given moment the majority of the hair follicles in any skin area are in the resting phases. These resting hairs cannot be affected by Flash N' Go™. However, hairs in the growing Anagen phase will respond to Flash N' Go™ applications. It is important to understand that it may take a full hair growth cycle to realize complete hair removal results with Flash N' Go™.



9.3. Plan your Flash N' Go™ hair removal for best results

A typical full hair growth cycle may take 18-24 months. During this time multiple Flash N' Go™ sessions may be required in order to achieve long term hair removal.

The efficiency of hair removal varies from person to person according to body area, hair color, and how Flash N' Go™ is used.

Typical Flash N' Go™ hair removal plan during a full hair growth cycle:

- The first **3-4 hair removal sessions** with Flash N' Go™ will be approximately **two weeks apart**.
- Hair removal **sessions 5-7** with Flash N' Go™ will be approximately **four weeks apart**.
- After that you will typically use Flash N' Go™ again **from time to time** if and when needed, until long-term results are achieved.

This is the recommended treatment schedule that has proven to produce the best results, but you may plan your personal treatment schedule differently and still get satisfactory results.

Note that treating the same body part more often than once in two weeks, will not improve hair removal results.

Typical maintenance with Flash N' Go™ after achieving long-term hair removal:

Due to hormonal or other physiological changes dormant hair follicles may become active. Maintenance hair removal sessions with Flash N' Go™ may be required from time to time.

10. How To Use Flash N' Go™

10.1. Flash N' Go™ Setup

1. Remove Flash N' Go™ *BASE UNIT*, *APPLICATOR* and other components from box.
2. Insert the *APPLICATOR* into its cradle in the Flash N' Go™ *BASE UNIT*.
3. Verify that the *DISPOSABLE LAMP CARTRIDGE* is inserted correctly into the *APPLICATOR*.
4. Plug the power cord into the Flash N' Go™ *BASE UNIT* socket.
5. Plug the other end of the power cord into an electrical outlet.

Your Flash N' Go™ is now ready to start.

10.2. Treating with Flash N' Go™ for the first time

The skin should be **shaved**, **clean**, **dry** and **free** of any powders, antiperspirants or deodorants.

1. Press the *POWER ON/OFF SWITCH*. The *POWER INDICATOR LIGHT* will turn on and a fan sound (similar to the sound of a hairdryer) will start.
2. Approximately 3.5 seconds after pressing the *POWER ON/OFF SWITCH*, the *READY INDICATOR LIGHT* will turn on and the device beeps. The device sets itself to deliver the lowest energy level pulses. The device is then ready for you to trigger the first pulse.
3. If the energy level should be higher than the lowest, press the *ENERGY LEVEL SETTING BUTTONS* using the "-" or "+" to respectively decrease or increase the energy level, until the desired energy level is set. *ENERGY LEVEL INDICATOR LIGHTS* will coincide with the energy level setting. (See "Energy Level" frame).
4. Apply the *APPLICATOR* firmly to the skin, making sure the skin is spread evenly and smoothly. Make sure the *APPLICATOR TIP* is in full contact with the skin.
5. Press the *PULSE BUTTON*. The device will first determine the color of your skin.
   If the color of the skin is light enough for safe application, the device will flash a pulse of light onto your skin. You will see a bright flash of light and simultaneously hear a subtle pop sound, which is a normal noise for the device. You may feel a mild sensation of warmth and tingling.
   Flash N' Go™ will immediately recharge for the next pulse. After 3.5 seconds the *READY INDICATOR LIGHT* will turn on again and the device will beep.
   If you see no light pulse, and the 5 green energy level LEDs blink for 3 seconds, your skin tone is too dark for safe application. Try using the device on a different body part or contact the Flash N' Go support.
6. Remove the *APPLICATOR TIP* from the treated area of skin.
7. Move the *APPLICATOR TIP* to another area of skin.
   Use the pressure marks the device just made in your skin to guide you for proper positioning of the next pulse, avoiding both gaps and overlaps between pulses (See "Covering skin areas" frame).
   Warning: Do not treat the same area of skin more than once per hair removal

session! Treating the same area of skin more than once per session increases the likelihood of adverse effects.

8. Repeat the process starting again with Step 5.

Energy Level

Energy level determines the intensity of the Flash N' Go™ light pulse delivered to your skin, from the lowest level (-) to the highest level (+). Corresponding *INDICATOR LIGHTS* on the *CONTROL PANEL* represent the increases in energy. As energy level increases, so does hair removal results as well as the risk of possible side effects and complications.

Always start your first Flash N' Go™ hair removal session at the lowest energy setting.

If you experience little or no discomfort during and after the hair removal session using the lowest energy level, raise the energy level by one *INDICATOR LIGHT* at the next session, and so on for each subsequent session.

Do not raise the energy level if you experience abnormal discomfort during or after treating with Flash N' Go™ (See section 2.6 - "Possible Side Effects"). ***Do not raise the energy level during hair removal session even if you experience no discomfort. Discomfort may also appear some time after the session.***

Whenever Flash N' Go™ is turned on its energy level will automatically be reset to the lowest energy level. Only one *ENERGY LEVEL INDICATOR LIGHT* will be on.

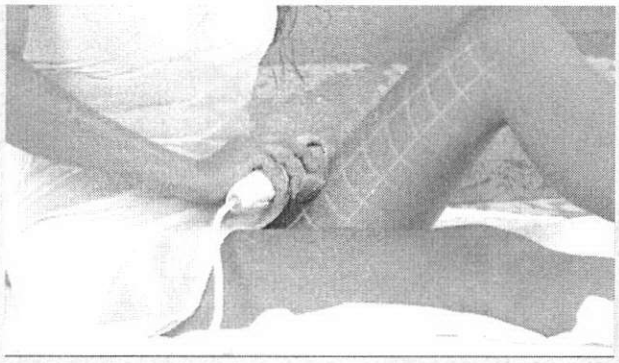
To set the energy level, press the *ENERGY LEVEL SETTING BUTTONS* using "-" or "+" to respectively decrease or increase the energy level. The number of *ENERGY LEVEL INDICATOR LIGHTS* will coincide with the change in energy level.

For your safety, when using Flash N' Go™ for the very first time, the system is automatically set to deliver the first 50 pulses at the lowest energy level, and the next 200 pulses at up to level 3.

To cancel these safety settings press and hold the "+" and "-" *ENERGY LEVEL SETTING BUTTONS* simultaneously until you hear 2 consecutive "beep" sounds. To **restore** these safety settings press and hold the "+" and "-" *ENERGY LEVEL SETTING BUTTONS* simultaneously until you hear 3 consecutive "beep" sounds.

Covering skin areas

Flash N' Go™ pulses should be administered in rows, starting at one end of each row and progressing sequentially towards the other end. This technique allows better control of skin coverage, and helps you avoid treating the same area more than once or overlapping skin areas



When applied to the skin, the Flash N' Go™ *APPLICATOR TIP* is designed to create temporary pressure marks on the treated area. These visible marks can be used for proper positioning of the next pulse.

Try to avoid overlapping pulses!

Do not treat the same area of skin more than once per hair removal session!

If your skin blisters or burns, STOP USE IMMEDIATELY!

10.3. What to Expect when treating with Flash N' Go™?

For many people, using Flash N' Go™ may be their first experience with a light-based device designed for home use. Flash N' Go™ is simple to use, and hair removal sessions go by quickly. During a Flash N' Go™ session it is **normal** to experience and feel:

- **A Flash of Light** – The bright light of Flash N' Go™ will not harm the eyes when applied to non-facial sites, and special eye-protection is not needed when using Flash N' Go™.
- **A Fan Noise** – The cooling fan in Flash N' Go™ makes noise similar to a hairdryer. This is normal.
- **A Pop Sound with Each Pulse** – When a pulse of HPL™ light is activated, it is normal to hear a subtle pop sound simultaneously with the flash of light.
- **Moderate Pressure of the *APPLICATOR*** – This is necessary and helpful for placement of adjacent pulses of light, and is part of the unique safety feature of Flash N' Go™.
- **A Sensation of Warmth and Tingling** – During each pulse of light it is normal to feel a mild sensation of warmth and tingling from the light energy. Remember it is important to always use low energy settings for initial hair removal sessions. You may feel some warmth for up to an hour after your Flash N' Go™ session.
- **Some Mild Red or Pink Color** – During and just after your Flash N' Go™ session it is not uncommon to see some very mild, pink-like color of the skin. This is usually most noticeable around the hairs themselves. However if you see full redness of the skin, blistering or burns stop use of Flash N' Go™ immediately.

10.4. After treating with Flash N' Go™

- When Flash N' Go™ session has been completed turn Flash N' Go™ off by pressing the *POWER ON/OFF SWITCH*. (Be sure to remember the last energy level setting you used, as it will not be restored when turning Flash N' Go™ on again.)
- Unplug the power cord from the electrical outlet.
- After each hair removal session it is recommended that you clean your Flash N' Go™ device, especially the *APPLICATOR TIP* (See section 5.1: "Cleaning Flash N' Go™").
- After cleaning, it is recommended to store your Flash N' Go™ device in its original box, and keep it away from water.

Skin care following hair removal session

Do not expose treated areas of skin to the sun. Be sure to carefully protect the treated skin with sunscreen, throughout the hair removal period and for at least 2 weeks following the last Flash N' Go™ session.

Side effects and complications

Some patients may experience pigmentation changes resulting from treating with Flash N' Go™. These effects, if they occur, are generally mild and transient.

In case you experience any complication (See section 2.6 Possible Side Effects using Flash N' Go™) ***please contact your physician immediately.***

11. Maintenance of Flash N' Go™

11.1. Cleaning Flash N' Go™

After each hair removal session, it is recommended to clean your Flash N' Go™ device, and especially the *APPLICATOR TIP*.

- Unplug Flash N' Go™ before cleaning.
- Use a dry, clean cloth and a specially formulated cleaner for electronic equipment to gently wipe Flash N' Go™ surface, and especially the *APPLICATOR TIP*.
  Never immerse Flash N' Go™ or any of its parts in water!

11.2. Replacing the LAMP CARTRIDGE

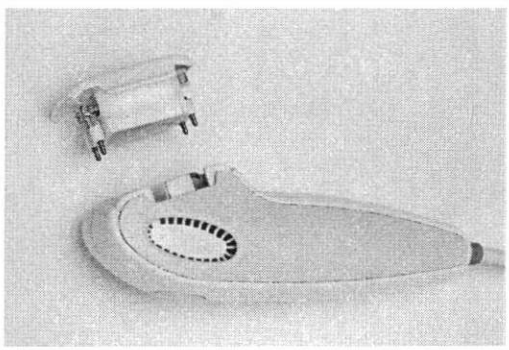
The Flash N' Go™ *DISPOSABLE LAMP CARTRIDGE* can fire 750 light pulses that would typically cover 2 Legs, Arms, Under arms, and Bikini line. Pulse intensity is determined only according to the energy level setting of the device. There is no decrease of energy during the usable lifetime of the *LAMP CARTRIDGE*.

When a *DISPOSABLE LAMP CARTRIDGE* has reached 90% of its possible lifetime the *CARTRIDGE 90% USAGE INDICATOR LIGHT* on the *CONTROL PANEL* will be activated, indicating that the *DISPOSABLE LAMP CARTRIDGE* should soon be replaced.

Once all 750 pulses in a *DISPOSABLE LAMP CARTRIDGE* have been used the *CARTRIDGE 100% USAGE INDICATOR LIGHT* will be activated, indicating that further pulses can not be emitted.

In order to continue the hair removal session, it will now be necessary to replace the *DISPOSABLE LAMP CARTRIDGE*.

Note: A *DISPOSABLE LAMP CARTRIDGE* should also be replaced if large spots appear inside it or if its *LENS* is broken.



To replace a *DISPOSABLE LAMP CARTRIDGE:*

1. Press the *POWER ON/OFF SWITCH* to turn Flash N' Go™ off.
2. Unplug the power cord from the electrical outlet.
3. Grasp the used *DISPOSABLE LAMP CARTRIDGE* on both sides, pull it out of the

socket and discard with normal trash.

4. Unwrap a new *DISPOSABLE LAMP CARTRIDGE.*
5. Line up the holes in the *APPLICATOR* socket with the metal and plastic hinges in the new *DISPOSABLE LAMP CARTRIDGE,* and push it gently into place.

If correctly installed, the *DISPOSABLE LAMP CARTRIDGE* will spring back when pushed in and released.

12. Troubleshooting

12.1. "My Flash N' Go™ does not start."

- Make sure the power cord is properly connected to the Flash N' Go™ device.
- Make sure the power cord is plugged into an electrical outlet on the wall.

12.2. "A light pulse is not emitted when I press the PULSE SWITCH."

- Make sure that you have good contact with the skin and that the *APPLICATOR TIP* is evenly and firmly pressed to the skin. For your safety, the *PULSE BUTTON* will activate a pulse only if the *APPLICATOR TIP* is firmly pressed against the skin.
- Skin color sensor stopped the light pulse, your skin may be to dark for using the Flash N' Go. Try to apply Flash N' Go™ again.
- Check the *CARTRIDGE 100% USAGE INDICATOR*. If it is on, disconnect Flash N' Go™ and replace the *DISPOSABLE LAMP CARTRIDGE*.
- Make sure that the *READY INDICATOR* is on.
    a. If within 10 seconds the *READY INDICATOR* remains off turn Flash N' Go™ off and back on by pressing the *POWER ON/OFF SWITCH* twice.
    b. If the problem persists, contact your local Flash N' Go™ Customer Service Center.
- Check the *SYSTEM WARNING INDICATOR LIGHT*.
    c. If the light is on turn Flash N' Go™ off and back on by pressing the *POWER ON/OFF SWITCH* twice.
    d. If the problem persists, contact your local Flash N' Go™ Customer Service Center.

If these problems persist, contact your local Flash N' Go™ Customer Service Center.

Do not attempt to open or repair your Flash N' Go™ device. Only authorized Flash N' Go™ repair centers are permitted to perform repairs.

Opening Flash N' Go™ may expose you to dangerous electrical components and to pulsed light energy, either of which may cause serious bodily damage and/or permanent eye injury.

Trying to open Flash N' Go™ may also damage the device and will void your warranty.

Please contact Flash N' Go™ Customer Service if you have a broken or damaged device in need or repair.

13. Customer Service

For more information about Flash N' Go™ please enter www.silkn.com.

If your Flash N' Go™ is broken, damaged; in need of repair, or for any other Flash N' Go™ user assistance, please contact Flash N' Go™ Customer Service:
1-877-DO-SILKN / 1-877-367-4556
contact@silkn.com

14. Frequently Asked Questions

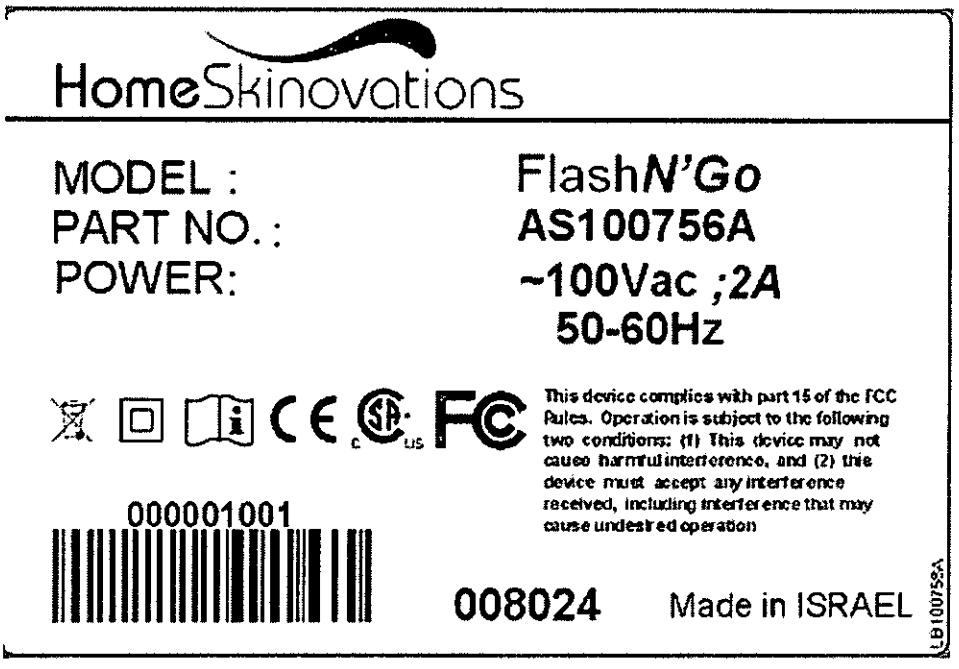
1. ***Does Flash N' Go™ really work?***
   Yes. In clinical trials held by physicians, Flash N' Go™ was proven to safely achieve long-term hair removal results.
2. ***Where on my body can I use Flash N' Go™?***
   The Flash N' Go™ device has been designed for body hair removal anywhere below the neck. The most common areas treated with Flash N' Go™ are: legs, underarms, arms and bikini line. It is not recommended to use Flash N' Go™ on the face. Flash N' Go™ is not suitable for everyone. We recommend that you read all the Flash N' Go™ warnings and contraindications in this User's Manual.
3. ***How long does a Flash N' Go™ treatment session take?***
   The time can vary depending on the area of the body treated. A full leg can take up to 30 minutes, or two underarms could take 10 minutes. Because Flash N' Go™ runs on regular electric power it can be used for as long as needed to complete a full hair removal session of the desired body part(s).
4. ***Is Flash N' Go™ safe?***
   Flash N' Go™ has been designed with your safety in mind, and tested and approved by top dermatologists and plastic surgeons to meet their safety standards for a home-use device. But like any skin product or electronic device, one must use according to the operating instructions and user precautions.
5. ***Will Flash N' Go™ hurt?***
   When used properly most users of Flash N' Go™ report feeling a slight sensation of heat at the time of the pulse of light. Users with thicker and darker hairs may feel slightly more discomfort, but this discomfort subsides once the hair removal session is completed. For your convenience Flash N' Go™ has five setting levels that can be used according to your sensitivity.
6. ***How often should I use Flash N' Go™?***
   Hair removal sessions with Flash N' Go™ should be spaced every two weeks for the first three to four sessions. After that hair removal sessions should be done if hairs have grown back, until the desired results are achieved.
7. ***Is Flash N' Go™ effective on white, grey or blonde hairs?***
   Flash N' Go™ works best on darker hair types, or hair that contains more melanin. Melanin is the pigment that gives hair and skin their color, and will absorb light energy. Black and dark brown respond the best, although brown and light brown hairs will also respond but typically require more hair removal sessions. Red may show some response. White, grey or blonde hairs usually don't respond to Flash N' Go™ though some users have noted results after multiple hair removal sessions.
8. ***Can I use Flash N' Go™ on brown or black skin***
   Do not use Flash N' Go™ on naturally dark skin complexion! Flash N' Go™ removes unwanted hair by selectively addressing hair pigment. Varied quantities of pigment also exist in the surrounding tissue of skin. The quantity of pigment in a particular person's skin, which is manifested by their skin complexion, determines the degree of risk they are exposed to using Flash N' Go™. Treating dark skin with Flash N' Go™ can result in adverse effects such as burns, blisters, and skin color changes (hyper- or hypo-pigmentation).
9. ***When will I see results from Flash N' Go™?***
   As with any light-based or laser hair removal device, results are not immediate, and in fact you may not think anything happened at all. Hair may sometimes appear to be growing back after a hair removal session, but typically after two weeks many of these hairs will simply fall out. Additionally hairs grow in three different stages and only hairs in an active growth stage will be affected by Flash N' Go™. This is one of the main reasons that multiple sessions are required to achieve the desired result.

10. ***Can a man use Flash N' Go™?***
    Though designed exclusively for women, Flash N' Go™ may be suitable for use by men. However, hairs on men, typically those on the chest, will require more hair removal sessions than that of women to get the desired results. As with women, using Flash N' Go™ on men's facial hair such as beard and mustache, is not recommended.
11. ***Why is my hair growing, even though I treated it a week ago?***
    It is quite common for hair to appear as if it is still growing up to two weeks after a hair removal session with Flash N' Go™. This process is known as "ejection" and at around two-weeks you'll see that these hairs simply fall out or slide out with a slight tug. (We don't however recommend pulling on the hairs – just let them come out naturally.) It is also possible that some hairs, due to missed application or different stages of growth, were not affected by Flash N' Go™. These hairs will be treated in follow-up sessions, and hence the reason multiple hair removal sessions are needed to get the best result with Flash N' Go™.
12. ***I've heard that some hairs grow back lighter and finer after light based hair removal?***
    This phenomenon is well documented amongst aestheticians and doctors using light and laser devices for hair removal. It is possible that some hairs will grow back lighter and finer after hair removal with Flash N' Go™. Usually these hairs are a fraction of what was originally there, and continued use may have a desirable effect on them.
13. ***Why can't I treat myself if I have an "active" suntan?***
    Do not use Flash N' Go™ on tanned skin or after sun exposure! Tanned skin and particularly following sun exposure, contains large quantities of the pigment Melanin. This applies to all skin types and complexions, including those which don't seem to tan quickly. The presence of large quantities of Melanin exposes the skin to higher risk of adverse effects when using Flash N' Go™ including burns, blisters, and skin color changes (hyper- or hypo-pigmentation).
14. ***Is long-term use of Flash N' Go™ dangerous for my skin?***
    The use of light and laser energy in aesthetic medicine has been well documented for over 15 years in professional peer-reviewed journals, and by well respected institutions like the Mayo Clinic. These journals and institutions have not reported any side-effects or damage from long-term use of light and laser device.
15. **Can I use Flash N' Go™ to remove my chin hair or elsewhere on my face?**
    It is not recommended to use Flash N' Go™ on the face or neck. Unlike body hair, most of women's potential facial hair remains inactive and hidden, while only a fraction of it grows and surfaces. Exposing facial hair to the light pulses of Flash N' Go™ may remove apparent hair but simultaneously stimulate unwanted growth of hidden hair. In addition, using Flash N' Go™ to remove facial hair may cause serious eye injury.
16. ***How long should I wait to treat with Flash N' Go™ after unprotected exposure to the sun?***
    One should wait 4 weeks before using Flash N' Go™ after unprotected exposure to the sun. However, if there is ever any uncertainty about sun exposure please contact your physician or Home Skinovations customer support.
17. ***Should I do anything before using Flash N' Go™?***
    Before any Flash N' Go™ session it is important to avoid sun exposure on the treated area for at least four weeks. A high level UV Sun Screen (SPF 50+) will help, as will clothing covering the treated area. The area to be treated should also be cleaned with mild soap and water, and the hairs shaved down to skin level.
18. ***How should I care for the treatment area after using Flash N' Go™?***
    The area treated with Flash N' Go™ can be cleaned and maintained with standard skin care products. Special care must be taken to avoid unprotected sun exposure. Strong sunscreens (50+ SPF) and covering clothing are suitable for protection from the sun.
19. ***Should I pull the hairs out after treatment?***
    No, let the hairs gradually fall out on their own. This may take up to 2 weeks.

15. Specifications

Spot size	2cm x 3cm [6cm^2]
Speed	1 pulse every 3.5 second: 1.7 cm^2/sec
Technology	New Home Pulsed Light™
Max Energy Level	Max 5J/cm^2
Wavelength	475-1200nm
Charging time / Power source	Continuous operation
Electrical requirements	100-240VAC, 2A
Time needed to treat lower legs	30 minutes
Operation and Safety	*SKIN COLOR SENSOR* seamlessly ensures use only on appropriate skin types.
package size	Height 9 inch, Width 9 inch, Depth 5.2 inch
System weight	4 pounds

16. Labeling



Class II equipment

Degree of protection against electric shock: type BF applied part

WEEE - Waste Electrical and Electronic Equipment

CE Mark

Follow operating instructions

This device comply with part 15 of the (FCC) Federal Communications Commission.

CSA Mark for USA and Canada

Degree of protection against ingress water: ordinary

This device is not suitable for use in the presence of flammable anesthetic mixture with air or with Oxygen or Nitrous Oxide.

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HomeSkinovations

EC Declaration of Conformity

We Home Skinovations Ltd. declare under our sole responsibility that the home Skin treatment products

Brand Name:	***Home Skinovations***
Model Name:	***Flash N' Go, Disposable Lamp Cartridge***
Models Number	**AS100001E,AS100674B,AS100756A**

are fully in conformity with the essential requirements of Council Directive 89/336/EEC and 73/23/EEC amended by Directives 93/68/EEC.

This declaration is based on the full compliance of the products with the following European standards:

EMC:	**EN 61000-3-2:2000; (A2:2005),** **EN 61000-3-3:1995; (A1:2001)** **EN 55014-1:2000; (A2:2002),** **EN55014-2:1997; (A1:2001)**
Electrical safety:	**EN 60335-1:2002; (A1:2004; A12:2006),** **EN 60335-2-23:2003,** **EN 60335-2-27:2003**
Human Exposure to electromagnetic field radiated	**EN 50364:2001**

Manufacturer:

Home Skinovations Ltd.
Apolo Building, Shaar Yokneam,
POB 533, Yokneam 20692, ISRAEL
Tel: +972-4-9097470
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Authorized Representative:

Home Skinovations GMBH
Dr. Kurt Huber Str. 6
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Fax +49-89-64919531

Signed:

Gabi Lavi
General Manager
Yokneam, February 4, 2008

Signed:

Dr. Amir Waldman
VP Regulatory & Clinical Affairs
Yokneam, February 4, 2008

For Information: On the basis of this declaration, these products and packaging will bear the following mark:

CE

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Flash N' Go™ is a **physician recommended** and innovative light-based device for hair removal in the **privacy of your home**. **Safe**, **easy to use** and **cost effective**, Flash N' Go™ achieves **marked clinical results** while offering personal convenience.

Flash N' Go™ utilizes the highly sophisticated and new **Home Pulsed Light™ (HPL™)** technology developed by **Home Skinovations Ltd**.

Chapter 20
Performance testing – Clinical

Clinical Information

Introduction

Clinical trials were carried out in order to verify the safety and effectiveness of the Silk'n Flash N Go.

A prospective, multi-center study was carried out on patients with different skin color, age. (b) (4), enrolled and completed protocol. Investigator determined patient eligibility to participate in the study according to inclusion / exclusion criteria.

After completing the informed consent form, the investigator performed a base line hair count. Patients treated according to the treatment protocol. (b) (4)
(b) (4)

The patients had various skin pigmentations which varied from skin type (b) (4) different hair color. Effectiveness (b) (4) post treatment results to those of the pre-treatment. Percentage of hair reduction was calculated, and the resulting average hair reduction for all patients was (b) (4) months, (b) (4). Safety was evaluated by monitoring immediate reaction and adverse effects. (b) (4)
(b) (4)
were no other adverse effects associated with the treatment.

Clinical study

Method

The information, which is presented in this report, was obtained from a multi center clinical study that worked under IRB approved protocol specified in the relevant section below. The study was carried out at 3 centers in the U.S., Canada, and Israel.

Study Sponsor:
Home Skinovations Ltd.

Study monitor:
Dr. Amir Waldman

Apolo Buld. P.O.B. 533
Yokneam Illit 20692 Israel

Home Skinovations Ltd.
Apolo Buld. P.O.B. 533
Yokneam Illit 20692 Israel

The centers that conducted the study:

(b) (4)

[redacted]

Treatment protocol

The medical device that was used for this study was Silk'n Flash N Go, used for the clinical study under IRB approval. The detailed protocol, informed consent form, Post treatment instruction can be found in Appendix 1. Highlights of the study protocol are presented in this section. The device was used with the following parameters: Light optical output power (b) (4) [redacted]

This is a prospective clinical study of (b) (4) [redacted] designed to determine the safety and efficacy of the Silk'n Flash N Go device is an over the counter device intended for the removal of unwanted hair. Flash N Go is also intended for permanent reduction in hair regrowth defined as a long-term, stable reduction in hair counts following a treatment regime.

Purpose and objective

Purpose: The purpose of this clinical investigation is to study and document the use of the Silk'n Flash N Go, as an over the counter device, for permanent hair reduction.

Objectives: The objectives of the study are to determine the safety and effectiveness of low energy light pulses for permanent hair reduction.

Patient selection

Each patient was evaluated by the investigator to ensure that they met the inclusion / exclusion criteria of the study.

Inclusion Criteria

1- Presence of unwanted hairs on the body, [redacted]

2- Skin Type [redacted] (Fitzpatrick)

3- Females older than 21 years of age, must be either post-menopausal or surgically sterilized, or using a medically acceptable form of birth control (i.e., oral contraceptives, IUD, contraceptive implant, barrier methods with spermicide or abstinence).

4- Informed consent agreement by the subject.

5- Willingness to follow the treatment schedule and post treatment care

Exclusion Criteria

1. Malignant or pre-malignant pigmented lesions in the area to be treated
2. Scarring or infection of the area to be treated
3. Known photosensitivity
4. Pregnancy
5. Subjects with Diabetes (Type I or II)
6. Presence of a suntan in the area to be treated
7. Use of medication known to induce photosensitivity

8. Known anticoagulative or thromboembolic condition
9. Subjects with a pacemaker or internal defibrillator
10. Use of NSAIDS two weeks prior to, and two weeks following the treatment
11. Subjects that used waxing or other methods of photo-epilation 3 months prior to treatment

Clinical Procedure

Pre-Procedure Evaluation

1- The Investigator discussed with the subject other available treatment options including the Silk'n Flash N Go hair removal system.

2- During the first visit, the investigator obtained an informed consent from the subject, clearly indicating her understanding of the requirements and risks involved with study participation, including but not limited to:

a. (b) (4)
b.
c.
d.
e.
f.
g.
h.
i.

3- A full detailed subject chart recorded initial hair count in the area to be treated. Initial hair count was preformed to assess treatment efficacy as the treatment progressed.

4- (b) (4)

If the subject met with all inclusion and exclusion criteria, the investigator obtained signed Informed Consent, enrolled the subject into the study, and recorded required data on the appropriate study data form. The pre-treatment data was stored in the computer under the subject study number ID.

A copy of the Informed Consent Form (ICF) and a copy of a Case Report Form (CRF) are presented as part of appendix 1.

Treatment procedure

The treatment performed in the investigator clinic by a trained Nurse or technician.

Treatment Parameters

Instructions:

All patients received treatments according with the user manual. (b) (4)

(b) (4)

Treatment test spot

To perform the Treatment test spot, follow sections 1-6 and wait 15 minutes to check if any side effects are noted:

1. In the area to be treated, hairs should be trimmed to 3/32 inch length, (1-2 mm), or shaved 3 days prior to the treatment.
2. Clean the skin from the trimmed hairs.
3. Hold the applicator and ensure that the light output window is clean.
4. Switch on the system and set the energy level.
5. Place the Applicator on the treatment area and apply slight pressure. Press the trigger switch to emit light pulse.
6. Move the applicator to the next spot to ensure full coverage of the area to be treated.
7. Repeat the test spot procedure for 3 pulses.
8. If side effects are noted after 15 minutes, reduce the energy level by one level to lower setting.

9. Transient Erythema and follicular redness are normal reactions as well as smell of burned hairs.

10. If no side effects are noted after 15 minutes, complete the treatment to cover entire area to be treated.

Post Treatment Care.

Apply moisturizer after the treatment.

Use high factor sunscreen and protect the treated area from sunlight for at least 2 days after the treatment. Tanning after a treatment may cause hyper-pigmentation.

Repetitive treatments

Treatments will be performed (b) (4) [redacted]

Photographs using the digital camera system should be taken before treatment and at (b) (4) [redacted]

Complications

If an unanticipated adverse event occurs at any time during or after the use of the system, the Investigator must report it to the sponsor. A serious adverse event or complication directly attributable to the use of the System will be reported to the Sponsor as soon as possible within twenty-four (24) hours or sooner.

Data Analysis

Hair loss at each follow up session was calculated as the ratio of the number of hairs after the treatment compared with the hair count prior to treatment. Hair count will be preformed by the investigator.

Results

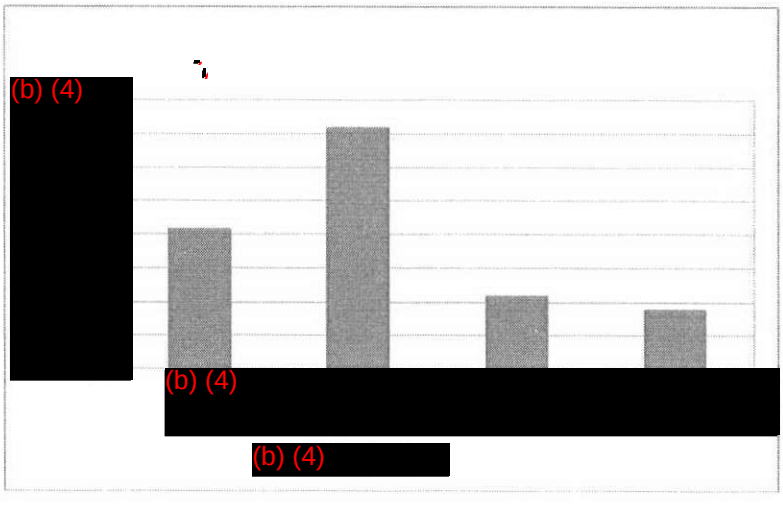
A total of (b) (4) [redacted] volunteered to participate in the study. All of them were treated under the study protocol. Treated area for all patients were (b) (4) [redacted] (b) (4) [redacted] A fellow physician, that didn't enroll the patients, performed evaluation of the treatment results by hair count at the (b) (4) [redacted] follow up session. Hair

clearance was calculated as the percentage of (b) (4) follow up count compared with the initial hair count.

Patient information summary

The population that was studied covered a range of ages, and skin pigmentations. These distributions are shown in the graphs in Figures 1, 2 and 3. Raw data tables showing patient information can be found in table 1.

(b) (4)



(b) (4)

Treatment results summary

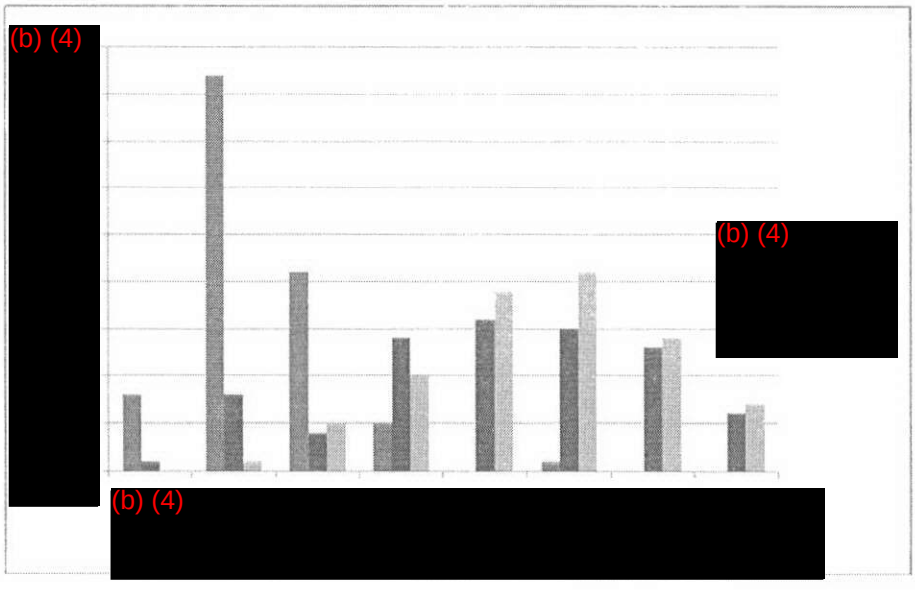
Hair reduction was calculated by dividing the (b) (4) follow up count by the initial baseline hair count. The overall hair clearance for all patients, and all sites, (b) (4)

Figure 2 summarizes distribution of participants by hair-reduction/clearance category. (b) (4)

months and is in average (b) , while the majority of the participant experienced (b) - (b) (4) The (b) (4)

groups, which proves that the hair count is stable and therefore (b) (4) of the hairs in the treated area achived. (b) (4)

(b) (4)



(b) (4)

Complications

The immediate skin reaction (b) (4)

(b) (4) other side effects were noted.

Conclusion

The results presented above lead to the conclusion that the Silk'n Flash N Go is safe and effective as an over the counter device intended for the removal of unwanted hair, and for permanent reduction in hair regrowth defined as a long-term, stable reduction in hair counts following a treatment regime.

(b) (4)

(b) (4)

Clinical Study to Determine the Safety and Efficacy of the Silk'n Home Pulsed Light Device

Clinical Investigation Plan

Date: (b) (4)

Protocol number: (b) (4)

Version (b) (4)

Sponsor:

Home Skinovations Ltd.

P.O.B. 533 Yokneam Illit

20692 Israel

Tel: 972-4-9097471

Fax: 972-4-9097470

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Protocol Summary

This is a clinical study to determine the efficacy and safety of low energy intense pulsed light, (IPL) device for hair removal. Treatment sites will include (b) (4) (b) (4).

The system uses two filtered Xenon lamps in a hand held applicator that generates a pulse of light. The principle of selective photo-thermolysis has been studied extensively for hair removal applications due to the wide-spread use of this technology. The light penetrates the epidermis to the dermis and is absorbed by the Melanin in the hair shaft. The heat generated by the absorbed light is then dissipated to the follicle and generates local thermal damage, causing reduction in hair growth. This technology has been used extensively by many devices to generate hair loss using lasers or filtered Xenon flash lamps, mostly in doctors' offices.

Present methods of hair removal:

1. Depilators
2. Shaving
3. Waxing
4. Laser or light based treatments.

The proposed method is based on the principal of selective photo-thermolysis using pulse light in (b) optical fluences of up to 5 J/cm^2. Light spectrum is set by the optical filter to 475-1200 nm, which is highly absorbed by the hair shaft Melanin. The use of (b) (4) energy is expected to be safe even on darker skin types, and the ability to control the energy output will allow the user safe and effective treatment.

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Name and Intended Use of Device

Proprietary name:	Silk'n
Common name:	Intense pulse light system
Intended Use:	The device is indicated for body hair removal ([redacted])

Purpose and Objectives

Purpose:	The purpose of this clinical investigation is to check the efficiency and safety of the Silk'n hair removal device.
Objectives:	The objective of the study is to determine the ability of inducing hair loss with a low power photo-epilation system.

Scope and Duration of the Study

Scope:	The clinical study will include [redacted] subjects at [redacted]
Duration:	Eligible subjects will receive [redacted] treatments according to the study protocol and will be followed for a perio[redacted] document safety and efficacy.

Substantial equivalence and risk level

The overall specifications, principle of operation, performance characteristics of the Silk'n device are substantially equivalent to those of the predicate device- Silk'n (Home Skinovations Ltd., K072906). The Silk'n, similar to its predicate device, is a non significant risk device. None the less, in order to establish the margins of the treatment parameters and determine the most effective and case specific parameters, we further wish to examine and optimize the safety and efficacy of the Silk'n device per clinical indication.

Subject Selection

Investigator will determine patients eligibility to participate in the study according to inclusion / exclusion criteria.

Inclusion Criteria

1- Presence of unwanted hairs on the body, (b) (4))

2- Skin Type (b) (4)

3- Males and females older than 21 years of age but not more than 60 years of age.

4- If female, must be either post-menopausal or surgically sterilized, or using a medically acceptable form of birth control (i.e., oral contraceptives, IUD, contraceptive implant, barrier methods with spermicide or abstinence).

5- Informed consent agreement by the subject.

6- Willingness to follow the treatment schedule and post treatment care

Exclusion Criteria

1. Malignant or pre-malignant pigmented lesions in the area to be treated
2. Scarring or infection of the area to be treated
3. Known photosensitivity

4. Pregnancy
5. Subjects with Diabetes (Type I or II)
6. Presence of a suntan in the area to be treated
7. Use of medication known to induce photosensitivity
8. Subject is on anticoagulative medication or thromboembolic condition
9. Subjects with a pacemaker or internal defibrillator
10. Use of NSAIDS two weeks prior to, and two weeks following the treatment
11. Subjects that use waxing or other methods of photo-epilation 3 months prior to treatment

Note: the device is not to be used on the face

Discontinuation

Subjects enrolled in the study will be free to discontinue their participation in the study at any time. A decision to discontinue participation will not prejudice their medical care. In such instances, Investigators will attempt to obtain clinical results and side effect evaluation concerning the subject prior to his/ her withdrawal.

Clinical Procedure

Pre-Procedure Evaluation

1- The Investigator will discuss with the subject many available treatment options including the Silk'n Hair Removal System and other treatment modalities.

2- During the first visit, the investigator will obtain an informed consent from the subject, clearly indicating his/her understanding of the requirements and risks involved with study participation, including but not limited to:

a. (b) (4) [redacted]

b. (b) (4)

c.

d.

e.

f.

g.

h.

3- A full detailed subject chart will record initial hair count in the area to be treated. Initial hair count will be used to assess treatment efficacy as the treatment progresses.

4- (b) (4)

If the subject meets all inclusion and exclusion criteria, the investigator will obtain signed Informed Consent, enroll the subject into the study, and record required data on the appropriate study data form. The pre-treatment data will be stored in the computer under the subject study number ID.

A copy of the Informed Consent Form (ICF) and a copy of a Case Report Form (CRF) are attached to this protocol.

Treatment

The treatment will be performed in the investigator clinic by a trained Nurse or technician.

Treatment Parameters

Energy level should match the subject skin type. Test pulse energy should be set according with the attached table:

	Energy level for test pulse
Skin type (b) (4) [redacted]	(b) (4) [redacted]
Skin type	
Skin type	

Treatment test spot

Treatment test pulse should be preformed on the darker part of the area that is going to be treated by the Silk'n. If for example the arm is to be treated, the test pulse should be preformed on the outer part of the arm where it is usually darker than the inner part of the arm.

If no skin reaction was noted 15 minutes after the test pulse, (see test pulse instruction in the next section), a second test pulse should be preformed at one level higher than the first pulse. If no skin reaction was noted perform the treatment.

Treatment

To perform the Treatment, follow steps 1-6 and wait 15 minutes to check if any side effects are noted:

1. In the area to be treated, hairs should be trimmed to 3/32 inch length,(1-2 mm), or shaved 3 days prior to the treatment.
2. Clean the skin from the trimmed hairs.
3. Hold the applicator and ensure that the light output window is clean.
4. Switch on the system and set the energy level.
5. Place the Applicator on the treatment area and apply slight pressure. The light window should be in good contact with the skin, press the trigger switch to emit light pulse.

6. Move the applicator to the next spot to ensure full coverage of the area to be treated.
7. Repeat the test spot procedure for 3 pulses.
8. If side effects are noted after 15 minutes reduce the energy level by one level to lower setting.
9. Transient erythema and follicular redness are normal reactions as well as smell of burned hairs.

If no skin reaction noted after 15 minutes complete the treatment to cover entire area to be treated.

After the session is finished the applicator should be clean using isopropyl alcohol.

Post Treatment Care.

The investigator should supply moisturizer for subjects use after the treatment.

Use high factor sunscreen (SPF of 15 or greater), and protect the treated area from sunlight for at least 2 days after the treatment. Tanning after a treatment may cause hyper-pigmentation.

Repetitive treatments

(b) (4)

[redacted]

Data Analysis

Hair loss at each follow up session will be calculated as the ratio of the number of hairs after the treatment compared with the hair count prior to treatment. Hair count will be performed by the investigator or clinic staff.

Materials

Silk'n Hair Removal Device will be placed at the participating institution, maintained and serviced as needed. Home Skiovations Ltd. will provide the system to the institutions for the duration of the clinical investigation.

Training Requirements

Both the Investigator and the Sponsor, prior to any independent use of the device, will agree as to the Investigator's training requirements. Prior to the study, the sponsor will ensure that the investigators have received training regarding use of the device.

Risk/ Benefit Analysis

Risks

The potential risks for adverse effects of the treatment procedure include, but are not limited to, (b) (4) [redacted]

(b) (4) [redacted]

Benefits

Potential benefits include reduction of unwanted hair from the skin.

Alternatives

Present methods of skin treatments are by laser or light based devices as well as epilation, waxing, shaving, and depilators. Published studies confirm that these systems provide a reliable, usually complete treatment. Temporary dyschromias, and in rare instances, scarring have occurred as a result of this treatment.

Informed Consent

The Investigator will obtain written Informed Consent prior to the anticipated scheduled procedure. The investigator will inform the subject as to the experimental procedure to be applied.

The investigator will assure the subject that his or her decision regarding participation in the study will have no bearing on the quality of medical care received and that the decision whether to participate in or withdraw from the study is strictly voluntary.

If the system is used on a subject without obtaining an Informed Consent, the Investigator must report the use to the Sponsor and the reviewing IRB.

Records and Reports

Data from the pre-treatment evaluation, the treatment procedure (complication, if any), the post-procedural evaluations and all follow-up evaluations will be recorded directly on the clinical data forms prepared for the study.

All specified records and reports concerning the clinical study will be forwarded to the Sponsor within a reasonable amount of time. The Investigators shall retain copies of all documentation for a period of two years following the date on which the entire clinical investigation is terminated or discontinued.

Confidentiality

This study is confidential. Information made public regarding subjects enrolled in this study will not disclose the name of any individual.

Monitoring Procedures

The study will be monitored by representatives of Home Skinovations Ltd. by telephone, in writing and during on-site visits. At the very least, site visits will be scheduled prior to the initiation of the study, on the occasion of the initial use of investigational devices, and at the end of the study. The purpose of site visits will be to ensure compliance with the investigational plan, to ensure appropriate use of investigational devices, and to inspect and retrieve study data.

Investigator Certification

Home Skinovations Ltd. certifies that each Investigator who takes part in this study will read and sign the Investigator's Agreement. Original signed Agreements will be retained

by Home Skinovations Ltd. No Investigators will be added to the investigation until they have signed the Agreement.

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APPENDIX - 1: STUDY SCHEMATICS

Visit#	(b) (4)		
Week#	(b) (4)		
Informed Consent Form	X		
Inclusion/ Exclusion	X		
Medical History	X		
Test spot	X		
Treatment	X	X	
Hair Count	X		X
Photography	X		X
Adverse Events Evaluation	X	X	X

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Appendix 3 - Case report form

Visit 1 – Study Entry Data Patient Id:

Date of this assessment: ___/___/___

Subject Demographics:

Date of Birth : ___/___/___

Male/Female

Gender (Enter appropriate response): _____

Subject History (Enter appropriate response):

Signed Informed Consent Form? _____

Skin Type: _____

Deep suntan present? _____

Known photosensitivity? _____

Pregnancy? _____

Use of acceptable birth control method? _____

Date of last menstrual period? _____

With Diabetes (Type I or II)? _____

Use of medication known to induce photosensitivity? _____

Scarring/ Infection present? _____

Known anticoagulative or thromboembolic condition? _____

Use of Accutane within past 6 months? _____

Use of aspirin or other NSAIDs two weeks prior to, and for two weeks following the treatment? _____

With a pacemaker or internal defibrillator? _____

Older than 21 years? _____

All questions above should be answered for subject to be enrolled in this study.

Other Relevant Medical Conditions or Further Comments on the Above:

_____

_____

Investigator Initials: _____ Date: _____

Visit 1 – Subject Medical History

Date of this assessment: ____/____/____

Additional relevant medical history, if any Check here if none _____

Relevant Medical History	Check if condition is ongoing

Comments:

_____

_____

_____

_____

Investigator Initials: _____ Date: _____

Treatment follow up form Date of this assessment: ____/____/____
Investigator Assessment:
Clinical Observation: 0 = absent, 1 = mild, 2 = moderate, 3 = severe

Target Area : _____

Skin type_____

	Erythema	**Edema**	**comments**
(b) (4) [redacted]			

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INFORMED CONSENT FORM

Study Title: Clinical Study to Determine the Safety and Efficacy of the Silk'n Home Pulsed Light Device

Study Doctor

Name

Address

Telephone Number

INTRODUCTION:

This Informed Consent form is being presented to you, because after a discussion about this research study and being verbally informed, you have indicated that you are interested in participating in this research study for a device (Silk'n Home Use Hair Removal Device) for hair removal. The purpose of this document is to inform you in writing of the purpose of the research, a description of the procedures to be followed, possible risks and discomforts, possible benefits, and of basic ground rules which will govern this research project. After reading this from and having all your question answered, if you decide to participate, you should return this consent form to the study doctor's office, sign this form on the last page, initial and date each prior page in the presence of the study stuff. Please read this form carefully before you make your decision. You may refuse to participate in this study and that decision will not be held against you, nor will it change any matters between you and this office, and you will continue to receive the same level of health care.

Subjects who may not participate are those who have:

- Scarring in the proposed treatment area.
- Have had a prior treatment of the area with another laser or light-based device.
- Are pregnant, or planning a pregnancy.
- Have diabetes.

- Have a suntan in the area.
- Are using a medication that sensitizes skin to light or are taking blood-thinners or use pain relievers on a regular basis such as aspirin, Motrin®, Advil®, Naprosyn®, Aleve® two weeks prior to, and two weeks following the treatment.

PURPOSE:

The purpose of this research study is to determine the safety and effectiveness of the use of Silk'n device, for hair removal. The system is based on the principle of selective photo-thermolysis (breakdown of the hair follicle due to heat from intense pulse light), that has been studied and used extensively for hair removal uses.

The light penetrates the top layer of the skin to the deeper layer and is absorbed by the melanin (dark pigment) in the hair shaft. The heat generated by the absorbed light is then spread to the follicle and generates local heat damage, causing reduction in hair growth.

(b) (4) .

PROCEDURES:

If you agree to participate (b) (4) study, you will be required to make as many as (b) (4) (b) (4) receiving up to (b) , according to the study doctor's decision, and the achieved results. The first visit will determine if you are eligible to be in this study. (b) (4) prior to the first treatment, all other treatments of hair removal are prohibited in the area to be treated. Females of child-bearing potential must use of adequate birth control (i.e. oral contraceptives, IUD, contraceptive implant, barrier methods with spermicide or abstinence). You will be asked to provide a detailed medical history (particularly about any medications that affect the skin), have your skin and hairs examined to determine what skin type you have and to select the area for the study procedure. The actual treatment session should last approximately 20 minutes. All treatments will be administered by nurse or trained technician. Test spot will be performed on the area where the actual treatment is going to be (b) (4) (b) . The test spot involves 3 applications and follow up of 15 minutes to assure that no adverse reaction is noted.

Before the treatment, photographs will be taken of the designated treatment area. These pictures may be used by the Sponsor (Home Skinovations Ltd.) in the future for educational and marketing purposes. Your identity will be masked in the picture. At the first treatment session, a hair count will be performed, and the best settings for the system output will be determined before the full treatment followed by a rest period to observe those effects. The area to be treated should be shaved 3 days prior to treatment. Afterwards, you will be given instructions on the care of the treated area and things to avoid.

In the event were any side effect are noted, a follow-up appointment will be made for the first or the second day after the treatment to re-examine your skin. You will be asked about any discomfort and reactions you may be experiencing. Another photograph of the treated area may be taken. The visit should last approximately 20 minutes.

(b) (4) [redacted]. An examination of the treated area will be done to evaluate your skin's condition. Each visit should last approximately 20 minutes.

(b) (4) [redacted] Photographs of the treated skin and a hair count will be taken. Each of the follow up sessions should last approximately 15 minutes.

(b) (4) [redacted], unless you are experiencing a complication. If so, you will be asked to return for further examinations until it resolves. A photograph of the treated area may be taken and the results will be assessed. Your participation in the study will then end.

RISKS AND DISCOMFORTS:

The device may cause the following skin reactions: redness, pain, blistering, crusting, swelling, decrease or increase of skin color and scarring. There is a chance the area could become infected (especially if it is not kept clean or you pick at any crusts or scabs). The study doctor will advise you in a set of instructions how to avoid such complications. An antibiotic cream or ointment may be needed. If so, the study doctor will provide it to you at no charge. You should report any reactions or problems with the treated site to the study doctor promptly. Some risks are

unforeseeable. Any new findings that develop during the course of this investigation, which may relate to your willingness to continue your participation, will be provided to you.

BENEFITS:

You may experience hair loss in the area that is treated. There is no guarantee that you may experience any improvement. Your participation may help in the development of a device for the treatment of unwanted hair.

ALTERNATIVES:

Current methods available for hair removal treatments include:

1. Depilators
2. Shaving
3. Waxing
4. Laser or light-based treatments
5. Electrolysis

You do not have to participate in this research study to receive hair removal treatment.

CONTACTS:

If you experience a study-related problem, or if you have any questions at any time about the study, contact Dr. *[name]* at *[telephone number]*.

If you have any questions about your rights as a research participant or related concerns or complains, you may contact the (b) (4) (b) (4). The (b) (4) is a committee that has reviewed this research study to help ensure that your rights and welfare as a research participant are protected and that the study will be carried out in an ethical manner. Review and approval of this study by the (b) (4) is not an endorsement of the study or its outcome.

RESEARCH PARTICIPATION INFORMATION

You can obtain information about participating in research studies from a number of sources. A few are:

- Center for Information and Study on Clinical Research Participation (CISCRP): www.ciscrp.org
- Food and Drug Administration (FDA): www.fda.gov
- Office for Human Research Protections (OHRP): www.hhs.gov/ohrp
- National Institute of Health: clinical trials.gov
- National Cancer Institute: www.nci.nih.gov
- CenterWatch: www.centerwatch.com
- Various large university websites
- Various associations and societies concerned with specific diseases websites."

FINANCIAL:

To help defray the costs of your participation, you will be paid [redacted] for each visit. If you complete the study, you will be paid an additional bonus of [redacted]. The maximum compensation for subjects participation in the study is [redacted]

COSTS:

There will be no costs to you for office visits, examinations, antibiotic cream, and procedures as part of this study.

COMPENSATION FOR INJURY:

If a research-related injury occurs, the sponsor, Home Skinovations Ltd. will pay for any treatment of research-related injury, which will be provided by the study doctor. However, the sponsor will not pay for pre-existing conditions or for any conditions arising after the study. Also, you will not receive compensation for wages associated with lost-time at your workplace. However, by signing this form you have not given up any of your legal rights.

CONFIDENTIALITY AND AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION:

A federal regulation called the "Health Insurance Portability and Accountability Act" (HIPAA), describes how your personal health information may be used, disclosed and made accessible to you. This privacy rule is designed to protect the confidentiality of your personal health information.

This study can be performed only by collecting and using your personal health information. Your study records will be kept as confidential as possible under local, state and federal laws. Personnel from the following organizations may examine your study records: the sponsor, [Home Skinovations Ltd.], personnel associated with this study, regulatory agencies, such as the (b) (4) [redacted] Because of the number of individuals who may see your records, absolute confidentiality cannot be guaranteed.

Personal health information that may be used and disclosed includes that which is obtained to determine your eligibility to participate and that which is collected from the procedures that are carried out. It may identify you by name, address, telephone number, Social Security Number, study number, date of birth or other identifiers. Once the information is disclosed, it is possible that it may be re-disclosed, at which time it may no longer be protected by federal regulations, but may be by state laws. If the final study data are prepared for publication and other reports, your identity will not be revealed. Under these federal privacy regulations, you have the right to see and copy any of the information gathered about you, until your study records are no longer kept by the study doctor. However, it may not be available until the study has been completed.

You may, by written notice to the study doctor, cancel your authorization to use or disclose your personal information at any time. If you withdraw your authorization, the information collected up to that time may still be used to preserve the scientific integrity of the study. By signing this consent form, you authorize these uses and disclosures of your personal information. If you do not authorize these uses and disclosures, you will not be able to participate in the study. This authorization does not have an expiration date.

VOLUNTARY PARTICIPATION/ WITHDRAWAL:

Your participation in this study is voluntary and, if you decide to withdraw at any time, you may do so without penalty or giving up any benefits to which you are otherwise entitled. You may be discontinued from the study by the study doctor for reasons of, but not limited to, (1) a severe adverse reaction, (2) the study is stopped, (3) your failure to follow instructions, (4) the study doctor determines it is your best interest.

PHOTOGRAPH CONSENT

Photographs and digital images will be taken of your treated areas as a requirement for participating in this study. These photographs and digital images will not reveal your identity, but they may not be used without your written consent. By checking the box below, you give your permission to use photographs and digital images of your treated areas, which were taken during this study, for the purposes of professional publications, training, education or sales. You will automatically be withdrawn from the study, should you choose not to give your consent at this time.

I may cancel or withdraw my photography consent at any time during or after my participation in this study. I must do so in writing and submit that withdrawal of consent to Dr. _____. I agree to have photographs taken as a part of this study as described in this paragraph."

❑ YES _____ (initial) ❑ NO _____ (initial)

CONSENT:

I have read this consent form, have had any questions answered and understand the purpose, procedures, risks and other aspects of the study. I voluntarily agree to participate in this research study. I will be given a signed and dated copy of this consent form.

_____
Subject's Name (printed)

_____ Date: _____
Subject's Signature

_____
Person conducting consent process

_____ Date: _____
Study Doctor's Signature

POST-TREATMENT INSTRUCTIONS

Following Treatment:

There may be a stinging or sunburn sensation accompanying your treatment. This will subside over the next several hours and can be relieved with the application of a cool compress or an ice pack to the treated area.

Immediately following treatment with the device, there will be generalized redness, often accompanied by smell of burned hairs. These effects are generally temporary and should resolve over the next several hours.

Precautions:

Avoid direct sun exposure or tanning beds between treatments. A sunscreen with an SPF 15 or higher should be used when sun exposure cannot be avoided.

Avoid injury to the area. Do not rub, scratch, or pick at the treated skin. Treating the skin gently will decrease the chance of any problems.

Make-up application over the treatment area should be avoided if any scaling or crusting appears.

Shower or bathe as usual with a mild soap, but remember the treated area may be temperature sensitive. Avoid the use of exfoliants, loofa sponges, and aggressive scrubbing of the treatment area. While the area is still red or healing, use a soft cloth to pat the area dry.

Contact this office immediately; Dr. [Name], [Telephone number] with any questions.

Clinical Study to Determine the Long Term Efficacy of the Silk'n Home Pulsed Light Device

Clinical Investigation Plan follow-up Study

Date: (b) (4)

Protocol number: (b) (4)

Version (b) (4)

Sponsor:

Home Skinovations Ltd.

P.O.B. 533 Yokneam Illit

20692 Israel

Tel: 972-4-9097471

Fax: 972-4-9097470

Protocol Summary

This is a clinical study to determine the long term efficacy of a low energy intense pulsed light, (IPL) device for hair removal. The study involves one follow up session on subjects that participated in the HR-2 study.

The system uses two filtered Xenon lamps in a hand held applicator that generates a pulse of light. The principle of selective photo-thermolysis has been studied extensively for hair removal applications due to the wide-spread use of this technology. The light penetrates the epidermis to the dermis and is absorbed by the Melanin in the hair shaft. The heat generated by the absorbed light is then dissipated to the follicle and generates local thermal damage, causing reduction in hair growth. This technology has been used extensively by many devices to generate hair loss using lasers or filtered Xenon flash lamps, mostly in doctors' offices.

Name of Device Used

Proprietary name:	Silk'n
Common name:	Intense pulse light system
Intended Use:	The device is indicated for permanent hair reduction

Purpose and Objectives

Purpose:	The purpose of this clinical investigation is to check the long term efficiency of the Silk'n for permanent

hair reduction.

Objectives: The objective of the study is to determine the ability of inducing permanent hair reduction with a low power photo-epilation system.

Scope and Duration of the Study

Scope: The clinical study will include (b) (4)

Duration: (b) (4)

Risk level

There is no risk involved in this study as no treatment will be performed. (b) (4) (b) (4).

Subject Selection

Investigator will ask all participants in the previous (b) (4) to be part of this study.

Inclusion Criteria

1- Participation in the (b) (4)

Exclusion Criteria

2- (b) (4)

(b)

(b) (4)

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Discontinuation

Subjects enrolled in the study will be free to discontinue their participation in the study at any time. A decision to discontinue participation will not prejudice their medical care. In such instances, Investigators will attempt to obtain clinical results and side effect evaluation concerning the subject prior to his/ her withdrawal.

Procedure

Evaluation

If the subject meets all inclusion and exclusion criteria, the investigator will obtain signed Informed Consent, enroll the subject into the study, and record required data on the appropriate study data form. The evaluation data will be stored in the computer under the subject study number ID.

A copy of the Informed Consent Form (ICF) and a copy of a Case Report Form (CRF) are attached to this protocol.

Procedure

(b) (4) [redacted]

Data Analysis

(b) (4) [redacted]

Risks

(b) (4) [redacted]

Informed Consent

The Investigator will obtain written Informed Consent prior to the anticipated scheduled procedure. The investigator will inform the subject as to the evaluation procedure to be applied.

The investigator will assure the subject that his or her decision regarding participation in the study will have no bearing on the quality of medical care received and that the decision whether to participate in or withdraw from the study is strictly voluntary.

If the evaluation is performed on a subject without obtaining Informed Consent, the Investigator must report the violation to the Sponsor and the reviewing IRB.

Records and Reports

Data from the evaluation, the procedure (complication, if any), the post-procedural evaluations and all follow-up evaluations will be recorded directly on the clinical data forms prepared for the study.

All specified records and reports concerning the clinical study will be forwarded to the Sponsor within a reasonable amount of time. The Investigators shall retain copies of all documentation for a period of two years following the date on which the entire clinical investigation is terminated or discontinued.

Confidentiality

This study is confidential. Information made public regarding subjects enrolled in this study will not disclose the name of any individual.

Monitoring Procedures

The study will be monitored by representatives of Home Skinovations Ltd. by telephone, in writing and during on-site visits. At the very least, site visits will be scheduled prior to the initiation of the study, on the occasion of the initial use of investigational devices, and at the end of the study. The purpose of site visits will be to ensure compliance with the

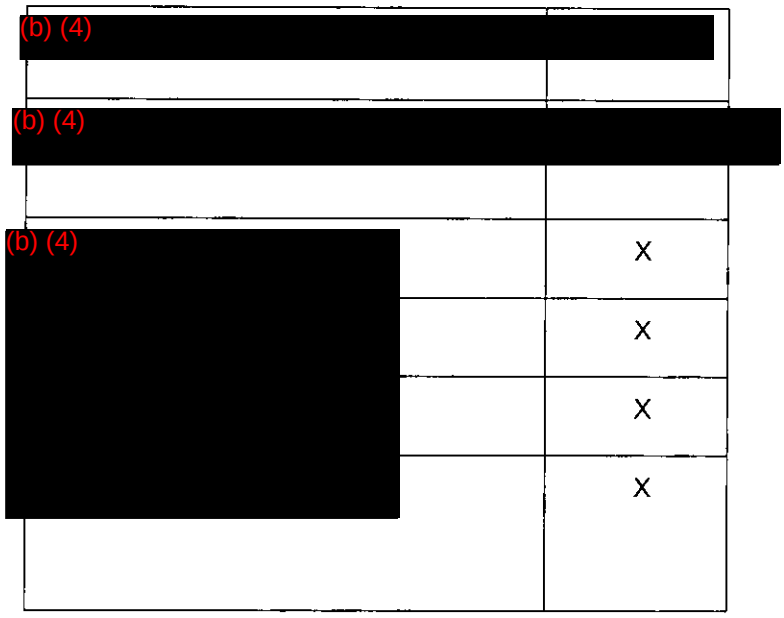
investigational plan, to ensure appropriate use of investigational devices, and to inspect and retrieve study data.

Investigator Certification

Home Skinovations Ltd. certifies that each Investigator who takes part in this study will read and sign the Investigator's Agreement. Original signed Agreements will be retained by Home Skinovations Ltd. No Investigators will be added to the investigation until they have signed the Agreement.

(b) (4)

APPENDIX - 1: STUDY SCHEMATICS



Appendix 3 - Case report form

Visit 1 – Study Entry Data Patient Id:

Date of this assessment: ____/____/____

Subject Demographics:

Date of Birth : ____/____/____

Gender (Enter appropriate response): Male/Female

Subject History (Enter appropriate response):

Signed Informed Consent Form? _____

Skin Type: _____

Deep suntan present? _____

Known photosensitivity? _____

Pregnancy? _____

Use of acceptable birth control method? _____

Date of last menstrual period? _____

With Diabetes (Type I or II)? _____

Use of medication known to induce photosensitivity? _____

Scarring/ Infection present? _____

Known anticoagulative or thromboembolic condition? _____

Use of Accutane within past 6 months? _____

Use of aspirin or other NSAIDs two weeks prior to, and for two weeks following the treatment? _____

With a pacemaker or internal defibrillator? _____

Older than 21 years? _____

All questions above should be answered for subject to be enrolled in this study.

Other Relevant Medical Conditions or Further Comments on the Above:

_____

_____

Investigator Initials: _____ Date: _____

Hair count:

INFORMED CONSENT FORM

Study Title: Clinical Study to Determine the Long Term Efficacy of the Silk'n Home Pulsed Light Device

Study Doctor

Name

Address

Telephone Number

INTRODUCTION:

This Informed Consent form is being presented to you, because after a discussion about this research study and being verbally informed, you have verified that you previously participated in the (b) research study for a device (Silk'n Home Use Hair Removal Device) for permanent hair removal. The purpose of this document is to inform you in writing of the purpose of the research, a description of the procedures to be followed, possible risks and discomforts, possible benefits, and of basic ground rules which will govern this research project. After reading this from and having all your question answered, if you decide to participate, you should return this consent form to the study doctor's office, sign this form on the last page, initial and date each prior page in the presence of the study stuff. Please read this form carefully before you make your decision. You may refuse to participate in this study and that decision will not be held against you, nor will it change any matters between you and this office, and you will continue to receive the same level of health care.

Subjects who may not participate are those who have:

- (b) (4)

Subject's initials_____

Date_____

PURPOSE:

The purpose of this research study is to determine the long term effectiveness of the use of Silk'n device, for permanent hair reduction.

This study will include (b) (4)
(b) (4)

PROCEDURES:

If you agree to participate in this one follow-up visit, you will be required to come to the study doctor's office. (b) (4)
(b) (4)

Photographs will be taken of the designated treatment area. These pictures may be used by the Sponsor (Home Skinovations Ltd.) in the future for educational and marketing purposes. Your identity will be masked in the picture.

The examination should last approximately 15 minutes. After the visit your participation in the study will end.

ALTERNATIVE TO PARTICIPATION

(b) (4)

RISKS AND DISCOMFORTS:

(b) (4)

BENEFITS:

Your participation may help in the development of a device for the treatment of unwanted hair.

CONTACTS:

If you experience a study-related problem, or if you have any questions at any time about the study, contact Dr. *[name]* at *[telephone number]*.If you have any questions about your rights as a research participant or related concerns or complains, you may contact the (b) (4)
(b) (4) You may also
(b) (4)

Subject's initials_____

Date_____

study to help ensure that your rights and welfare as a research participant are protected and that the study will be carried out in an ethical manner. Review and approval of this study by the Essex IRB is not an endorsement of the study or its outcome.

RESEARCH PARTICIPATION INFORMATION

You can obtain information about participating in research studies from a number of sources. A few are:

- Center for Information and Study on Clinical Research Participation (CISCRP): www.ciscrp.org
- Food and Drug Administration (FDA): www.fda.gov
- Office for Human Research Protections (OHRP): www.hhs.gov/ohrp
- National Institutes of Health: www.nih.gov
- www.womancando.org
- National Cancer Institute: www.nci.nih.gov
- CenterWatch: www.centerwatch.com
- Various large university websites
- Various associations and societies concerned with specific diseases websites."

FINANCIAL:

To help defray the costs of your participation, you will be paid $50 for your visit.

COSTS:

There will be no costs to you for the office visit, examination, or photographs as part of this study.

CONFIDENTIALITY AND AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION:

A federal regulation called the "Health Insurance Portability and Accountability Act" (HIPAA), describes how your personal health information may be used, disclosed and made accessible to you. This privacy rule is designed to protect the confidentiality of your personal health information.

This study can be performed only by collecting and using your personal health information. Your study records will be kept as confidential as possible under local, state and federal laws. Personnel from the following organizations may examine your study records: the sponsor,

[Home Skinovations Ltd.], personnel associated with this study, regulatory agencies, such as the (b) (4) [redacted] of the number of individuals who may see your records, absolute confidentiality cannot be guaranteed.

Personal health information that may be used and disclosed includes that which is obtained to determine your eligibility to participate and that which is collected from the procedures that are carried out. It may identify you by name, address, telephone number, Social Security Number, study number, date of birth or other identifiers. Once the information is disclosed, it is possible that it may be re-disclosed, at which time it may no longer be protected by federal regulations, but may be by state laws. If the final study data are prepared for publication and other reports, your identity will not be revealed. Under these federal privacy regulations, you have the right to see and copy any of the information gathered about you, until your study records are no longer kept by the study doctor. However, it may not be available until the study has been completed.

You may, by written notice to the study doctor, cancel your authorization to use or disclose your personal information at any time. If you withdraw your authorization, the information collected up to that time may still be used to preserve the scientific integrity of the study. By signing this consent form, you authorize these uses and disclosures of your personal information. If you do not authorize these uses and disclosures, you will not be able to participate in the study. This authorization does not have an expiration date.

VOLUNTARY PARTICIPATION/ WITHDRAWAL:

Your participation in this study is voluntary and, if you decide to withdraw at any time, you may do so without penalty or giving up any benefits to which you are otherwise entitled. You may be discontinued from the study by the study doctor for reasons of, but not limited to, (1) a severe adverse reaction, (2) the study is stopped, (3) your failure to follow instructions, (4) the study doctor determines it is your best interest.

This Space Intentionally Left Blank

Subject's initials_____

Date_____

PHOTOGRAPH CONSENT

Photographs and digital images will be taken of your treated areas as a requirement for participating in this study. These photographs and digital images will not reveal your identity, and they may not be used without your written consent. By checking the box below, you give your permission to use photographs and digital images of your treated areas, which were taken during this study, for the purposes of professional publications, training, education or sales. You will automatically be withdrawn from the study, should you choose not to give your consent at this time.

I may cancel or withdraw my photography consent at any time during or after my participation in this study. I must do so in writing and submit that withdrawal of consent to Dr. _____. I agree to have photographs taken as a part of this study as described in this paragraph."

❑ YES _____ (initial) ❑ NO _____ (initial)

CONSENT:

I have read this consent form, have had any questions answered and understand the purpose, procedures, risks and other aspects of the study. I voluntarily agree to participate in this research study. I will be given a signed and dated copy of this consent form.

_____
Subject's Name (printed)

_____ Date: _____
Subject's Signature

_____
Person conducting consent process

_____ Date: _____
Study Doctor's Signature

Appendix 1

Flash N Go (cleared) submission and all communication with FDA

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(b) (4)

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

Re: Letter dated September, (b) (4)

(b) (4)

Thank you for your letter dated (b) (4) in response to our 510K submission (b) (4)

Please find the requested information according to the order asked in your letter:

1. (b) (4)
2. Software level of concern and all applicable software document are presented in appendix 1.
3. (b) (4)
4. (b) (4)

   Therefore no new questions regarding biocompatibility should rise.
5. The Flash N Go should be used on clean skin area therefore the hairs should be shaved or trimmed prior to the procedure and the skin surface should be clean. As part of the clinical study with the Silk'n patient

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preformed all part of the protocol by themselves including shaving/ trimming the area to be treated by the Silk'n.

6-15 The user manual was changed according to your recommendation and presented in appendix 3.

We trust that the information included in this application will be adequate to allow for its prompt review. Please contact me if there are any questions.

Sincerely yours,

Dr. Amir Waldman
VP regulatory affairs
Home Skinovations Ltd.

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Appendix 1
Software level of concern and all required documents

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Yokneam 20692, ISRAEL

(b) (4) [redacted]

Flash N' Go Software Level of Concern

- Light pulse generation is enabling by hardware, no software fault can activate light pulse.
- Software fault may cause only higher light energy output pulse than requested by user. The max light energy output is limits by hardware.
- Color Sensor malfunction, software disable the light pulse.

Max light energy pulse energy is limits by hardware to the maximum charging voltage in case of software fault. (b) (4) [redacted].

(b) (4) [redacted]

In the most vulnerable user (dark skin type) were the energy setting was lowest ((b) [redacted]), a software fault may deliver double the energy. This may results in superficial burn with pigmentation changes and possible minor scaring.

Determining Level of Concern

According to the "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*"

Major Level of Concern *(If the answer to any one question below is Yes, the Level of Concern for the Software Device is likely to be Major)*		
No.	**Question**	**Answer**
1	Does the Software Device qualify as Blood Establishment Computer Software?	No
2	Is the Software Device intended to be used in combination with a drug or biologic?	No
3	Is the Software Device an accessory to a medical device that has a Major Level of Concern?	No
4.a	Does the Software Device control a life supporting or life sustaining function?	No
4.b	Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators?	No
4.c	Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury?	No
4.d	Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death?	No
4.e	Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?	No

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Yokneam 20692, ISRAEL

Moderate Level of Concern *(If the Software Device is not Major Level of Concern and the answer to any one question below is Yes, the Level of Concern is likely to be Moderate.)*		
No.	**Question**	**Answer**
1	Is the Software Device an accessory to a medical device that has a Moderate Level of Concern?	No
2	Prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device?	Yes
3	Could a malfunction of, or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?	No

Conclusion:

The Flash N' Go software level of concern is: **Moderate**!

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Flash N' Go

Software Verification and Validation Plan

DO1009131

	Role	Name	Signature	Date
(b) (4)				

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Revisions

Rev.	Page	Description	Approval	Date
(b) (4)				

NY

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Table of Contents

Home Skinovations Ltd.
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Yokneam, 20692, Israel

1 Introduction and overview

1.1 Purpose of this document

The purpose of this document is to provide an overview of the design and development of the Flash N' Go firmware. It will serve as a guide to the developers satisfying the client requirements and the specifications. This document will also be used in the verification and validation of the project.

1.2 Scope of the development Project

This project, named Flash N' Go, will consist of Base unit that contain the MCU firmware and the Applicator which contain the Disposable Lamp Cartridge and the Pulse button.

1.3 Definitions, Acronyms and Abbreviations

Term	Definition
Validation	Assure that the software system (function and performance) conform to user needs and intended use(s). Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled
Verification	A systematic procedure of review, analysis, and testing, employed throughout the software development cycle to assure that the software design outputs meet the design inputs (all design requirements). Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.
Walkthrough	A type of design review in which several participants review a work product. The objective of the meeting is to discover faults in the product
SRS	System requirements specification
SwRS	Software requirements specification
VVP	Verification and validation plan
DHF	Design History File

1.4 References

ID	Reference
IEEE-Std-1012	Std 1012-1998 IEEE Standard for Software Verification and Validation. IEEE Standards Collection: Software Engineering. The Institute of Electrical and Electronics Engineers, Inc., 1998

Document	Location
Software Requirements Specification documents	DHF

1.5 Overview of Document

This document describes the testing procedures and requirements that will be implemented for our project. The first section goes over review, walkthroughs, inspections, and audits and gives a schedule for them the next section talks about how each component of the system will be tested. Then is a section of how the system will be tested as a whole. The following sections is about how to tract defects. After that we have a section that maps the requirements in the SRS to their description in the SwDD. We next have a section that gives the test requirements for each of the components. And finally we have the test requirements for the release of the project.

2 Reviews; walkthroughs; inspections; and audits

2.1 Schedule of reviews, etc.

Refer to project development plan document.

2.2 Procedure for reviews, etc.

The following procedure has been used to review the documents that we have completed so far. First ideas are contributes as to what the document should contain, then one person from the group puts all idea into the document (refer to design verification SW Life Cycle).

3 Component Test Plans and Procedures

3.1 Component and Integration Test strategy overview

Each software component should have the capability of being tested "individually" within the development environment. As a minimum, test cases should be developed to cover "black box" or functional requirements and component interfaces. "White box" testing to measure percentage code path coverage is also desirable.

Each component based on safety requirements shall have test case(s), and a test procedure(s).

Integration testing will be performed in 2 cycles:

The first cycle focus on the interface requirements for the various design entity that make up Flash N' Go Firmware. Special tools and concepts may be developed in order to help facilitate integration testing. Emulator was used to test the functionality of each design entity and the following test attributes were applied:

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- Critical functions and Tasks (Normal Task; Interrupt Tasks)
- Boundary conditions.
- (b) (4)
- Incorrect and unexpected sequences and timing.
- Reaction of the firmware to system faults and failures.
- (b) (4)
- The Man Machine Interface.

The second cycle is integration with the real hardware and formal test procedures was followed and cover all the functional behavior of the system in normal progressive order and out of normal progressive order.

3.2 *Component Test description*

Below we summarize the modules, functionality, testing strategy, and test sets that we will be employing:

Design Entities	Functionality/Tasks	Testing Strategy	Test sets
1. App entity - Main	- Init task that initializes the MCU pinout, variables (b) (4) - ERROR handler that is used to respond to errors. - IDLE task that is used as - Capacitor Voltage handler that is used to manage the capacitor voltage. (b) (4)	Unit testing	(b) (4) MPLAB ICD 2 emulator and developer environment
2. App entity - ISR	ISR task is called every 50ms and is used for timing purpose	Code Verification	Developer constructed debugger environment
3. RFID entity – I2C:communication protocol	Receive; Send; Transmit; Stop;	Communication protocol verification	I2C verification tools
(b) (4)			

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Design Entities	Functionality/Tasks	Testing Strategy	Test sets
(b) (4)	;Read ; Write ; Deactivate		MPLAB ICD 2 emulator and developer environment
6. Capacitor Voltage entity	- Measure capacitor voltage - Charge Capacitors	Unit testing	MPLAB ICD 2 emulator and developer environment
7. Code Self Check entity	Firmware code memory verification	Unit testing	Developer constructed debugger environment
8. Misc entity	Create short delay time	Unit testing	Developer constructed debugger environment
9. MMI entity	LEDs Indication. Buttons polling, New system Level Limitation	Unit testing	MPLAB ICD 2 emulator and developer environment
10. Error entity	Check Errors	Unit testing	MPLAB ICD 2 emulator and developer environment
(b) (4)			

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3.3 Integration test description

3.3.1 Initialization

Test case group identification	Flow of initialization in the init state
Features to be tested	Reset and initialization
Testing Approach	Behavioral and functional testing
Pass/Fail criteria	Refer to software system test plan for detailed criteria that the product must satisfy in order to pass this test case group.

3.3.1.1 Initialization test case #1 – Normal flow

Test case identifier	System Initialization with correct firmware.
Input	Firmware is ready for integration testing
Expected output	Software initialized and pulse emission is enabled
Environment	Refer to software system test plan for detailed test environment requirements, including software, hardware and monitoring equipment.
Special Procedures	NA
Precedence and dependencies	The test case steps should follow the software detailed design sec 4.2.3
References	Software System test plan and results document

3.3.1.2 Initialization test case #2 –out of Normal flow

Test case identifier	Initialization with corrupted firmware or other hardware and software errors.
Input	Firmware is ready for integration testing
Expected output	Software initialized and Error LED displayed with pulse emission is disabled.
Environment	Refer to software system test plan for detailed test environment requirements, including software, hardware and monitoring equipment.
Special Procedures	Make use of special code with wrong check sum of the firmware.
Precedence and dependencies	NA
References	Refer to software system test plan for detailed test environment requirements, including software, hardware and monitoring equipment.

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3.3.2 Set Energy Level

Test case group identification	Flow of set energy level
Features to be tested	Enables the capacitors charging and checks when the charged capacitors have reached to the required level.
Testing Approach	Behavioral and functional testing
Pass/Fail criteria	Refer to software system test plan for detailed criteria that the product must satisfy in order to pass this test case group.

3.3.2.1 Set Energy Level test case #1 – Normal flow

Test case identifier	System set energy level (General actions / Treatment)
Input	Firmware is ready for integration testing
Expected output	The capacitors charged to the required level
Environment	Refer to software system test plan for detailed test environment requirements, including software, hardware and monitoring equipment.
Special Procedures	NA
Precedence and dependencies	Initialization test case #1 – Normal flow completed successfully.
References	Refer to software system test plan for detailed test environment requirements, including software, hardware and monitoring equipment.

3.3.2.2 Set Energy Level test case #2 – out of Normal flow

Test case identifier	Error handling of set energy level functionality(e.g. hardware will prevent the software from exceeding a maximal allowed charge voltage)
Input	Firmware is ready for integration testing
Expected output	All errors described in the software design document are performed.
Environment	Refer to software system test plan for detailed test environment requirements, including software, hardware and monitoring equipment.
Special Procedures	NA
Precedence and dependencies	Set Energy Level test case #1 – Normal flow completed successfully
References	Refer to software system test plan for detailed test environment requirements, including software, hardware and monitoring equipment.

3.3.3 Pulse Handler

Test case group identification	Pulse Handler functionality
Features to be tested	Emission of pulse upon successful fulfillment of required conditions
Testing Approach	Behavioral and functional testing
Pass/Fail criteria	Refer to software system test plan for detailed criteria that the product must satisfy in order to pass this test case group.

3.3.3.1 Pulse Handler test case #1 – Normal flow

Test case identifier	Verify generate a pulse
Input	Firmware is ready for integration testing
Expected output	Power meter display actual pulse emitted value.
Environment	Refer to software system test plan for detailed test environment requirements, including software, hardware and monitoring equipment.
Special Procedures	NA
Precedence and dependencies	Set Energy Level test case #1 – Normal flow completed successfully
References	Refer to software system test plan for detailed test environment requirements, including software, hardware and monitoring equipment.

3.3.3.2 Pulse Handler test case #2 – out of Normal flow

Test case identifier	Error handling of generates a Pulse.
Input	Firmware is ready for integration testing
Expected output	No measurement value on Power meter display 9Pulse is not generated).
Environment	Refer to software system test plan for detailed test environment requirements, including software, hardware and monitoring equipment.
Special Procedures	NA
Precedence and dependencies	Set Energy Level test case #1 – Normal flow completed successfully and Pulse Handler test case #1 completed successfully
References	Refer to software system test plan for detailed test environment requirements, including software, hardware and monitoring equipment.

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3.3.4 Monitor the capacitors voltage

Test case group identification	Monitor the capacitors voltage functionality
Features to be tested	Charge or discharge according to the Energy Level
Testing Approach	Behavioral and functional testing
Pass/Fail criteria	Refer to software system test plan for detailed criteria that the product must satisfy in order to pass this test case group.

3.3.4.1 Monitor the capacitors voltage test case #1 – Normal flow

Test case identifier	Capacitors charging
Input	Firmware is ready for integration testing
Expected output	Capacitors charged and LED indicators turn on.
Environment	Refer to software system test plan for detailed test environment requirements, including software, hardware and monitoring equipment.
Special Procedures	NA
Precedence and dependencies	Set Energy Level test case #1 – Normal flow completed successfully
References	Refer to software system test plan for detailed test environment requirements, including software, hardware and monitoring

3.3.4.2 Monitor the capacitors voltage test case #2 – out of Normal flow

Test case identifier	Error handling of capacitors charging
Input	Firmware is ready for integration testing
Expected output	Capacitors can not be charged and Error LED indicators turn on.
Environment	Refer to software system test plan for detailed test environment requirements, including software, hardware and monitoring equipment.
Special Procedures	NA
Precedence and dependencies	Monitor the capacitors voltage test case #1 – Normal flow completed successfully
References	Refer to software system test plan for detailed test environment requirements, including software, hardware and monitoring

(b) (4)

Test case group identification	(b) (4)
Features to be tested	(b) (4)
Testing Approach	Behavioral and functional testing
Pass/Fail criteria	Refer to software system test plan for detailed criteria that the product must satisfy in order to pass this test case group.

3.3.5.1 (b) (4)

Test case identifier	(b) (4)
Input	Firmware is ready for integration testing
Expected output	Capacitors charged and LED indicators turn on.
Environment	Refer to software system test plan for detailed test environment requirements, including software, hardware and monitoring equipment.
Special Procedures	NA
Precedence and dependencies	Turn on system, Use color Panel I (Go)
References	Refer to software system test plan for detailed test environment requirements, including software, hardware and monitoring

3.3.5.2 (b) (4)

Test case identifier	(b) (4)
Input	Firmware is ready for integration testing
Expected output	Capacitors can not be charged and Error LED indicators turn on.
Environment	Refer to software system test plan for detailed test environment requirements, including software, hardware and monitoring equipment.
Special Procedures	NA
Precedence and dependencies	Turn on system, Use color Panel II (No go)
References	Refer to software system test plan for detailed test environment requirements, including software, hardware and monitoring

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3.3.6 Hardware Check

Test case group identification	Hardware and software recovery
Features to be tested	Monitor hardware for abnormal or fault condition
Testing Approach	Behavioral and functional testing
Pass/Fail criteria	Refer to software system test plan for detailed criteria that the product must satisfy in order to pass this test case group.

3.3.6.1 Hardware Check test case #1 – Normal flow

Test case identifier	Verify system recovery
Input	Firmware is ready for integration testing
Expected output	Error LED is turned on and the firmware is stuck in an infinite loop.
Environment	Refer to software system test plan for detailed test environment requirements, including software, hardware and monitoring equipment.
Special Procedures	NA
Precedence and dependencies	All normal functional test cases are completed successfully
References	Refer to software system test plan for detailed test environment requirements, including software, hardware and monitoring

3.3.6.2 Hardware Check test case #2 – out of Normal flow

Test case identifier	Verify watchdog functionality within out of normal flow of software
Input	Special test firmware is ready for integration testing
Expected output	The system will repeatedly sound a beep for ready, delay then reset.
Environment	Refer to software system test plan for detailed test environment requirements, including software, hardware and monitoring equipment.
Special Procedures	Add an infinite loop after system ready sounds
Precedence and dependencies	NA
References	Refer to software system test plan for detailed test environment requirements, including software, hardware and monitoring

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4 System Test Plans and Procedures

4.1 System test Strategy Overview

System testing will be based on system level scenarios and system level requirements such as safety, regulatory, performance and capacity..

4.1.1 Scenarios

Each system level scenario should have an associated system level test case. This provides traceability and validates/verifies that the scenario has been implemented. The collection of "system" level scenarios tests could make up the majority of the tests called out in the software system test plan. Scenario test cases could be developed in parallel with Flash N' Go software.

4.1.2 Safety and Regulatory

Safety and regulatory requirements described in the Flash N' Go System SRS and Risk Analysis must have test cases that verify Flash N' Go software compliance.

4.1.3 Performance

Performance requirements such as time for capacitor to be charged, need to be verified for all life cycle phases and should be part of the core system tests.

4.1.4 Regression

Testing that is used to confirm the system functionality has not been comprised by incremental code upgrades, improvements, and bug fixes. These tests may also have a specific focus on SPR resolution. A regression test should be developed to confirm that a SPR has been resolved. This test should remain in the regression test suite throughout product life.

4.1.5 Reliability/Stress/Simultaneity

Part of the system testing should include the means necessary to measure software reliability. Stress and Simultaneity testing should be designed to provide maximum functionality coverage.

4.2 System Test Description

Refer to Software System test plan and results

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5 Defect tracking plans

This defect tracking document will include severity of the error (critical, high, medium, trivial), the phase in which the error is inserted and detected (requirements, coding, design, alpha test, beta test or acceptance test) and the user responsible for following up on the error. An appropriate description of the error detected should be provided as an abstract.

as a tester the user will record the software fault detected. The user will then notify the development team that a defect has been opened. The developer will resolve the defect and give the tester a new fixed version.

After the defect is verified the initial tester will run through the same steps to ensure that the original problem is corrected. The error will be closed after ensuring the problem is fixed else reopened for revaluation. As a developer, the user will monitor the open defects. If the user comes across a defect that was opened against code that he/she is responsible for, the user will view the defects details. After proper understanding of the defect the user will correct the code and put it into the verify state.

6 Traceability from SRS to SDD

Refer to the traceability matrix document.

7 Test requirements cross-reference Matrix

Refer to the traceability matrix document.

8 Acceptance Test and Preparation for delivery

8.1 Procedure by which the software product will be acceptance tested

The Flash N' Go firmware will be tested by the team, the client, a teacher, and a group of 8th grade students.

- The team will test all the test cases defied in the software system test plan to ensure they work as they are expected.

8.2 Specific acceptance criteria

Refer to the acceptance criteria of the system V&V.

8.3 Scenario by which the software product will be installed.

The system will be delivered with the firmware download to the device at the production.

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Flash N' Go

Unresolved Software Anomalies

DO1009171

	Role	Name	Signature	Date
(b) (4)				

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Revisions

Rev.	Page	Description	Approval	Date
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Table of Contents

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1 Introduction

1.1 Purpose

The purpose of this document is to present a list of all unresolved software anomalies.

1.2 Scope

This document is used to specify software anomalies as specified in the "Guidance for the Content of Pre-market Submissions for Software Contained in Medical Devices"

1.3 Definitions

The following table defines terms and definitions used:

Term	Definition
SPR	Software Problem Report

1.4 References

The following table lists all documents which supply inputs to this document:

Document	Doc No.	Revision	Location
Software System Verification and Validation Plan	DO1009131	1	DHF

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2 Unresolved Anomalies – Software Ver. 1.0.0

Bug No.	Problem	Impact on device performance	Timeframes for correcting the problem (where appropriate).

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Flash N' Go

Software Rivision History

DO1009161

Authorization			
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1. General

A software history revision log is provided below. Clearance is being thought for version **[1.2.0]**, which is the most recent version of the software.

2. Revision Level History

Revision number	Creation date	Notes
(b) (4) [redacted]		

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1. Traceability Analysis

The following table gives information on the traceability between software requirements and detailed design and the corresponding verification and validation test that addresses that requirement.

Software Requirement Identifier	Software Design Identifier	V&V Test
2.2 (a)	2.1.5	9.1.1
2.2 (b)	2.1.1	9.2.1;9.2.2 (safety related)
2.2 (c)	2.1.5	9.4.2
2.2 (d)	2.1.3	9.1.1;9.2.3
2.2 (e)	2.1.2	9.1.4; 9.1.6; 9.2.3(4); 9.2.4(6); 9.3.3
2.2 (f)	2.1.7	9.1.2;9.1.3
2.2 (g)	2.1.4	9.3.1; 9.3.2; 9.3.3; 9.4.3
3.1.1.1	HW Design	9.1.1 (1)
3.1.1.2	HW Design	9.1.1 (1)
3.1.1.3	4.6.1.2	9.1.1(2)
3.1.1.4	4.6.2.4	9.4.2(3)
3.1.1.5	4.6.2.1;4.6.2.2	9.1.1(3)
3.1.1.6	4.6.1.1	9.1.1(3)
3.1.1.7	4.6.2.3;4.6.3	9.1.1(3)
3.1.1.8	4.6.1.5	9.2.4(8)
3.1.1.9	4.6.1.6	9.2.4(10)
3.1.1.10	4.6.1.3	9.2.2(1)
3.1.2.1	2.2.1	9.3.3(1-2)
3.1.2.2	2.2.2	9.2.3(4)
3.1.2.3	2.2.3	9.2.3;9.2.4
3.1.2.4	2.2.4	9.1.1(3)
3.1.2.5	2.2.5	9.1.1(3)
3.1.2.6	2.2.6	9.3.1
3.1.2.7	2.2.7	9.2.7, 9.3.7
3.1.2.8	2.2.8	9.2.7, 9.3.7
3.1.3	2.2	9.1.5 (1-4)
3.1.4.1	5.2.2.1	9.1.6 (1-2)
3.2.1	4.2	9.2.1(1-2);9.2.2(1-2)
3.2.1.3.1	4.2.1	9.2.3
3.2.1.3.2	5.2.1.1	9.2.1
3.2.1.3.3	4.2.3	9.2.1
3.2.1.3.4	4.7.2;4.7.3;4.7.4;4.7.5;4.7.6	9.1.1 (2)
3.2.1.3.5	5.2.2.3	9.1.1 (4); 9.1.4 (2)
3.2.1.3.6	4.6.1.1;5.2.6.1	9.2.3
3.2.1.3.7	5.2.3	9.2.3(4)
3.2.1.3.8	4.6.1.4;4.6.3	9.1.1 (3; step 3)
3.2.1.3.9	4.6.1.2;5.2.6.1	9.1.1 (6)
3.2.2.3.1	5.2.6.2	9.1.1(3;step1 and 2)

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Software Requirement Identifier	Software Design Identifier	V&V Test
3.2.2.3.2	5.2.6.1	9.2.3
3.2.2.3.3	5.2.6.1	9.1.4 (2)
3.2.2.3.4	5.2.6.3	9.2.6
3.2.2.3.5	5.2.6.4	9.2.6
3.2.3	5.2.1.1	9.4.2
3.2.3.3.1	5.2.1.1,	9.4.2
3.2.3.3.2	5.2.1.1	9.2.4(1-3)
3.2.4	5.2.1.1	9.2.4
3.2.4.3.1	5.2.3.1	9.2.4(4-7)
3.2.4.3.2	5.2.3.2	9.1.1 (6)
3.2.4.3.3	5.2.1.1	9.2.5, 9.2.6
3.2.5.3.1	4.7.2	9.3.1
3.2.5.3.2	4.7.3	9.3.2
3.2.5.3.3	4.7.4	9.3.3
3.3.1	5.2.6	9.1.1 (4)
3.3.2	5.2.1.2	9.1.3(1-3);9.2.4(7)
3.3.3	4.7	9.3.1;9.3.2;9.3.3
3.3.4	5.2.3	9.1.2(1-2);9.2.4(6)
3.3.5		
3.4.1	5.2.2.3.6	9.4.2
3.4.2	5.2.4	9.4.1
3.4.3	5.2.1.1	9.3.1-9.3.3
3.4.4	5.2.1.1	9.2.4(12;13;14;15)

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Flash N' Go

Traceability Analysis

DO1009151

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Flash N' GO

Software Detailed Design Spcifcation

DO1008811

	Role	Name	Signature	Date
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Table of Contents

2.1.5 MMI

The MMI is used to manage turn ON/OFF LEDs check the keys and turn ON/OFF the buzzer, Limit new system levels

2.1.6 Light Pulse handler

The light pulse handler is used to set the Light enable signal if conditions are met.

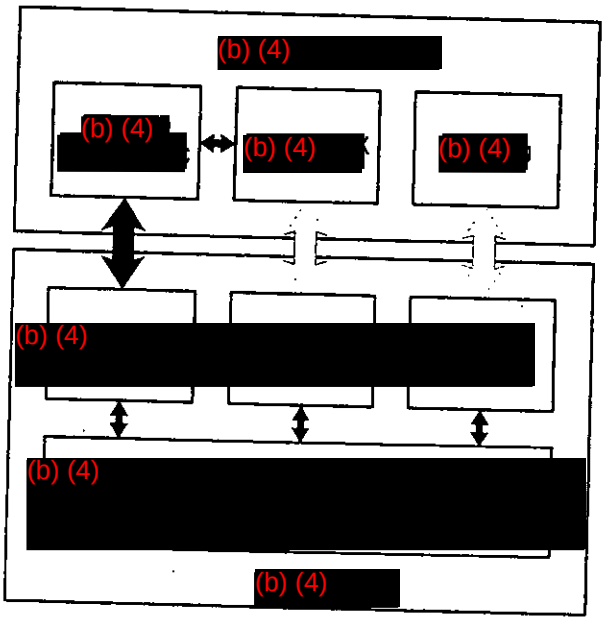
2.1.7 Timer ISR

The Timer ISR is used to measure time, handle timer variables, and check for time outs

(b) (4)

2.2 *Hardware Software Interfaces*

(b) (4)



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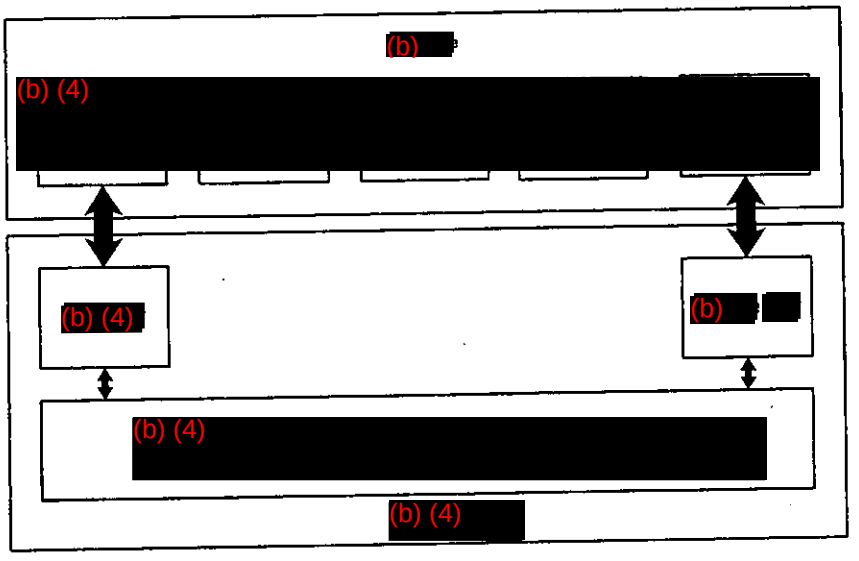
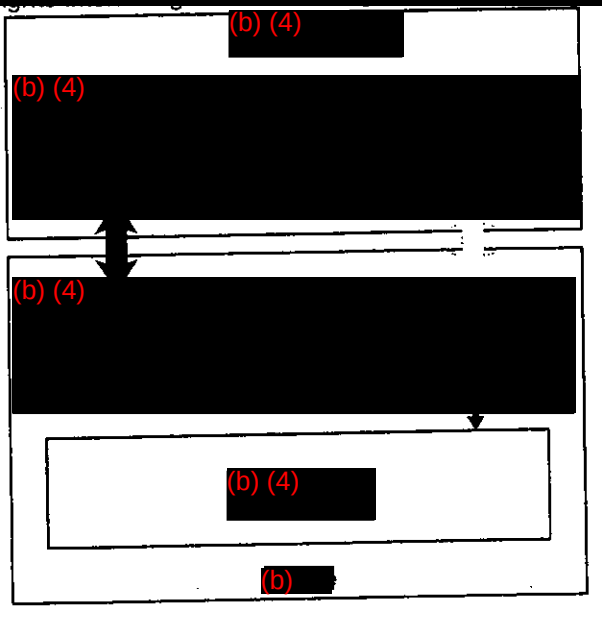
2.2.2 Capacitor interfacing

(b) (4)



2.2.3 Indication lights

(b) (4)



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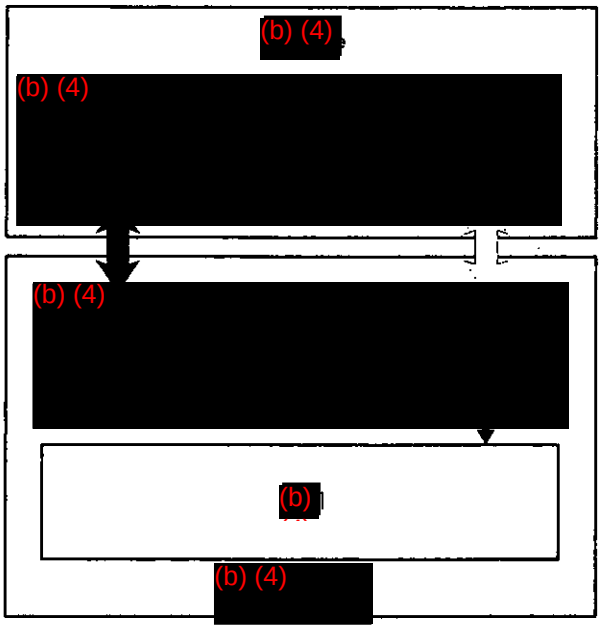
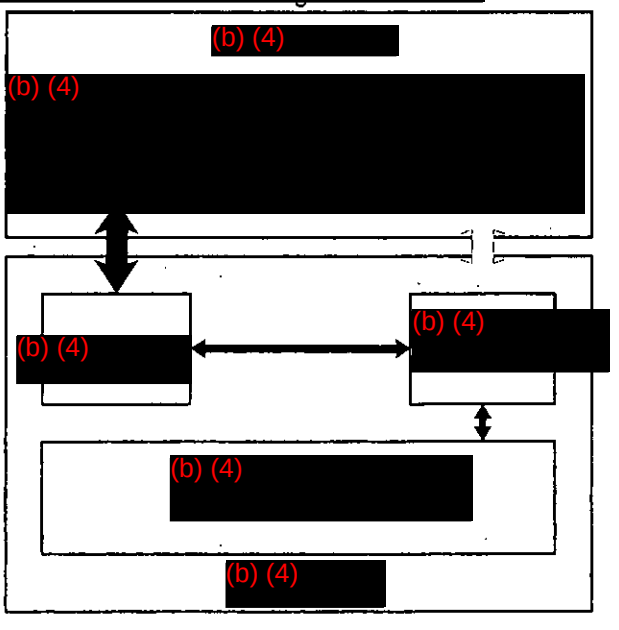
2.2.4 KEY polling

(b) (4)



2.2.5 Buzzer interface

(b) (4)



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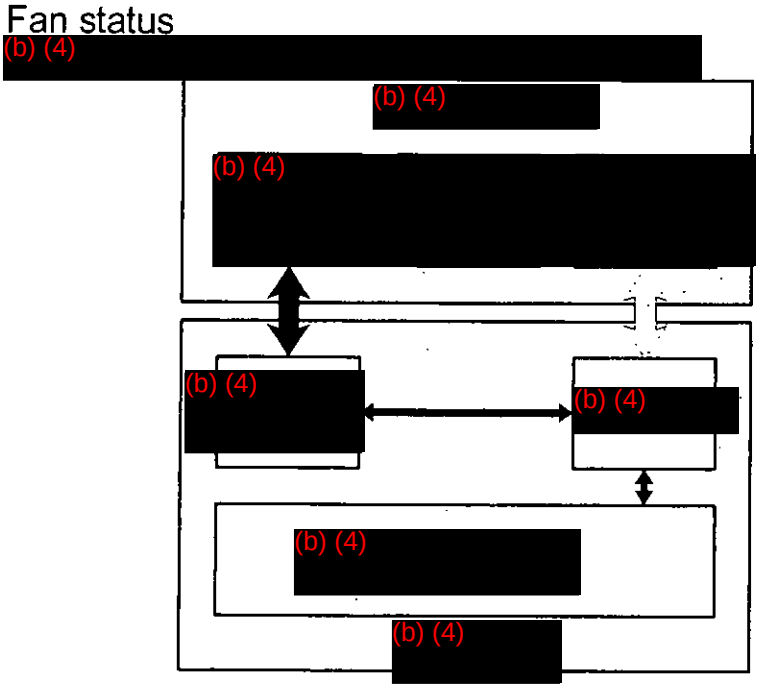
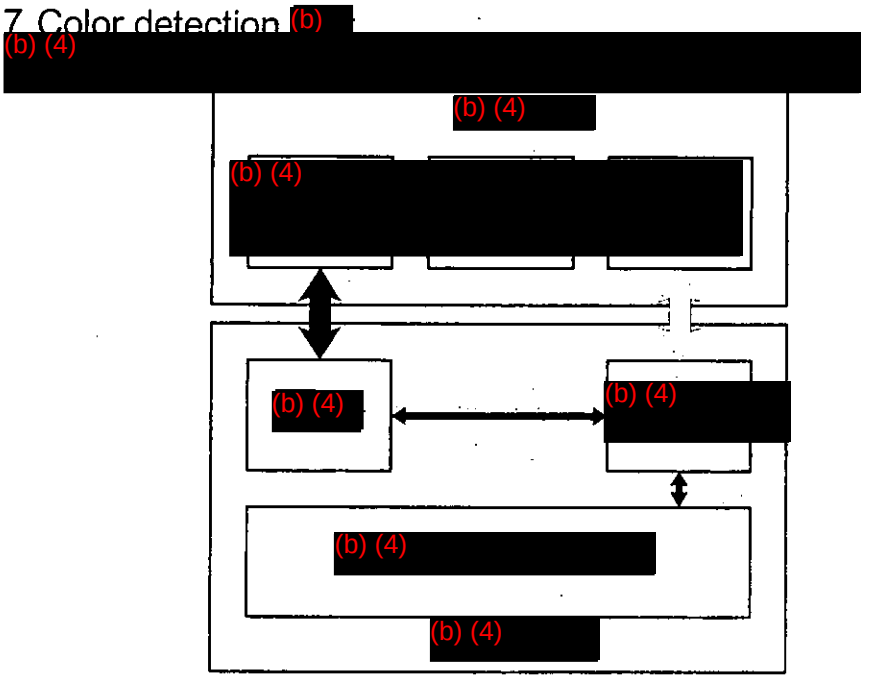
2.2.6 Fan status



2.2.7 Color detection (b)



2.2.8 Color detection (b) (4)

(b) (4)

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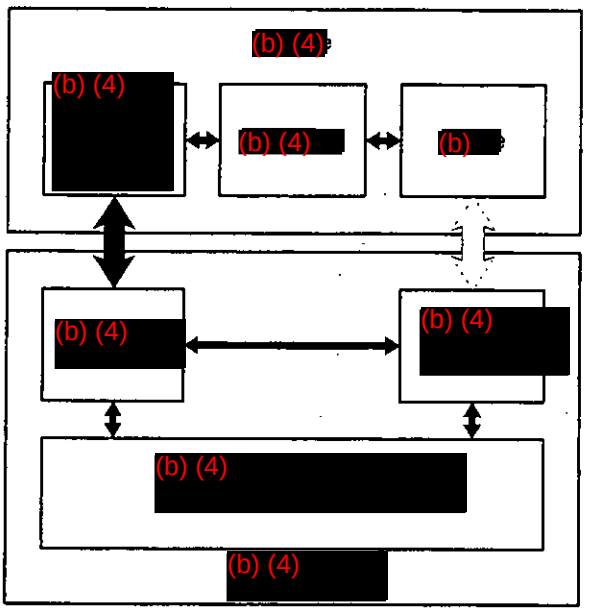

2.3 Theory of Operation

The software will first initialize the hardware. Then initialize the software flags and variables. The software then will start a normal operation of charging capacitors waiting for a trigger button and generating a light pulse. During this time the software will check for any problems and will halt if any problem occurs.

3 Design Rationale

The software structure is based on the need fro a simple, small sized customized to the system hardware design.

4 Architecture

4.1 Operating System

The operating system is built from the ground up using a simple design. The software operating system consists of an executive loop that invokes a series of functions in a round-robin fashion along with interrupts that provide pre-emptive processing. The functions invoked by the executive loop are called tasks. Each task provides a unique set of functionality. Some of the tasks that make up the software include the, high-voltage ramping task, and count rate protection task, among others.

4.2 Resets and Initialization

4.2.1 Power-On Reset

Upon POR the SW will wait for (b) , then will start the initialization process.

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4.2.2 Watch-Dog

A WD reset occurs if the software fails to clear the WD timeout counter.

4.2.3 Complete initialization sequence

A complete initialization sequence is performed (b) (4)
(b) (4))

- Configures MCU pins
- Initialize the I/Os.
- Setup the LED indications.
- Check the code corruption by comparing the checksum of the ROM; if the checksum failed error LED is turned on and the software code is disabled.
- Initialize flags.
- (b) (4)

4.3 Interrupt service routine

Interrupt service routines (b) (4) pre-emptive processing in the software. Since the operating system consists of a round-robin loop that executes tasks in a pre-determined order, only interrupts can provide pre-emptive processing.
This section includes the WD timer and the Timer interrupts.

4.3.1 WD timer interrupt

The WD timer will generate a non mask-able interrupt that will restart the MCU the same as POR.

4.3.2 Timer interrupt

The timer interrupt is set to occur every 50ms, timers are decremented down to zero and, Keys are sampled and checked.

4.4 Tasks

Tasks are invoked in round-robin fashion by the executive loop. The executive loop does manage the switching in and out of tasks, the tasks, therefore, must be capable of retaining their own state information. To ensure timely progress through the executive loop, tasks must execute quickly and return control to the executive loop. To accomplish this, each task runs to completion.

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4.4.1 Normal Tasks

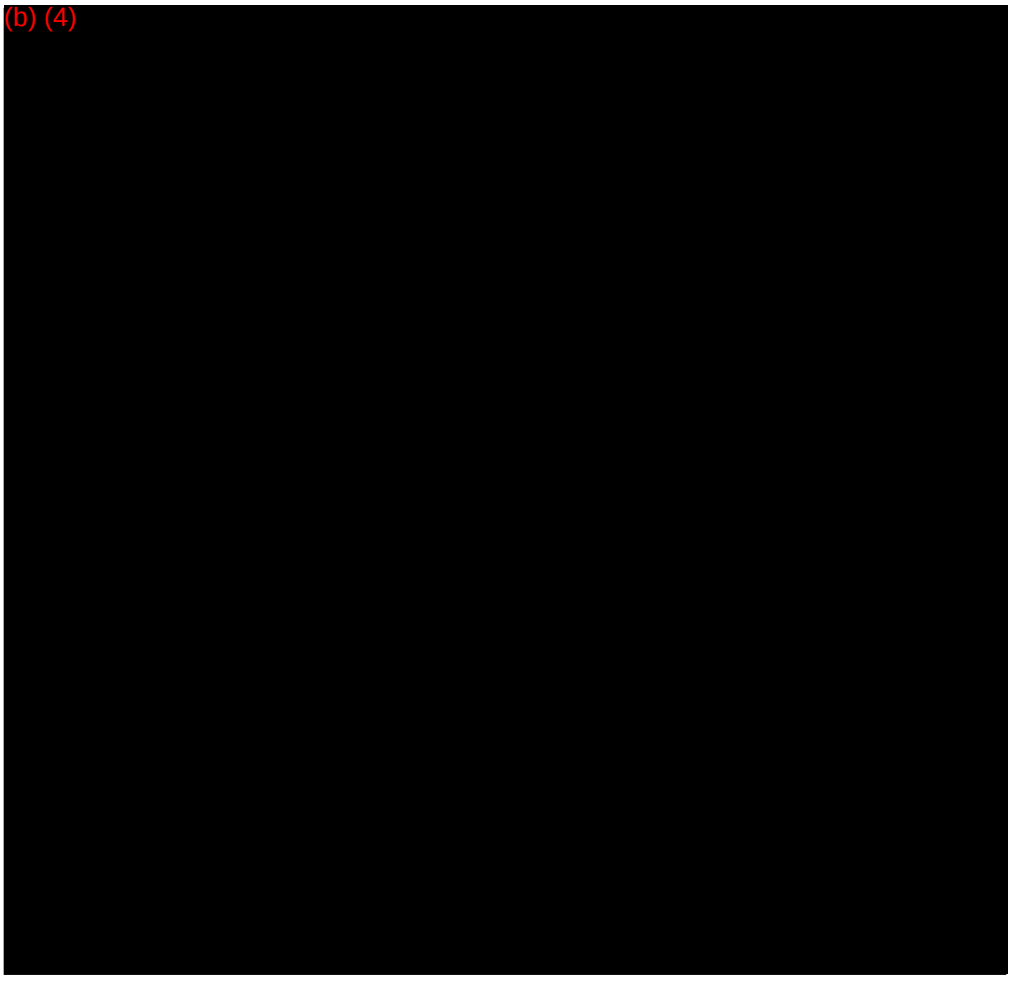
The normal tasks of the software include interfacing with the (b) (4), capacitor voltage management, MMI, (b) (4) error handling

4.4.2 Interrupt Tasks

Interrupt tasks include time based task including timing, key polling

4.5 State machine Description

(b) (4)



4.5.1 Init State

In this state the Firmware initiates MCU registers, verifies Firmware code (b) (4), initiates variables and flags (b) (4)

4.5.2 Idle state

In this state the firmware checks the keys (b) (4)
(b) (4)

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4.5.3 Charge state

In this state the Firmware enables the capacitor charging (b) (4) (b) (4)

4.5.4 Pulse state

In this state the Firmware generates a light pulse.

4.5.5 Error state

In this state the Firmware will handle errors were an error LED is turned on and the Firmware is stuck in an infinite loop.

4.6 Presentation view

4.6.1 LEDs

4.6.1.1 Level Indication

There are 5 Level Indication LEDs that indicate the flash level. During Error the Level indication shows the error code. Upon Hand piece push button press Level indication will indicate Miss-matched color

4.6.1.2 Ready Indication

The Ready LED indicates that the unit is ready for next pulse.

4.6.1.3 Error Indication

The Error LED indicates that a fault occurred and the unit is in a fault protection.

4.6.1.4 Buzzer Enabled Indicator

The Buzzer LED indicates that the buzzer is enabled and will sound when required.

(b) (4)

4.6.2 Keys

4.6.2.1 Energy Plus

The Energy Plus key is used to increase the light pulse level (b) (4) (b) (4)

4.6.2.2 Energy Minus

The Energy Minus key is used decrease the light pulse level (b) (4)

4.6.2.3 Buzzer Enable/Disable

The Buzzer key, switches the buzzer mode between On and Off.

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4.6.2.4 Hand piece button

The hand piece button is used to fire a single pulse of light.

4.6.3 Buzzer

The Buzzer is used to indicate to the user that the next pulse can be fired.

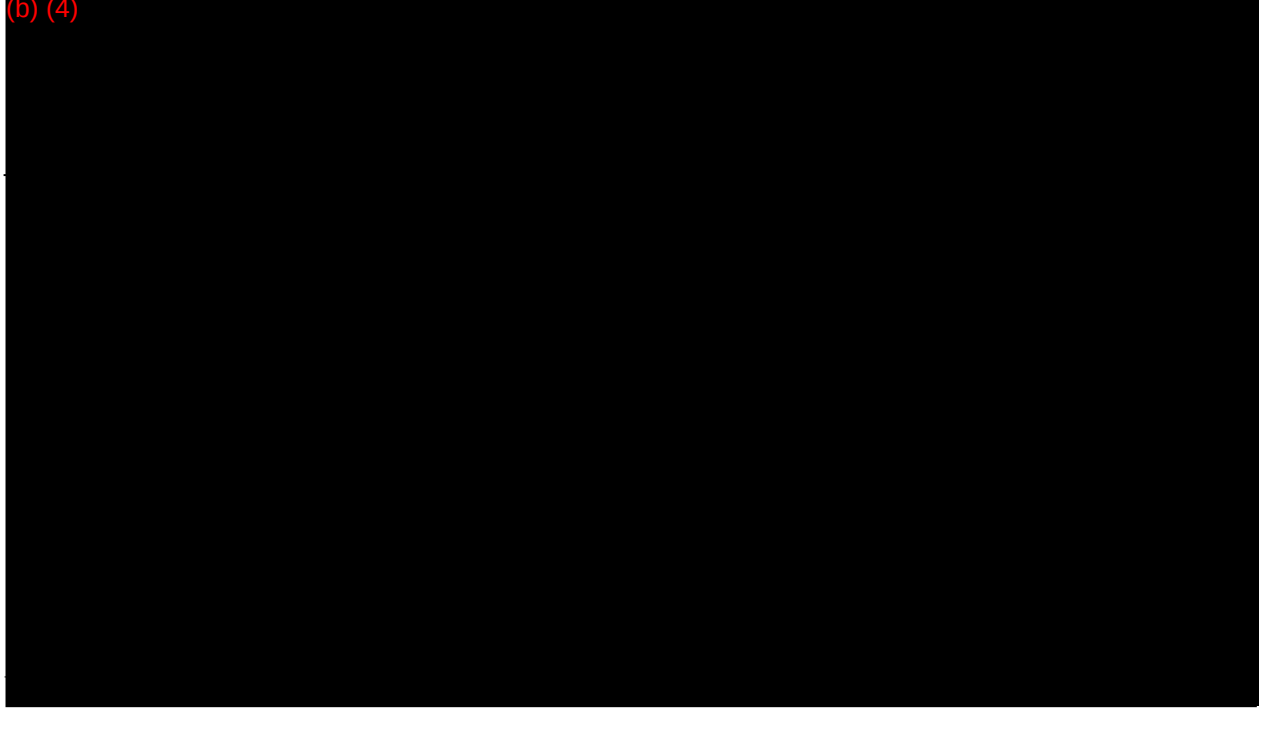
4.7 Error handling

Upon any error turn the system OFF, wait for a few minutes, turn the system ON. If the error re-occurs turn the system OFF, and contact service.

4.7.1 Corrupt Firmware code

Corrupt firm code will be handled by setting up the error LED and going into an endless loop.

(b) (4)



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5 Detailed Design Description

5.1 External Interface Data Elements

Interface	Type	Direction	Data Elements Description
KEYS	Digital	Input	Key event handler
Hand Piece PB	Digital	Input	Fire light pulse
LEDS	Digital	Outputs	User indications
Buzzer	Digital	[redacted]	[redacted]
[redacted]	[redacted]	Input / Output	Cartridge interface
IPL	Digital	Output	Generate light pulse
Fan OK	Digital	Input	Fan status
[redacted]	[redacted]	[redacted]	[redacted]
Color Detection LED	Digital	Output	Color LED

(b) (4)

5.2 Design entities

5.2.1 APP entity

5.2.1.1 Main

The Main includes several tasks

- Init task that initializes the MCU pinout, variables.
- [redacted]
- ERROR handler that is used to respond to errors.
- IDLE task that is used as
- Capacitor Voltage handler that is used to manage the capacitor voltage.
- Pulse task that is used enable a light pulse when pulse conditions are met

5.2.1.2 Isr

ISR task is called every 50ms and is used for timing purpose

(b) (4)

[redacted]

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(b) (4)

5.2.3 Capacitor Voltage

5.2.3.1 Mesure_capacitor_voltage

The mesure_capacitor_voltage is used to sample the voltage using the MCUs built in ADC and calculate the voltage

5.2.3.2 Charge_capaciors

The charge_capacitors is used to enable the capacitor charging

5.2.4 Code Self Check

5.2.4.1 Check_program_memory

The check_progrrram_memory is used to validate the Firmware code

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5.2.5 Misc

5.2.5.1 Short_delay

The short_delay is used to create a short delay time

5.2.6 MMI

5.2.6.1 Mode_status

The mode_status is used to update the mode LEDs to the current mode.

5.2.6.2 Buttons_status

The buttons_status is used to poll the system keys and respond to the valid combinations.

5.2.6.3 Level_limitation

Level limitation is used to limit the energy level 4 and 5 for a new system, only level 1 to 3 are allowed for 250 first pulses

5.2.6.4 Turning on/off Level_limitation

Level limitation can be turned on/off by pressing the (=) and (-) keys simultaneously 3 short beeps indicate limitation on (pulse counter set to 250) , 3 short beeps indicate limitation off

5.2.7 Error

5.2.7.1 Check_error_status

The check_error_status is used to handle a condition were the pulse counter reaches zero.

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Flash N' Go

Software Requirements Specification

DO1009141

	Role	Name	Signature	Date
Written by				

(b) (4)

[redacted]

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Revisions

Rev.	Page	Description
(b) (4)	[redacted]	

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Table of Contents

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1. Introduction

1.1 Purpose

The purpose of this document is to provide a consistent and complete description of the requirements for the software of Flash N' Go. The requirements will be presented using textual descriptions to explain concepts, different types of diagrams to illustrate complicated interactions, and tables to relate relevant information.

The intended audience of this document is all of the managers and engineering involving the development of the MCU firmware software. This includes, but is not limited to, software developers, project managers, quality assurance personnel, and customers.

1.2 Scope

The firmware of the Slik'n is responsible for the normal and efficient operation of all of the other components within the Flash N' Go device. The controller's main goal is essentially to handle input requests from other components and respond accordingly with generating pulses.

It is important to note that this SwRS document only pertains to the requirements of the software of the MCU. It does not include requirements for the hardware that it will be deployed on. It also does not include requirements for the other components of the Flash N' Go device. Other components are mentioned because the requirements of the controller are indeed based on the interactions between it and the other components of the system; however, the requirements of the other components, as well as the overall Flash N' Go device itself, is outside the scope of this document and is therefore not included.

1.3 Definitions

The following table defines terms and definitions used in this SRS:

Term	Definition
SwRS	Software Requirements Specification
V&V	Verification and Validation
MMI	Man Machine Interface
CPU	Central Processing Unit
I/O	Input/ Output
Control Panel	Two operation button and LED Display
C	Program language for microcontrollers.
PS	Power Supply
RAM	Random Access Memory

Term	Definition
I^2C communication	I2C communications standard
Cartridge Memory	EEPROM
PB	Push Button
HP	Hand Piece

1.4 References

The following table lists all documents which supply inputs to this SRS:

1) Flash N' Go operation Manual.
2) Flash N' Go System Requirements Specification
3) IEC 60601-1-4 General requirements for safety programmable electrical medical system.
4) IEEE 830-1998 standard for creating SRS documents is IEEE Recommended practice for software requirements specification by IEEE-SA computer society (IEEE-SA Standards Boards, 1998)

1.5 SRS Organization

In section 2 we will give a general overview of the functionality of Flash N' Go firmware. It is used to establish a context for both the informal requirements definition and for technical requirement specifications in the next chapter. This section consists of six subsections, as follows:

- Product perspective.
- Product functions.
- User characteristics.
- Constrains.
- Assumptions and dependencies.
- Apportioning and requirements.

In section 3 we will give a detailed overview of the functional and non-functional requirements of the Flash N' Go firmware. This section consists of six subsections, as follows:

- External interfaces.
- System features .
- Performance requirements.
- Design constrains.
- Software system attributes.

1.6 Overview

The purpose of the software in the Flash N' Go device:

- Control user interacts with the device (Power On/Off switch; Energy level settings buttons; Buzzer enable/disable and Pulse Button).
- Check the Hardware status and inform user through the indicators light.

1.7 Requirement Statement Identification Convention

The requirement statement identification convention is based on section numbering.

2. Overall description

This section describes the general factors that affect the Flash N' Go firmware software requirements. This section does not state specific requirements; instead it provides a background for those requirements, which are defined in detail in Section 3.

The Flash N' Go firmware will allow an operator to view system status and generate pulses.

The major functions of the Flash N' Go firmware are: MMI, Setup and Initialization; Error Handler; Pulse Handler; Capacitor voltage handler; RFID Handler; ISR Timer;

2.1 Product perspective

The Flash N' Go firmware directly interacts with the following other components of the entire device:

Indicators Light:

Desired parameters.

Pulse Button:

Desired parameters.

Energy Level Settings Buttons:

Desired parameters.

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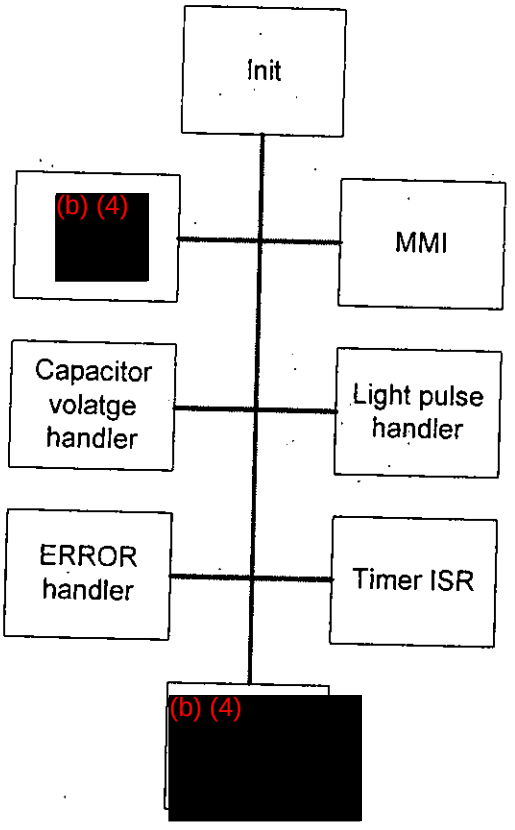
Context Diagram



2.2 *Product Functions*

The firmware is responsible for the following functions:

a) Manage Man Machine Interface.

b) Manage setup and initialization.

c) Pulse Handler.

d) Capacitor voltage handler.

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f) ISR Timer.

g) Error handler.

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2.3 User characteristics

Users are required to be familiar with the Operation Manual and the use of the Flash N' Go device.

The users of the firmware are essentially the other components of the device that interact with it. The integral characteristic that these other components must have is being able to process and react to the request sent to it by the controller in a timely fashion.

2.4 General constrains

The following constraints were factors in the development of the detailed requirements for the Flash N' Go firmware:

a) Regulatory policies – according to the software life cycle procedure.
b) Hardware limitations – The Flash N' Go firmware will reside on hardware MCU PIC16F887.

2.5 Assumptions and dependencies

The software is strongly hardware dependent;

3. Requirement Specifications

This section of the SwRS contains the Flash N' Go firmware requirements to a level of detail sufficient to enable designers to design the system, and acceptance testers to test that the device satisfies the requirements.

These software requirements will be revised by the system engineer to reflect the final approved Flash N' Go architecture design. This will be done before high-level software design phase. Every stated requirement is externally perceivable by users, operators, or other external systems.

This section describes each input into the software, every output from the software, and all functions performed by the software.

3.1 Interface Requirements

3.1.1 User Interfaces

The MMI will be implemented to allow the user to communicate with the device:

3.1.1.1 Power On/Off switch

The power on button shall activate the HW and the software will be activated as a result.

3.1.1.2 Power Indicator Light

The power indicator lights shall turn on after pressing the Power On/Off switch.

3.1.1.3 Ready Indicator Light

3.1.1.3.1 The ready indicator light shall turn on after pressing the Power On/Off switch.

3.1.1.3.2 The Ready Indicator Light shall turn on each time after a pulse has been fired and a time out had passed.

3.1.1.4 Pulse Button

The user shall handle pulses by pressing the Pulse Button on the Applicator unit.

3.1.1.5 -/+ Energy Level Settings Buttons

The user shall select the required energy level using the Energy Level Settings Buttons. Pressing both (+) and (-) simultaneously shell toggle level limitation on / off.

3.1.1.6 Energy Level Indicator Light

The user shall observe the control panel for the proper energy level indicator lights on. The audio on/off switch used to enable/disable audible sound during normal operation.

3.1.1.7 Audio On/Off switch

The user shall hear a sound if (Audio is on) after the Ready indicator Light turned on.

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3.1.1.10 System Warning Indicator Light

The software shall turn on the System Warning Indicator once an error occurred.

3.1.2 Hardware Interface

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The detailed Flash N' Go hardware to software interfaces are described below to illustrate the key interfaces to the Flash N' Go software.

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[redacted]

3.1.2.2 Capacitor Interfacing

Refer to the Software Detailed Design Specification.

3.1.2.3 Indication Lights

Refer to the Software Detailed Design Specification.

3.1.2.4 Key Polling

Refer to the Software Detailed Design Specification.

3.1.2.5 Buzzer Interface

Refer to the Software Detailed Design Specification.

3.1.2.6 Fan status

(b) (4)

[redacted]

3.1.3 Software Interfaces

Flash N' Go software is using:

Microchip: MPLAB ICD 2 emulator and developer environment.

The interface requirements for this product are defined by the MPLAB ICD 2 Reference Manual.

Flash N' Go software is planning on using the following capabilities of MPLAB ICD 2 emulator:

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- During development using the Debug.
- Down load function.

(b) (4) [redacted]

3.2 System Features

3.2.1 Initialization

3.2.1.1 Purpose

The Flash N' Go shall initialize the software and Hardware for treatment start.

3.2.1.2 Stimulus/Response sequence

Press the power On/Off switch; the initialization process will be activated; the Ready Indicator Light will turn on, accompanied by a sound to indicate that your device is ready for its first pulse.

(b) (4) [redacted]

3.2.1.3 Associated functional requirements

3.2.1.3.1 The On/Off Power Switch shall be used to turn the device on/off.

3.2.1.3.2 The MCU internal registers and pin-outs shall be initialized.

3.2.1.3.3 The Software variables shall be initialized.

3.2.1.3.4 The software shall check the hardware.

3.2.1.3.5 The software shall read data from the RFID tag.

3.2.1.3.6 The level LED's shall indicate the current level.

3.2.1.3.7 The software shall activate the charger according to the required level (b) (4) [redacted]

3.2.1.3.8 The Buzzer shall sound to indicate your device is ready for its first use (b) (4) [redacted]

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3.2.1.3.9 The Ready LED shall be turned on to indicate the device is ready for its first pulse.

3.2.2 Set Energy Level

3.2.2.1 Purpose

The device shall have an energy setting buttons for (b) (4) (b) (4)

3.2.2.2 Stimulus/Response sequence

Press the -/+ Energy Level Setting buttons to switch between treatment energy levels.

3.2.2.3 Associated functional requirements

3.2.2.3.1 The Energy Level Setting Buttons shall be used to select one of the (b) (4) treatment energy

3.2.2.3.2 The Energy Level Indicator shall be turned on after selecting the required energy level.

3.2.2.3.3 The Energy setting buttons shall be used to turn off the Ready Indicator Light.

3.2.2.3.4 (b) (4)

3.2.2.3.5

3.2.3 Pulse Handler

3.2.3.1 Purpose

The device shall have a pulse handle to enable a pulse emission.

3.2.3.2 Stimulus/Response sequence

Press the Pulse button; Light pulse emitted only after software check required conditions.

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3.2.3.3 Associated functional requirements

3.2.3.3.1 The pulse handler shall emit pulse only upon the completion of the following conditions:

3.2.3.3.1.1 Pulse Counter is greater than zero.

3.2.3.3.1.2 Pulse Button and Lamp cartridge should be pressed.

3.2.3.3.1.3 Capacitor voltage has reached the required level.

3.2.3.3.1.4 Minimal time between two pulses should be TBD seconds.

(b) (4) [redacted]

3.2.3.3.2 The Pulse handler shall decrease the Pulse Counter by one.

3.2.4 Monitoring the Capacitors voltage

3.2.4.1 Purpose

This feature shall monitor the capacitors voltage.

3.2.4.2 Stimulus/Response sequence

If the software get event from the Energy Level Settings Buttons the capacitors will be charged or discharged according to the current Energy Level and the new selected energy level and according to the calibration factor.

3.2.4.3 Associated functional requirements

3.2.4.3.1 Monitoring the Capacitors Voltage shall be used to measure the capacitor voltage.

3.2.4.3.2 The Energy setting buttons shall be used as an event to Charge the Capacitors.

3.2.4.3.3 The capacitor voltage will vary according to the calibration factor.

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3.2.5 Hardware Check

3.2.5.1 Purpose

The Flash N' Go software shall monitor the hardware for abnormal or fault condition

3.2.5.2 Stimulus/Response sequence

Upon any fault or miss function of the hardware the software shall handle this as an error condition refer to the Error Detection and Handling section in this document

3.2.5.3 Associated functional requirements

3.2.5.3.1 Fan: The software shall monitor the Fan for miss function

3.2.5.3.2 Lamp too hot: The lamp temperature shall be checked to protect against over heated lamp

(b) (4) [redacted]

3.3 Performance Requirements

3.3.1 The software has the capability of responding to user inputs within a reasonable period of time.

3.3.2 Detects abnormalities and corrects them at least every 50 millisecond (The Timer interrupt is set to occur every 50ms), for example, monitoring of Capacitor voltage, Keypad.

3.3.3 Detects critical faults once per second, (b) (4) [redacted] and stop the system if necessary.

3.3.4 Within 5 seconds (b) (4) [redacted] capacitor should be charged up to required level.

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3.4 Safety Requirements

3.4.1 The software stop pulse emitted if the Applicator Tip is disconnected.

3.4.2 The corrupted firmware will be stopped by watchdog.

3.4.3 The software shall check the hardware and if error occurred; the system shall be shutdown.

3.4.4 The software shall perform CRC and checksum for communication error.

3.5 Logical Database Requirements

NA

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3.6 Design Constrains

3.6.1 Capacitors charge fault protection

A maximal time out of 5 seconds used in protection against fault in the capacitor charging

3.6.2 Charge level

Hardware will prevent the software from exceeding a maximal allowed charge voltage

(b) (4)

[redacted]

3.7 Software system attributes

3.7.1 Reliability

3.7.1.1 None the less we expect our system shall experience no severity 1 or 2.

3.7.2 Availability

3.7.2.1 In case of device failure, refer to operation manual section troubleshooting.

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[redacted]

3.7.4 Error Detection and Handling requirements

3.7.4.1 General

3.7.4.1.1 Firmware must be able to handle the errors produced by software code.

3.7.4.2 User Error

3.7.4.2.1 The firmware shall indicate system error by turn on the Error Indicator Light.

3.7.5 Maintainability

Refer to operation manual.

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3.7.6 Portability

NA

3.8 Testing Requirements

All files defined in the firmware shall be subject to the testing methodology defined in the V&V plan.

3.9 Other Requirements

3.9.1 Fault Detection and Isolation

Fault detection and isolation requirements specified by the MCU are met by the Diagnostic, Memory, Debugging features described in the "Flash N' Go Software Detailed Design" document.

3.9.2 Self Test

The firmware software shall perform self-test operations as an integral part of its normal activities. Refer to Software detailed design document for further information.

3.9.3 Redundancy Management and Hardware Re-configuration

MCU redundancy requirements are not handled by the Flash N' Go Software, but are instead covered by independently hardware subsections.

3.9.4 Watchdog Reset and crash recovery

If the MCU re-boots due to a fatal error or watchdog reset, the MCU start-up software shall not install any patches. The software will idle.

3.9.5 Bad Parameter Block Corruption Handling.

In the event that the firmware receives a parameter block whose computed integrity check code (CRC or Checksum) does not match the one contained within the block, the software will indicate the error in the LED and goes to endless loops.

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Appendix 2
From 3674

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 06-30-2008

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
Home Skinovations Ltd.

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
(b) (4)

3. ADDRESS *(Number, Street, State, and ZIP Code)*
Yokneam Industrial area
P.O.B 533 20692 ISRAEL

4. TELEPHONE AND FAX NUMBER *(Include Area Code)*
(Tel.) +972547404616
(Fax) +9724909 7471

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

~~Flash N Go~~

Flash N Go

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*
K082298

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

☐ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☒ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/ SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act. Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)
Amir Waldman

12. NAME AND TITLE OF THE PERON WHO SIGNED IN NO. 11
(Name) AMIR WALDMAN
(Title) VP Regulation

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12)*
Yokneam Industrial area
POB 533 20692 ISRAEL

14. TELEPHONE AND FAX NUMBER *(Include Area Code)*
(Tel.) +972547404616
(Fax) +9724909 7471

15. DATE OF CERTIFICATION
10/2/08

FDA-3674 (1/08) (FRONT)

PSC Graphics: (301) 443-1090 EF

DCY

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Appendix 3
Revised user manual

HomeSkinovations

Flash N' Go User manual

Print date: February 2008

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Table of Contents

Before using Flash N' Go™ for the first time, please read this User Manual in its entirety. Pay particular attention to sections on device use procedures, device operation, and after-use procedures.

We recommend you re-familiarize yourself with this User Manual before each use of Flash N' Go™.

Flash N' Go™ is a powerful electrical device. As such, it should be used with special attention to safety.

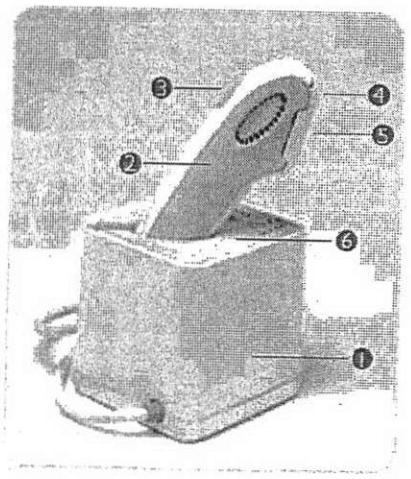
Please read all warnings and safety precautions before use, and strictly follow them when using Flash N' Go™

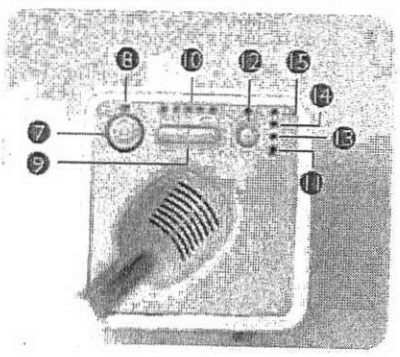
1. What is Flash N' Go™?

Flash N' Go™ is a light-based device for long-term hair removal designed for home-use.

1.1. Flash N' Go™ device description

Flash N' Go consists of a Base Unit, APPLICATOR and Disposable Lamp Cartridges.





1. BASE UNIT
2. APPLICATOR
3. PULSE BUTTON
4. DISPOSABLE LAMP CARTRIDGE
5. *SKIN COLOR SENSOR*
6. CONTROL PANEL
7. POWER ON/OFF SWITCH
8. POWER INDICATOR LIGHT
9. ENERGY LEVEL SETTING BUTTONS
10. ENERGY LEVEL INDICATOR LIGHTS
11. READY INDICATOR LIGHT
12. AUDIO ON/OFF SWITCH
13. CARTRIDGE 90% USAGE INDICATOR LIGHT
14. CARTRIDGE 100% USAGE INDICATOR LIGHT
15. SYSTEM WARNING INDICATOR LIGHT

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Your Flash N' Go™ consists of a *BASE UNIT* and an *APPLICATOR*.

On the *BASE UNIT* you can find the Flash N' Go™ *CONTROL PANEL* including *POWER ON/OFF SWITCH* and *POWER INDICATOR LIGHT*, the *ENERGY LEVEL SETTING BUTTONS* and *ENERGY LEVEL INDICATOR LIGHTS*, the *AUDIO ON/OFF SWITCH*, *READY INDICATOR*, *SYSTEM WARNING INDICATOR LIGHT* and *CARTRIDGE 90%* and *100% USAGE INDICATOR LIGHTS*.

On the Flash N' Go™ *APPLICATOR* you can find the *PULSE BUTTON*. The *DISPOSABLE LAMP CARTRIDGE* is located at the *APPLICATOR TIP*.

1.2. Package contents

Upon opening the Flash N' Go™ package, you will find the following parts:

- Flash N' Go™ *BASE UNIT* and *APPLICATOR*
- An AC cord
- A second *DISPOSABLE LAMP CARTRIDGE*
- This User's Manual and a Quick Start Guide leaflet
- An Instructional DVD

1.3. The Disposable Lamp Cartridge

The Flash N' Go™ *DISPOSABLE LAMP CARTRIDGE* can fire 750 light pulses (regardless of the energy level of these pulses). For average body size 750 light pulses could cover for example:

One treatment sessions of 2 Legs, 2 Arms, 2 Underarms, and Bikini line

Or

Two treatments sessions of 2 legs and 2 Underarms

Or

Ten treatments sessions of 2 Underarms and Bikini line

Depending on the body areas you wish to treat, you will typically need to use from one to seven *DISPOSABLE LAMP CARTRIDGES* during the first year of using Flash N' Go.

2. Flash N' Go™ Intended Use

Flash N' Go™ is intended for removal of unwanted hair.

Flash N' Go™ may be used to remove unwanted body hair. Ideal body areas for Flash N' Go™ use includes the underarms, bikini line, arms and legs.

3. Safety with Flash N' Go™

3.1. With Flash N' Go™ Safety Comes First

- **HPL™ technology in Flash N' Go™ - Superior safety with lower energy level**

  Home Pulsed Light™ technology is able to achieve long-term hair removal results at a fraction of the energy level used in other light-based hair removal equipment. The low energy used in Flash N' Go™ reduces its potential to cause harm or complications, and contributes to your overall safety.

- **Flash N' Go™ protects your eyes**

  The Flash N' Go™ *APPLICATOR* has a **built-in safety feature** for eye protection. It has been designed so that a light pulse can not be emitted when the *APPLICATOR* is facing open air. The safety switch is activated only when the *APPLICATOR TIP* is in full contact with the tissue and pressed.

- **Flash N' Go™ protects your skin**

  Flash N' Go™ comes with a *SKIN COLOR SENSOR* enabling use only on lighter skin complexions to ensure skin safety.

  Furthermore, the 2X3cm² *OPTICAL LENS* through which pulses of light are delivered is recessed inside the *LAMP CARTRIDGE* at the *APPLICATOR TIP*. This enables Flash N' Go™ to protect your skin by avoiding direct contact between the *OPTICAL LENS* and the skin.

4. Contraindications

Important Safety Information – Read Before Use!

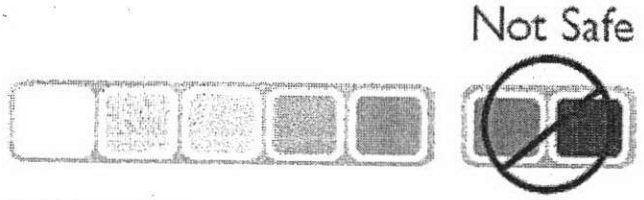
Flash N' Go™ is not designed for everyone. Please read and consider the information in the following section before use. For further information and personalized advice you may also visit www.silkn.com or your local Flash N' Go™ domain.

If you are unsure if Flash N' Go™ is safe for you to use, please ask your doctor or dermatologist!

- **DO NOT USE Flash N' Go™ on naturally dark skin complexion!**

Flash N' Go™ removes unwanted hair by selectively addressing hair pigment. Varied quantities of pigment also exist in the surrounding tissue of skin. The quantity of pigment in a particular person's skin, which is manifested by their skin complexion, determines the degree of risk they are exposed to using Flash N' Go™.

Treating dark skin with Flash N' Go™ can result in adverse effects such as burns, blisters, and skin color changes (hyper- or hypo-pigmentation).



DO NOT USE Flash N' Go™ on naturally dark skin!

A unique *SKIN COLOR SENSOR* is embedded in Flash N' Go™ to measure the treated skin complexion at the beginning of each session and occasionally during the session. *SKIN COLOR SENSOR* ensures that pulse will be emitted on suitable skin tones.

- **DO NOT USE Flash N' Go™ on tanned skin or after recent sun exposure!**

Tanned skin particularly following sun exposure, contains large quantities of the pigment Melanin. This applies to all skin types and complexions, including those which don't seem to tan quickly. The presence of large quantities of Melanin exposes the skin to higher risk when using Flash N' Go™.

Using Flash N' Go™ on skin that has been recently exposed to sunlight can result in adverse effects such as burns, blisters, and skin color changes (hyper- or hypo-pigmentation).

DO NOT USE Flash N' Go™ on tanned skin or after recent sun exposure! Such use can cause serious burns or skin injury. Avoid exposure to the sun for 4 weeks before your Flash N' Go™ treatment!

The unique Flash N' Go™ *SKIN COLOR SENSOR* will also help you avoid treating sun exposed skin.

- **DO NOT USE Flash N' Go™ on the face or neck**

Unlike body hair, most of women's potential facial hair remains inactive and hidden, while only a fraction of it grows and surfaces. Exposing facial hair to the light pulses of Flash N' Go™ may remove apparent hair but simultaneously stimulate unwanted growth of hidden hair.

Using Flash N' Go™ to remove facial hair may cause serious eye injury and may stimulate facial hair growth.

Flash N' Go™ is not recommended for use on the face or neck.

- **NOTE! Flash N' Go™ is not effective on light hair**

The Flash N' Go™ device is not effective on naturally white, grey, blond and red body hair. If your body hair is of these colors, Flash N' Go™ will not work on you.

5. When to avoid using Flash N' Go™?

Certain conditions may prevent the use of Flash N' Go™ temporarily. **DO NOT USE Flash N' Go™** if any of the following currently apply to you:

- If you are pregnant or nursing (lactating).
- If you were exposed to strong sunlight or an artificial tanning machine during the past 28 days.
- If you have a tattoo or permanent makeup on the area to be treated.
- If you have dark brown or black spots, such as large freckles, birth marks, moles or warts on the area to be treated.
- If you have eczema, psoriasis, lesions, open wounds or active infections, such as cold sore in the area to be treated. Wait for the effected area to heal before using Flash N' Go™.
- If you have a history of kelodial scar formation, a known sensitivity to light (photosensitivity) or are taking medication that makes the skin more sensitive to light, including non-steroidal anti-inflammatory agents, (e.g., aspirins, ibuprofens, acetaminophen), tetracyclines, phenothiazines, thiazide, diuretics, sulfonyluraes, sulfonamides, DTIC, fluorouracil, vinblastine, griseofulvin, Alpha-Hydroxi Acids (AHAs), Beta-Hydroxi Acids (BHAs), Retin-A®, Accutane® and/or topical retinoids.
- If you have abnormal skin conditions caused by diabetes, for example, or other systemic or metabolic diseases
- If you are currently or have recently been treated with Alpha-Hydroxi Acids (AHAs), Beta-Hydroxi Acids (BHAs), Retin-A®, topical retinoids or azelaic acid.

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- If you have been treated with Accutane® (isotretinoin) within the past 6 months.
- If you have been on a steroid regimen within the past 3 months.
- If you have a history of herpes outbreaks in the area of treatment, unless you have consulted your physician and received preventative treatment before using Flash N' Go™.
- If you suffer from epilepsy.
- If you have an active implant, such as a pacemaker, incontinence device, insulin pump, etc.
- If you have a disease related to photosensitivity, such as porphyria, polymorphic light eruption, solar urticaria, lupus, etc.
- If you have a history of skin cancer or areas of potential skin malignancies.
- If you have received radiation therapy or chemotherapy treatments within the past 3 months.
- If you have any other condition which in your physician's opinion would make it unsafe for you to be treated.

If you are unsure if Flash N' Go™ is safe for you to use, please consult with your doctor or dermatologist.

6. Precautions – How to use Flash N' Go™ Safely

- **Choose your energy levels CAREFULLY!**
  Energy level refers to the intensity of the light pulse that is projected on your skin during use, from the lowest level (-) to the highest level (+). *INDICATOR LIGHTS* on the *CONTROL PANEL* illustrate the energy level at which the machine is set. As the energy level increases, so do the results of Flash N' Go as well as the risk of side effects (see "Possible Side Effects" below).

  Always begin your first use of Flash N' Go™ at the lowest energy setting (one light at "-")!

  Only if you experience little or no discomfort during and after use of Flash N' Go™ at the lowest energy setting, raise the energy level by one *INDICATOR LIGHT* the next time you use Flash N' Go™, and so on for each subsequent hair removal session.

  For detailed instructions on energy level setting see "Energy Level" box in section 4.4 - "Treating with Flash N' Go™ for the first time".

- **Avoid adverse effects!**
  Do not treat the same area of skin more than once per hair removal session!
  Try to avoid overlapping pulses!
  If your skin blisters or burns, **STOP USE IMMEDIATELY!**

- **Avoid complications after use of Flash N' Go™!**
  Do not expose treated areas of skin to the sun!

Sun exposure includes unprotected exposure to direct sunlight of over 15 minutes constantly, or unprotected exposure to diffuse sunlight of over 1 hour constantly.

To protect recently treated skin when exposed to sunlight, be sure to thoroughly apply sunscreen SPF 30 or higher, for 2 weeks after each hair removal session.

- Always shave the area to be treated and make sure that the skin is clean and dry before using the Flash N' Go™.
- Cover birthmarks and tattoos before Flash N' Go™ application.
- Cover dark brown or black spots, such as large freckles, birth marks, moles or warts before Flash N' Go™ application.
- Never look directly at the light coming from the Flash N' Go™ *APPLICATOR* and *LAMP CARTRIDGE*..
- Do not use Flash N' Go™ on nipples and genitals (male or female).
- Do not use Flash N' Go™ on any body site where you might later want hair.
- Do not use Flash N' Go™ for any purpose other than hair removal.
- Never point the Flash N' Go™ *APPLICATOR* in an attempt to emit a light pulse into open space. Always make sure that the *APPLICATOR* is pointed at, and in full contact with the skin during application.
- Remove the Flash N' Go™ *APPLICATOR* from the skin if either the skin or the *APPLICATOR* is too hot.
- Never use flammable liquids such as alcohol (including perfumes, sanitizers, or other applications containing alcohol) or acetone to clean the skin before using Flash N' Go™.
- Use of Flash N' Go™ may cause temporary pigmentation changes (See "Possible Side Effects" below).
- Keep this device out of the reach of children. Do not use Flash N' Go™ on children or allow children to use it.

7. Reducing the risk of injury

As with any electrical device, certain precautions must be taken in order to ensure your safety when using Flash N' Go™.

- **Keep Flash N' Go™ away from water!**
  Flash N' Go™ is an electrical device. As such it should always be kept away from water.
  Do not place or store Flash N' Go™ where it can fall or be pushed into a tub, sink or any other vessel containing water. Do not place in, or drop into water or any other liquid.
  This may cause severe electrocution.
  Do not use Flash N' Go™ while bathing.
  Do not use Flash N' Go™ if it becomes damp or wet.
  Do not reach for Flash N' Go™ if it has fallen into water.
  Unplug Flash N' Go™ immediately if it has fallen into water.

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Keep Flash N' Go™ away from water!

- **Never open Flash N' Go™!**
  Do not attempt to open or repair your Flash N' Go™ device. Opening Flash N' Go™ may expose you to dangerous electrical components and to pulsed light energy, either of which may cause serious bodily damage and/or permanent eye injury.

Do not attempt to open or repair your Flash N' Go™ device. Only authorized Flash N' Go™ repair centers are permitted to perform repairs.

- Trying to open Flash N' Go™ may also damage the device and will void your warranty.
  Please contact Flash N' Go™ Customer Service if you have a broken or damaged device in need of repair.

- Use Flash N' Go™ only for its intended use and as described in its manual.
- Flash N' Go™ should never be left unattended when plugged into an outlet.
- Do not operate Flash N' Go™ if it has a damaged cord or plug and keep the power cord away from heated surfaces.
- Do not use Flash N' Go™ if you see or smell smoke when it is in use.
- Do not use Flash N' Go™ if it is not working properly or if it appears damaged.
- Do not use Flash N' Go™ if the fan vent in its *APPLICATOR* is cracked, coming off or missing.
- Do not use Flash N' Go™ if the *SKIN COLOR SENSOR* in its *APPLICATOR* is cracked, or broken.
- Do not use Flash N' Go™ if the outer shell is cracked or is coming apart.
- Do not use Flash N' Go™ with a damaged *DISPOSABLE LAMP CARTRIDGE*, or if its *OPTICAL LENS* is cracked, chipped or missing
- Always unplug Flash N' Go™ from the electrical outlet immediately after use.
- Unplug Flash N' Go™ before cleaning.
- Do not use Flash N' Go™ with any attachments or accessories not recommended by Home Skinovations Ltd.

8. Risks of using Flash N' Go Flash N' Go™

When used according to the instructions, side effects and complications associated with use of Flash N' Go™ are uncommon. However every cosmetic procedure,

including those designed for home use, involves some degree of risk. Therefore it is important that you understand and accept the risks and complications that can occur with pulsed light hair removal systems designed for home use.

Adverse Event	Likelihood of the Adverse Event	Adverse Effect	Likelihood of the Adverse Effect
Stacking or Overlapping of multiple pulses on the same skin spot	Minor	Minor Skin Discomfort	Minor
		Skin Redness	Minor
		Increased Sensitivity of the Skin	Minor
		Skin Wounds and Burns	Rare
		Scarring	Rare
		Pigment Changes	Rare
		Excessive Redness and Swelling	Rare
		Infection	Negligible
		Bruising	Negligible

- **Minor Skin Discomfort**
  Although home pulsed light hair removal is generally very well-tolerated, most users do feel some mild discomfort during use, usually described as being a mild stinging sensation on the treated skin areas. The stinging sensation usually lasts during the time of the application itself or for a few minutes thereafter. Anything beyond this minor discomfort is abnormal and means that either you should not continue to use Flash N' Go™ because you are unable to tolerate the hair removal application, or that the energy level setting is too high.

- **Skin Redness**
  Your skin may become red right after using Flash N' Go™ or within 24 hours of using Flash N' Go™. Redness generally clears up within 24 hours. See your doctor if redness does not go away within 2 to 3 days.

- **Increased Sensitivity of the Skin**
  The skin of the treated area is more sensitive so you may encounter dryness or flaking of the skin.

- **Skin Wounds and Burns**
  Very rarely, burns or wounds to the skin can occur following the application. The burn or wound can require a few weeks to heal and, extremely rarely, may leave a noticeable permanent scar.

- **Scarring**
  Although very rare, permanent scarring may occur. Usually when scarring occurs it is in the form of a flat and white lesion on the skin (hypotrophic). However, it can be large and red (hypertrophic) or large and extend beyond the margins of the injury itself (keloid). Subsequent aesthetic treatments may be required to improve the appearance of the scar.

- **Pigment Changes**
  Flash N' Go™ targets the hair shaft, in particular the pigmented cells in the hair follicle and the hair follicle itself. Nevertheless there is risk of temporary hyperpigmentation (increased pigment or brown discoloration) or hypopigmentation (whitening) to the surrounding skin. This risk of changes in skin pigmentation is higher for people with darker skin tones.

Usually discoloration or changes to skin pigment are temporary and permanent hyperpigmentation or hypopigmentation rarely occur.

- **Excessive Redness and Swelling**
  In rare cases treated skin may become very red and swollen. This is more common in sensitive areas of the body. The redness and swelling should subside within 2 to 7 days and should be treated with frequent applications of ice. Gentle cleansing is OK, but one should avoid exposure to sun.

- **Infection**
  Infection of the skin is exceedingly rare but is still a possible risk following a skin burn or wound caused by Flash N' Go™.

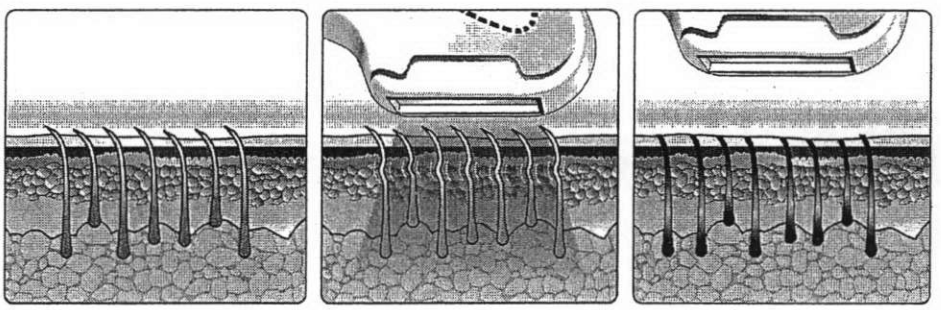
- **Bruising**
  Very rarely, use of Flash N' Go™ may cause blue-purple bruising that can last 5 to 10 days. As the bruising fades, there may be a rust-brown discoloration of the skin (hyperpigmentation) that can be permanent.

9. Long Term Hair Removal the Flash N' Go™ Way

Flash N' Go™ is a personal light-based device for long-term hair removal. The process of laser and light-based hair removal is well known and established. It has been proven in clinical use around the world for over 15 years as a safe and effective way to achieve long-term hair reduction.

9.1. How does light remove hair?

Light-based hair removal is based on the theory of selective photothermolysis in which optical energy is used to disable hair growth. In order to achieve such thermal effect the hair shaft needs to selectively absorb light energy and transform it into heat. This selectivity is achieved when optical energy that is delivered to the tissue is mostly absorbed by hair shaft pigment, while the skin and the surrounding tissue stays cool. Melanin is the pigment in the hair shaft that is responsible for the absorption of the light, which generates the heat that eventually disables hair growth. Therefore the more melanin present in the hair (i.e. the darker the hair) the more light that can be absorbed and the more effective light can be at removing hair.

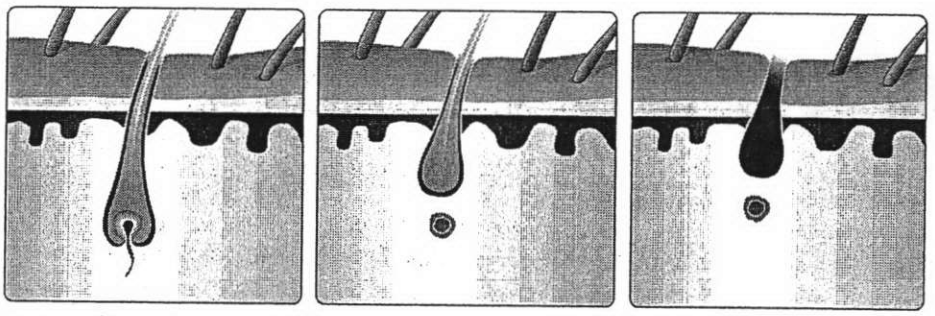


Before Flash N' Go™ Application **During Flash N' Go™ Pulse** **After Flash N' Go™ Application**

9.2. How does the hair growth cycle impact light-based hair removal?

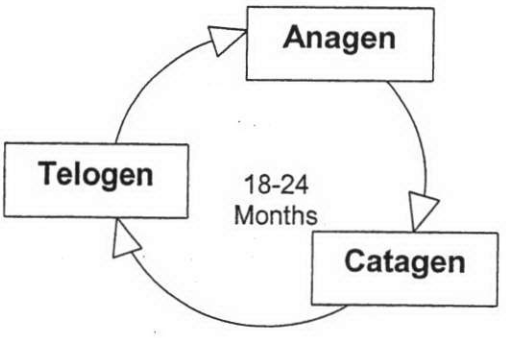
Every hair in our body goes through the three phases of the hair growth cycle: Anagen, Catagen and Telogen. These phases have an important impact on how the process of light-based hair removal works.

Anagen is the hair growth phase while Catagen and Telogen, both are resting phases.



Anagen–Growth phase **Catagen–Resting phase** **Telogen–Resting phase**

The time it takes to complete a full hair growth cycle varies from person to person and the location of the hair on the body, but is typically 18-24 months. At any given moment the majority of the hair follicles in any skin area are in the resting phases. These resting hairs cannot be affected by Flash N' Go™. However, hairs in the growing Anagen phase will respond to Flash N' Go™ applications. It is important to understand that it may take a full hair growth cycle to realize complete hair removal results with Flash N' Go™.



9.3. Plan your Flash N' Go™ hair removal for best results

A typical full hair growth cycle may take 18-24 months. During this time multiple Flash N' Go™ sessions may be required in order to achieve long term hair removal.

The efficiency of hair removal varies from person to person according to body area, hair color, and how Flash N' Go™ is used.

Typical Flash N' Go™ hair removal plan during a full hair growth cycle:

- The first **3-4 hair removal sessions** with Flash N' Go™ will be approximately **two weeks apart**.
- Hair removal **sessions 5-7** with Flash N' Go™ will be approximately **four weeks apart**.
- After that you will typically use Flash N' Go™ again **from time to time** if and when needed, until long-term results are achieved.

This is the recommended treatment schedule that has proven to produce the best results, but you may plan your personal treatment schedule differently and still get satisfactory results.

Note that treating the same body part more often than once in two weeks, will not improve hair removal results.

Typical maintenance with Flash N' Go™ after achieving long-term hair removal:

Due to hormonal or other physiological changes dormant hair follicles may become active. Maintenance hair removal sessions with Flash N' Go™ may be required from time to time.

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10. How To Use Flash N' Go™

10.1. Flash N' Go™ Setup

1. Remove Flash N' Go™ *Base Unit*, *Applicator* and other components from box.
2. Insert the *Applicator* into its cradle in the Flash N' Go™ *Base Unit*.
3. Verify that the *Disposable Lamp Cartridge* is inserted correctly into the *Applicator*.
4. Plug the power cord into the Flash N' Go™ *Base Unit* socket.
5. Plug the other end of the power cord into an electrical outlet.

Your Flash N' Go™ is now ready to start.

10.2. Treating with Flash N' Go™ for the first time

The skin should be **shaved**, **clean**, **dry** and **free** of any powders, antiperspirants or deodorants.

1. Press the *Power On/Off Switch*. The *Power Indicator Light* will turn on and a fan sound (similar to the sound of a hairdryer) will start.
2. Approximately 3.5 seconds after pressing the *Power On/Off Switch*, the *Ready Indicator Light* will turn on and the device beeps. The device sets itself to deliver the lowest energy level pulses. The device is then ready for you to trigger the first pulse.
3. If the energy level should be higher than the lowest, press the *Energy Level Setting Buttons* using the "-" or "+" to respectively decrease or increase the energy level, until the desired energy level is set. *Energy Level Indicator Lights* will coincide with the energy level setting. (See "Energy Level" frame).
4. Apply the *Applicator* firmly to the skin, making sure the skin is spread evenly and smoothly. Make sure the *Applicator Tip* is in full contact with the skin.
5. Press the *Pulse Button*. The device will first determine the color of your skin.
   If the color of the skin is light enough for safe application, the device will flash a pulse of light onto your skin. You will see a bright flash of light and simultaneously hear a subtle pop sound, which is a normal noise for the device. You may feel a mild sensation of warmth and tingling.
   Flash N' Go™ will immediately recharge for the next pulse. After 3.5 seconds the *Ready Indicator Light* will turn on again and the device will beep.
   If you see no light pulse, and the 5 green energy level LEDs blink for 3 seconds, your skin tone is too dark for safe application. Try using the device on a different body part or contact the Flash N' Go support.
6. Remove the *Applicator Tip* from the treated area of skin.
7. Move the *Applicator Tip* to another area of skin.
   Use the pressure marks the device just made in your skin to guide you for proper positioning of the next pulse, avoiding both gaps and overlaps between pulses (See "Covering skin areas" frame).
   Warning: Do not treat the same area of skin more than once per hair removal

session! Treating the same area of skin more than once per session increases the likelihood of adverse effects.

8. Repeat the process starting again with Step 5.

Energy Level

Energy level determines the intensity of the Flash N' Go™ light pulse delivered to your skin, from the lowest level (-) to the highest level (+). Corresponding *INDICATOR LIGHTS* on the *CONTROL PANEL* represent the increases in energy. As energy level increases, so does hair removal results as well as the risk of possible side effects and complications.

Always start your first Flash N' Go™ hair removal session at the lowest energy setting.

If you experience little or no discomfort during and after the hair removal session using the lowest energy level, raise the energy level by one *INDICATOR LIGHT* at the next session, and so on for each subsequent session.

Do not raise the energy level if you experience abnormal discomfort during or after treating with Flash N' Go™ (See section 2.6 - "Possible Side Effects"). ***Do not raise the energy level during hair removal session even if you experience no discomfort. Discomfort may also appear some time after the session.***

Whenever Flash N' Go™ is turned on its energy level will automatically be reset to the lowest energy level. Only one *ENERGY LEVEL INDICATOR LIGHT* will be on.

To set the energy level, press the *ENERGY LEVEL SETTING BUTTONS* using "-" or "+" to respectively decrease or increase the energy level. The number of *ENERGY LEVEL INDICATOR LIGHTS* will coincide with the change in energy level.

For your safety, when using Flash N' Go™ for the very first time, the system is automatically set to deliver the first 50 pulses at the lowest energy level, and the next 200 pulses at up to level 3.

To cancel these safety settings press and hold the "+" and "-" *ENERGY LEVEL SETTING BUTTONS* simultaneously until you hear 2 consecutive "beep" sounds. To **restore** these safety settings press and hold the "+" and "-" *ENERGY LEVEL SETTING BUTTONS* simultaneously until you hear 3 consecutive "beep" sounds.

Covering skin areas

Flash N' Go™ pulses should be administered in rows, starting at one end of each row and progressing sequentially towards the other end. This technique allows better control of skin coverage, and helps you avoid treating the same area more than once or overlapping skin areas

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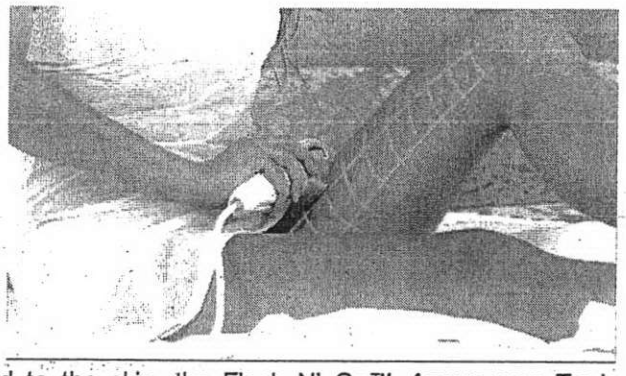

When applied to the skin, the Flash N' Go™ *APPLICATOR TIP* is designed to create temporary pressure marks on the treated area. These visible marks can be used for proper positioning of the next pulse.

Try to avoid overlapping pulses!

Do not treat the same area of skin more than once per hair removal session!

If your skin blisters or burns, STOP USE IMMEDIATELY!

10.3. What to Expect when treating with Flash N' Go™?

For many people, using Flash N' Go™ may be their first experience with a light-based device designed for home use. Flash N' Go™ is simple to use, and hair removal sessions go by quickly. During a Flash N' Go™ session it is **normal** to experience and feel:

- **A Flash of Light** – The bright light of Flash N' Go™ will not harm the eyes when applied to non-facial sites, and special eye-protection is not needed when using Flash N' Go™.
- **A Fan Noise** – The cooling fan in Flash N' Go™ makes noise similar to a hairdryer. This is normal.
- **A Pop Sound with Each Pulse** – When a pulse of HPL™ light is activated, it is normal to hear a subtle pop sound simultaneously with the flash of light.
- **Moderate Pressure of the *APPLICATOR*** – This is necessary and helpful for placement of adjacent pulses of light, and is part of the unique safety feature of Flash N' Go™.
- **A Sensation of Warmth and Tingling** – During each pulse of light it is normal to feel a mild sensation of warmth and tingling from the light energy. Remember it is important to always use low energy settings for initial hair removal sessions. You may feel some warmth for up to an hour after your Flash N' Go™ session.
- **Some Mild Red or Pink Color** – During and just after your Flash N' Go™ session it is not uncommon to see some very mild, pink-like color of the skin. This is usually most noticeable around the hairs themselves. However if you see full redness of the skin, blistering or burns stop use of Flash N' Go™ immediately.

10.4. After treating with Flash N' Go™

- When Flash N' Go™ session has been completed turn Flash N' Go™ off by pressing the *POWER ON/OFF SWITCH*. (Be sure to remember the last energy level setting you used, as it will not be restored when turning Flash N' Go™ on again.)
- Unplug the power cord from the electrical outlet.
- After each hair removal session it is recommended that you clean your Flash N' Go™ device, especially the *APPLICATOR TIP* (See section 5.1: "Cleaning Flash N' Go™").
- After cleaning, it is recommended to store your Flash N' Go™ device in its original box, and keep it away from water.

Skin care following hair removal session

Do not expose treated areas of skin to the sun. Be sure to carefully protect the treated skin with sunscreen, throughout the hair removal period and for at least 2 weeks following the last Flash N' Go™ session.

Side effects and complications

Some patients may experience pigmentation changes resulting from treating with Flash N' Go™. These effects, if they occur, are generally mild and transient.

In case you experience any complication (See section 2.6 Possible Side Effects using Flash N' Go™) ***please contact your physician immediately.***

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11. Maintenance of Flash N' Go™

11.1. Cleaning Flash N' Go™

After each hair removal session, it is recommended to clean your Flash N' Go™ device, and especially the *APPLICATOR TIP*.

- Unplug Flash N' Go™ before cleaning.
- Use a dry, clean cloth and a specially formulated cleaner for electronic equipment to gently wipe Flash N' Go™ surface, and especially the *APPLICATOR TIP*.
  Never immerse Flash N' Go™ or any of its parts in water!

11.2. Replacing the LAMP CARTRIDGE

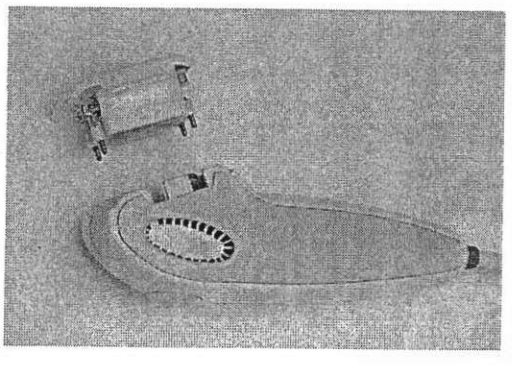
The Flash N' Go™ *DISPOSABLE LAMP CARTRIDGE* can fire 750 light pulses that would typically cover 2 Legs, Arms, Under arms, and Bikini line. Pulse intensity is determined only according to the energy level setting of the device. There is no decrease of energy during the usable lifetime of the *LAMP CARTRIDGE*.

When a *DISPOSABLE LAMP CARTRIDGE* has reached 90% of its possible lifetime the *CARTRIDGE 90% USAGE INDICATOR LIGHT* on the *CONTROL PANEL* will be activated, indicating that the *DISPOSABLE LAMP CARTRIDGE* should soon be replaced.

Once all 750 pulses in a *DISPOSABLE LAMP CARTRIDGE* have been used the *CARTRIDGE 100% USAGE INDICATOR LIGHT* will be activated, indicating that further pulses can not be emitted.

In order to continue the hair removal session, it will now be necessary to replace the *DISPOSABLE LAMP CARTRIDGE*.

Note: A *DISPOSABLE LAMP CARTRIDGE* should also be replaced if large spots appear inside it or if its *LENS* is broken.



To replace a *DISPOSABLE LAMP CARTRIDGE*:

1. Press the *POWER ON/OFF SWITCH* to turn Flash N' Go™ off.
2. Unplug the power cord from the electrical outlet.
3. Grasp the used *DISPOSABLE LAMP CARTRIDGE* on both sides, pull it out of the

12. Troubleshooting

12.1. "My Flash N' Go™ does not start."

- Make sure the power cord is properly connected to the Flash N' Go™ device.
- Make sure the power cord is plugged into an electrical outlet on the wall.

12.2. "A light pulse is not emitted when I press the PULSE SWITCH."

- Make sure that you have good contact with the skin and that the *APPLICATOR TIP* is evenly and firmly pressed to the skin. For your safety, the *PULSE BUTTON* will activate a pulse only if the *APPLICATOR TIP* is firmly pressed against the skin.
- Skin color sensor stopped the light pulse, your skin may be to dark for using the Flash N' Go. Try to apply Flash N' Go™ again.
- Check the *CARTRIDGE 100% USAGE INDICATOR*. If it is on, disconnect Flash N' Go™ and replace the *DISPOSABLE LAMP CARTRIDGE*.
- Make sure that the *READY INDICATOR* is on.
    a. If within 10 seconds the *READY INDICATOR* remains off turn Flash N' Go™ off and back on by pressing the *POWER ON/OFF SWITCH* twice.
    b. If the problem persists, contact your local Flash N' Go™ Customer Service Center.
- Check the *SYSTEM WARNING INDICATOR LIGHT*.
    c. If the light is on turn Flash N' Go™ off and back on by pressing the *POWER ON/OFF SWITCH* twice.
    d. If the problem persists, contact your local Flash N' Go™ Customer Service Center.

If these problems persist, contact your local Flash N' Go™ Customer Service Center.

Do not attempt to open or repair your Flash N' Go™ device. Only authorized Flash N' Go™ repair centers are permitted to perform repairs.

Opening Flash N' Go™ may expose you to dangerous electrical components and to pulsed light energy, either of which may cause serious bodily damage and/or permanent eye injury.

Trying to open Flash N' Go™ may also damage the device and will void your warranty.

Please contact Flash N' Go™ Customer Service if you have a broken or damaged device in need or repair.

13. Customer Service

For more information about Flash N' Go™ please enter www.silkn.com.

If your Flash N' Go™ is broken, damaged, in need of repair, or for any other Flash N' Go™ user assistance, please contact Flash N' Go™ Customer Service:
1-877-DO-SILKN / 1-877-367-4556
contact@silkn.com

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14. Frequently Asked Questions

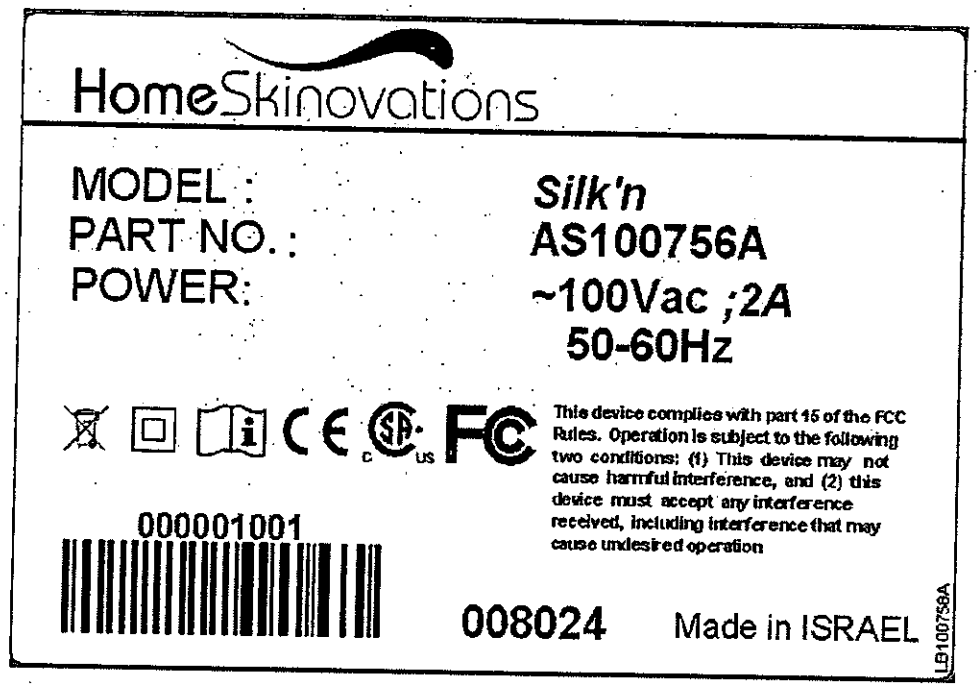
1. ***Does Flash N' Go™ really work?***
   Yes. In clinical trials held by physicians, Flash N' Go™ was proven to safely achieve long-term hair removal results.
2. ***Where on my body can I use Flash N' Go™?***
   The Flash N' Go™ device has been designed for body hair removal anywhere below the neck. The most common areas treated with Flash N' Go™ are: legs, underarms, arms and bikini line. It is not recommended to use Flash N' Go™ on the face. Flash N' Go™ is not suitable for everyone. We recommend that you read all the Flash N' Go™ warnings and contraindications in this User's Manual.
3. ***How long does a Flash N' Go™ treatment session take?***
   The time can vary depending on the area of the body treated. A full leg can take up to 30 minutes, or two underarms could take 10 minutes. Because Flash N' Go™ runs on regular electric power it can be used for as long as needed to complete a full hair removal session of the desired body part(s).
4. ***Is Flash N' Go™ safe?***
   Flash N' Go™ has been designed with your safety in mind, and tested and approved by top dermatologists and plastic surgeons to meet their safety standards for a home-use device. But like any skin product or electronic device, one must use according to the operating instructions and user precautions.
5. ***Will Flash N' Go™ hurt?***
   When used properly most users of Flash N' Go™ report feeling a slight sensation of heat at the time of the pulse of light. Users with thicker and darker hairs may feel slightly more discomfort, but this discomfort subsides once the hair removal session is completed. For your convenience Flash N' Go™ has five setting levels that can be used according to your sensitivity.
6. ***How often should I use Flash N' Go™?***
   Hair removal sessions with Flash N' Go™ should be spaced every two weeks for the first three to four sessions. After that hair removal sessions should be done if hairs have grown back, until the desired results are achieved.
7. ***Is Flash N' Go™ effective on white, grey or blonde hairs?***
   Flash N' Go™ works best on darker hair types, or hair that contains more melanin. Melanin is the pigment that gives hair and skin their color, and will absorb light energy. Black and dark brown respond the best, although brown and light brown hairs will also respond but typically require more hair removal sessions. Red may show some response. White, grey or blonde hairs usually don't respond to Flash N' Go™ though some users have noted results after multiple hair removal sessions.
8. ***Can I use Flash N' Go™ on brown or black skin***
   Do not use Flash N' Go™ on naturally dark skin complexion! Flash N' Go™ removes unwanted hair by selectively addressing hair pigment. Varied quantities of pigment also exist in the surrounding tissue of skin. The quantity of pigment in a particular person's skin, which is manifested by their skin complexion, determines the degree of risk they are exposed to using Flash N' Go™. Treating dark skin with Flash N' Go™ can result in adverse effects such as burns, blisters, and skin color changes (hyper- or hypo-pigmentation).
9. ***When will I see results from Flash N' Go™?***
   As with any light-based or laser hair removal device, results are not immediate, and in fact you may not think anything happened at all. Hair may sometimes appear to be growing back after a hair removal session, but typically after two weeks many of these hairs will simply fall out. Additionally hairs grow in three different stages and only hairs in an active growth stage will be affected by Flash N' Go™. This is one of the main reasons that multiple sessions are required to achieve the desired result.

10. ***Can a man use Flash N' Go™?***
    Though designed exclusively for women, Flash N' Go™ may be suitable for use by men. However, hairs on men, typically those on the chest, will require more hair removal sessions than that of women to get the desired results. As with women, using Flash N' Go™ on men's facial hair such as beard and mustache, is not recommended.
11. ***Why is my hair growing, even though I treated it a week ago?***
    It is quite common for hair to appear as if it is still growing up to two weeks after a hair removal session with Flash N' Go™. This process is known as "ejection" and at around two-weeks you'll see that these hairs simply fall out or slide out with a slight tug. (We don't however recommend pulling on the hairs – just let them come out naturally.) It is also possible that some hairs, due to missed application or different stages of growth, were not affected by Flash N' Go™. These hairs will be treated in follow-up sessions, and hence the reason multiple hair removal sessions are needed to get the best result with Flash N' Go™.
12. ***I've heard that some hairs grow back lighter and finer after light based hair removal?***
    This phenomenon is well documented amongst aestheticians and doctors using light and laser devices for hair removal. It is possible that some hairs will grow back lighter and finer after hair removal with Flash N' Go™. Usually these hairs are a fraction of what was originally there, and continued use may have a desirable effect on them.
13. ***Why can't I treat myself if I have an "active" suntan?***
    Do not use Flash N' Go™ on tanned skin or after sun exposure! Tanned skin and particularly following sun exposure, contains large quantities of the pigment Melanin. This applies to all skin types and complexions, including those which don't seem to tan quickly. The presence of large quantities of Melanin exposes the skin to higher risk of adverse effects when using Flash N' Go™ including burns, blisters, and skin color changes (hyper- or hypo-pigmentation).
14. ***Is long-term use of Flash N' Go™ dangerous for my skin?***
    The use of light and laser energy in aesthetic medicine has been well documented for over 15 years in professional peer-reviewed journals, and by well respected institutions like the Mayo Clinic. These journals and institutions have not reported any side-effects or damage from long-term use of light and laser device.
15. **Can I use Flash N' Go™ to remove my chin hair or elsewhere on my face?**
    It is not recommended to use Flash N' Go™ on the face or neck. Unlike body hair, most of women's potential facial hair remains inactive and hidden, while only a fraction of it grows and surfaces. Exposing facial hair to the light pulses of Flash N' Go™ may remove apparent hair but simultaneously stimulate unwanted growth of hidden hair. In addition, using Flash N' Go™ to remove facial hair may cause serious eye injury.
16. ***How long should I wait to treat with Flash N' Go™ after unprotected exposure to the sun?***
    One should wait 4 weeks before using Flash N' Go™ after unprotected exposure to the sun. However, if there is ever any uncertainty about sun exposure please contact your physician or Home Skinovations customer support.
17. ***Should I do anything before using Flash N' Go™?***
    Before any Flash N' Go™ session it is important to avoid sun exposure on the treated area for at least four weeks. A high level UV Sun Screen (SPF 50+) will help, as will clothing covering the treated area. The area to be treated should also be cleaned with mild soap and water, and the hairs shaved down to skin level.
18. ***How should I care for the treatment area after using Flash N' Go™?***
    The area treated with Flash N' Go™ can be cleaned and maintained with standard skin care products. Special care must be taken to avoid unprotected sun exposure. Strong sunscreens (50+ SPF) and covering clothing are suitable for protection from the sun.
19. ***Should I pull the hairs out after treatment?***
    No, let the hairs gradually fall out on their own. This may take up to 2 weeks.

15. Specifications

Spot size	2cm x 3cm [6cm^2]
Speed	1 pulse every 3.5 second: 1.7 cm^2/sec
Technology	New Home Pulsed Light™
Max Energy Level	Max 5J/cm^2
Wavelength	475-1200nm
Charging time / Power source	Continuous operation
Electrical requirements	100-240VAC, 2A
Time needed to treat lower legs	30 minutes
Operation and Safety	*Skin Color Sensor* seamlessly ensures use only on appropriate skin types.
package size	Height 9 inch, Width 9 inch, Depth 5.2 inch
System weight	4 pounds

16. Labeling



Class II equipment

Degree of protection against electric shock: type BF applied part

WEEE - Waste Electrical and Electronic Equipment

CE Mark

Follow operating instructions

This device comply with part 15 of the (FCC) Federal Communications Commission.

CSA Mark for USA and Canada

Degree of protection against ingress water: ordinary

This device is not suitable for use in the presence of flammable anesthetic mixture with air or with Oxygen or Nitrous Oxide.

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HomeSkinovations

EC Declaration of Conformity

We Home Skinovations Ltd. declare under our sole responsibility that the home Skin treatment products

Brand Name:	***Home Skinovations***
Model Name:	***Flash N' Go, Disposable Lamp Cartridge***
Models Number	**AS100001E,AS100674B,AS100756A**

are fully in conformity with the essential requirements of Council Directive 89/336/EEC and 73/23/EEC amended by Directives 93/68/EEC.

This declaration is based on the full compliance of the products with the following European standards:

EMC:	**EN 61000-3-2:2000; (A2:2005),** **EN 61000-3-3:1995; (A1:2001)** **EN 55014-1:2000; (A2:2002),** **EN55014-2:1997; (A1:2001)**
Electrical safety:	**EN 60335-1:2002; (A1:2004; A12:2006),** **EN 60335-2-23:2003,** **EN 60335-2-27:2003**
Human Exposure to electromagnetic field radiated	**EN 50364:2001**

Manufacturer:

Home Skinovations Ltd.
Apolo Building, Shaar Yokneam,
POB 533, Yokneam 20692, ISRAEL
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Authorized Representative:

Home Skinovations GMBH
Dr. Kurt Huber Str. 6
D-82031 Grünwald, GERMANY
Tel. +49-89-64919530
Fax +49-89-64919531

Signed:

Gabi Lavi
General Manager
Yokneam, February 4, 2008

Signed:

Dr. Amir Waldman
VP Regulatory & Clinical Affairs
Yokneam, February 4, 2008

For Information: On the basis of this declaration, these products and packaging will bear the following mark:

CE

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Flash N' Go™ is a **physician recommended** and innovative light-based device for hair removal in the **privacy of your home**. **Safe**, **easy to use** and **cost effective**, Flash N' Go™ achieves **marked clinical results** while offering personal convenience.

Flash N' Go™ utilizes the highly sophisticated and new **Home Pulsed Light™** (**HPL™**) technology developed by **Home Skinovations Ltd.**

HomeSkinovations

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Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

510(k) Submission for Flash N' Go

Home Skinovations Ltd.

August 10, 2008

HomeSkinovations

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Flash N' Go 510(k) Notification

(The Flash N' Go is an over the counter device intended for the removal of unwanted hair)

Table of contents

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August 10, 2008

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

Subject: 510(k) Submission for Flash N' Go

Dear Sir/Madam,

Home Skinovations Ltd. is submitting this premarket notification for the purpose of obtaining FDA marketing clearance for its product. A table of contents for this 510(k) application is presented immediately after this cover letter. The following is information required under 21 CFR 807.87:

This is to notify you of the intention of Home Sknovations Ltd. to manufacture and market the following device:

Please send all correspondence by fax (+972-4-9097471), in addition to mail

Trade/Proprietary name:	Flash N' Go
Common name:	Light based hair removal system
Classification name:	The subject of this application is a Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR 878.4810)
Product codes:	GEX
Class of device:	The device should be considered a class II device, as are the predicate devices.
Reason for Application:	New device.
Name and address of Manufacturer:	Home Skinovations Ltd.

	Apolo building POB 533 Yokneam 20692 ISRAEL Tel: +972(4)9097440 Fax: +972(4)9097471
Contact person:	Dr. Amir Waldman VP regulatory affairs Tel. +972-547-404616, +972-4-9097440 Fax +972-4-9097471 E-mail - amirw@silkn.com
Applicable standards:	Action taken by the person required to register to comply with the requirements of the Act under section 514 for performance standards or section 513 for special controls: There are no mandatory performance standards applicable to this device. There are voluntary performance standards that the Flash N' Go complies with as discussed in chapter 4.
Labeling/Promotional material:	The labeling and promotional materials for the Flash N' Go, and for the substantially equivalent predicate devices, are presented in later sections of this application.
Substantial equivalence predicate devices:	Flash N' Go is substantially equivalent to the following devices: • ABC hair removal system, Indication for use: "The ABC hair removal system is an over the counter device intended for adjunctive use with shaving for hair removal sustained with periodic treatments". Manufactured by Palomar Medical Technologies Inc. and subject of K060839. • Spectra hair removal laser system, Indication for use: The Spectra hair removal laser system is an

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over the counter device intended for adjunctive use with shaving for hair removal sustained with oeriodic treatments. Manufactured by SpectraGenics, Inc. and subject of K053527.

- Silk'n, Indication for use: The Silk'n is intended for removal of unwanted hair by using selective photothermal treatment. The device is generally indicated for dermatological use. The Silk'n is specifically indicated for patient removal of unwanted hair by using selective photothremal treatment under the direction of a physician, after training by a healthcare professional. Manufactured by Home Skinovations Ltd. and subject of K072906.

Confidentiality: The material in this application is considered confidential and is not meant for public release.

Truth and Accuracy Statement: A truthful and accurate statement, according to 21CFR 807.87(k), is presented after a separate page with the indications for use.

SMDA Safety and Effectiveness Summary: Summary of Safety and is presented following the table of contents.

The therapeutic light output of the Flash N' Go (b) (4) [redacted]

(b) (4) [redacted]

We trust that the information included in this application will be adequate to allow for its prompt review. Please contact me if there are any questions.

Sincerely yours,

Dr. Amir Waldman
VP regulatory affairs
Home Skinovations Ltd.

Amir Waldman

Chapter 1 Principle of operation

Introduction to Flash N' GO

The Flash N' Go device uses light energy in order to remove hairs. The Flash N' Go device is an over the counter device indicated for the removal of unwanted hair.

The treatment with Flash N' Go is based on the principle of *selective thermolysis.* According to this principle, parameters of optical energy (spectrum, exposure duration and energy density) are chosen and optimized to selectively treat hair and follicle without damaging the surrounding tissues.

Background

Optical energy can be used for thermal destruction of hair follicles. Optical energy penetrates through the upper skin and is absorbed by the pigment of the hair shaft and converted into heat energy, raising the hair temperature. The hair follicle structure has no optical contrast with surrounding tissue and does not selectively absorb light. Heat can be conducted from the shaft to the hair follicle thus creating heating of the follicle to temperatures that are higher than the temperature of the surrounding tissue. When the follicle reaches a high enough temperature, it is damaged and this leads to delay in hair growth.

In order to remove hair safely, the light energy type has to be selected in such a way that the skin or other healthy tissue absorbs the smallest portion of energy while the largest portion is absorbed by the hair shaft. The schematic representation of skin with hair is shown in Figure 1.

The term selective photothermolysis was coined to describe heating of pigmented targets by selectively absorbed pulses of light radiation. Laser-assisted photothermolysis is based on applying single wavelength, selectively absorbed by target[1]. This principle was later extended to multiple wavelengths[2].

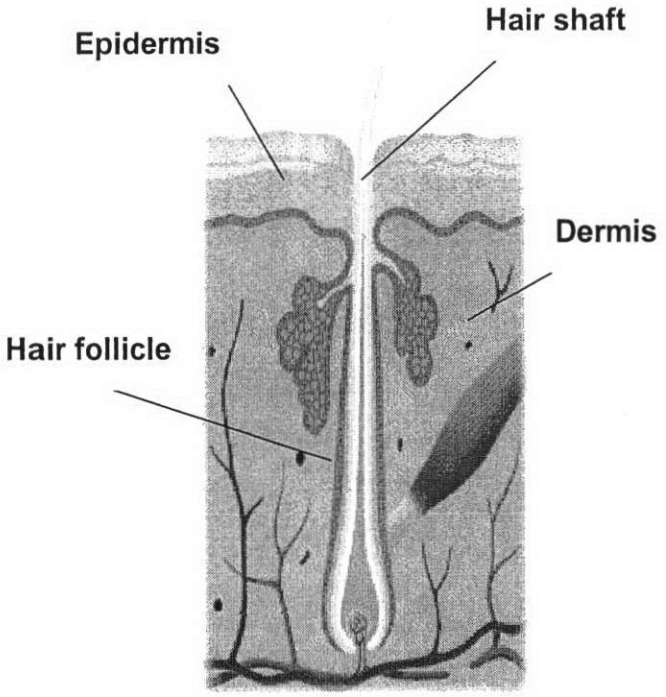

Figure 1. Schematic representation of skin with hair.

It was shown that different wavelengths could be absorbed by different parts of the target, providing more uniform heating of the treated object. However, in both cases the treated target that absorbs the light should have a higher absorption coefficient than the surrounding tissue. In the present device, this principle is applied by using low energy pulses of light.

The basic elements that are necessary to achieve selective Photo-thermolysis are:

- Energy that reaches and is preferentially absorbed by the desired target structures.
- Exposure duration less than, or equal to, the time necessary for the target structures to cool.

Selective Photo-thermolysis calls for the use of appropriate light energy parameters such as wavelength range and pulse duration to maximize the absorption of hair follicle within the irradiated area and minimize the heating of nearby tissue.

Selective Photo-thermolysis is successfully applied by light sources such as the Ruby laser, Alexandrite laser, Diode laser, Filtered Xenon Flash Lamp. The Flash N' Go uses the same principle of selective Photo-thermolysis; the skin is exposed to light

energy that penetrates through it and is absorbed in the hair shaft and follicle being treated. The parameters of the light energy generated by the Flash N' Go'n are optimized to achieve maximum selectivity and therefore are safe and effective.

The penetration of light into the skin and the absorption of the different components of the skin and the hair shaft are a function of the wavelength range of light used. Taking all skin chromophores into account, the visible , near-Infrared wavelengths are the most suitable for hair removal treatments. Indeed, most of the cleared devices, lasers and pulse light use spectral range of 400-1200 nm.

Light penetration depth as a function of wavelength is shown in Figure 2. Strong light absorption by blood limits the penetration in the spectral range of 400-600 nm. At higher wavelengths light penetration increases due, mostly, to decrease in the scattering coefficient. At wavelengths longer than 1300nm, the strong light absorption by water prevents its penetration into the dermis.

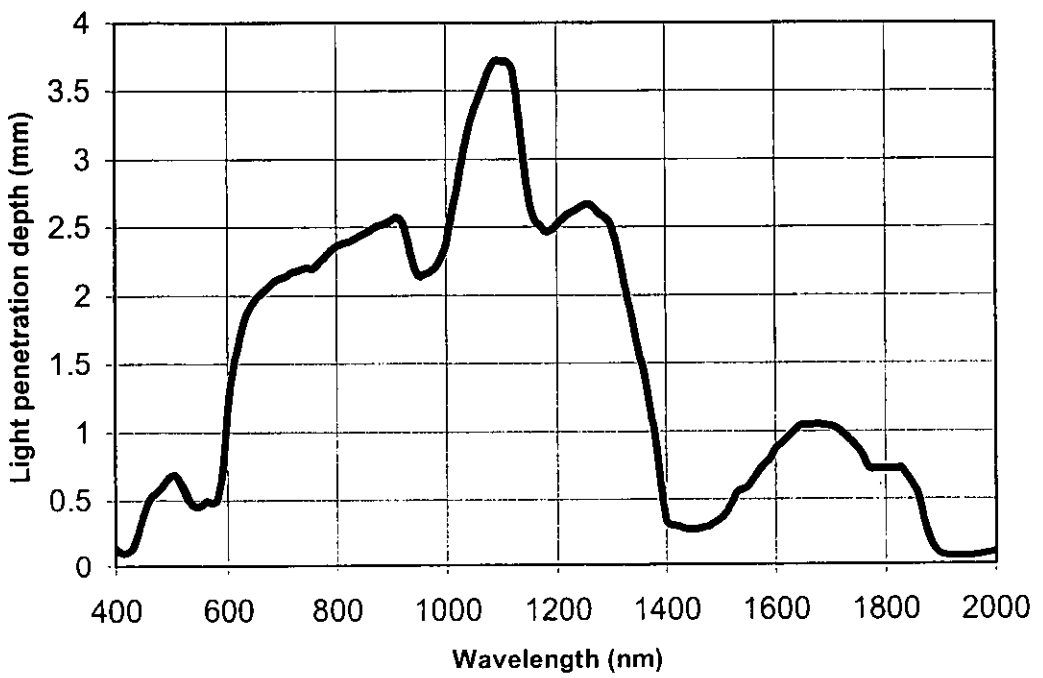

Figure 2. Light penetration depth into the skin as a function of wavelength.

The second requirement is the use of wavelengths in which light is preferably absorbed by the hair shaft compared to the surrounding tissue (dermis and epidermis). The absorption coefficients of epidermis and dermis are shown in Figure 3. The

graph, based on the data of Svaasand[3] and Anderson and Parish[4], is for skin with a 1% blood content.

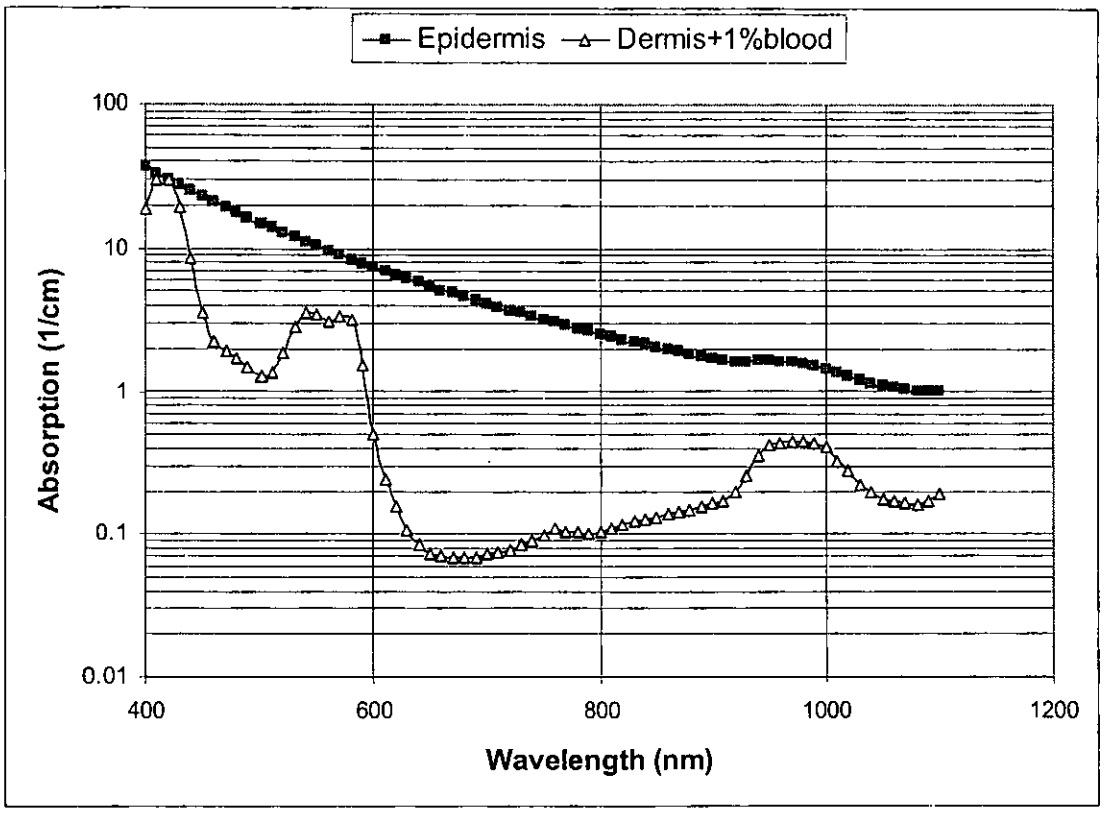

Figure 3. Absorption and scattering coefficient of epidermis and dermis with 1% of blood content in the wavelength range of 400-1200nm.

In the dermis, absorption in the wavelength range of 400-1200nm is determined by the blood content. In the range of 980-1000nm, dermal absorption is mainly due to water absorption peak. In contrast to the dermis, the absorption of the epidermis is mainly controlled by melanin content. Figure 3 clearly demonstrates this point since it is seen that the absorption coefficient in the epidermis does not show the influence of water or hemoglobin absorption.

The behavior of the absorption coefficient of hair is similar to that of the epidermis since it is mainly controlled by melanin. Light absorption for all hair colors decreases as wavelength increases. The absorption coefficient is directly related to the darkness of hair. Absorption is much higher for black hair than for blond hair. Figure 3 shows the difference between dermal and epidermal (melanin) absorption which is maximal at the shorter wavelengths around 400.

The result of this analysis is that effective and safe hair removal can be achieved at the spectral range of 475 to 1200nm.

Pulse width

Thermal conductivity plays an important role in optimizing selective Photo-thermolysis. The cooling time (thermal relaxation time) of biological objects with temperatures higher than the surrounding tissues is a function of their size. The cooling time, t, of a cylindrical object (such as a hair shaft) is calculated as:

$$t = \frac{d^2}{16\alpha} \qquad (3.4)$$

where α is the thermal diffusivity and d is the diameter of the cylindrical object[6].

The cooling time of a hair follicle is a function of its diameter. Cooling time varies by a factor of 10 between a 100 μm diameter hair and a 300 μm diameter hair.

Diffusivity of hair is about 0.5 10^{-7} m^2/sec. Dependence of hair cooling time as function of hair follicle diameter is shown in Figure 4.

Because our targets are both hair shafts and hair follicles, the pulse duration should be shorter than the thermal relaxation time of the hair shaft. Human hairs have diameters in the range of 100 μ to 300 μ.. Thus, pulse duration should be shorter than 10 milliseconds.

Importance of spot size

The geometry of irradiation plays an important role in achieving good penetration and controlling the scattering in the dermis. When the light is applied to the skin with a small spot size, the scattering of photons diffuses the beam rapidly. The fluence decreases very quickly as a function of depth. Using a spot size that is less than the light penetration depth, the energy distribution can be approximated to that of a spherical decay with the fluence decreasing, through scattering, proportionately to depth squared. With a large spot size, light penetration is more efficient since the "source" of photons has an almost planar geometry[2].

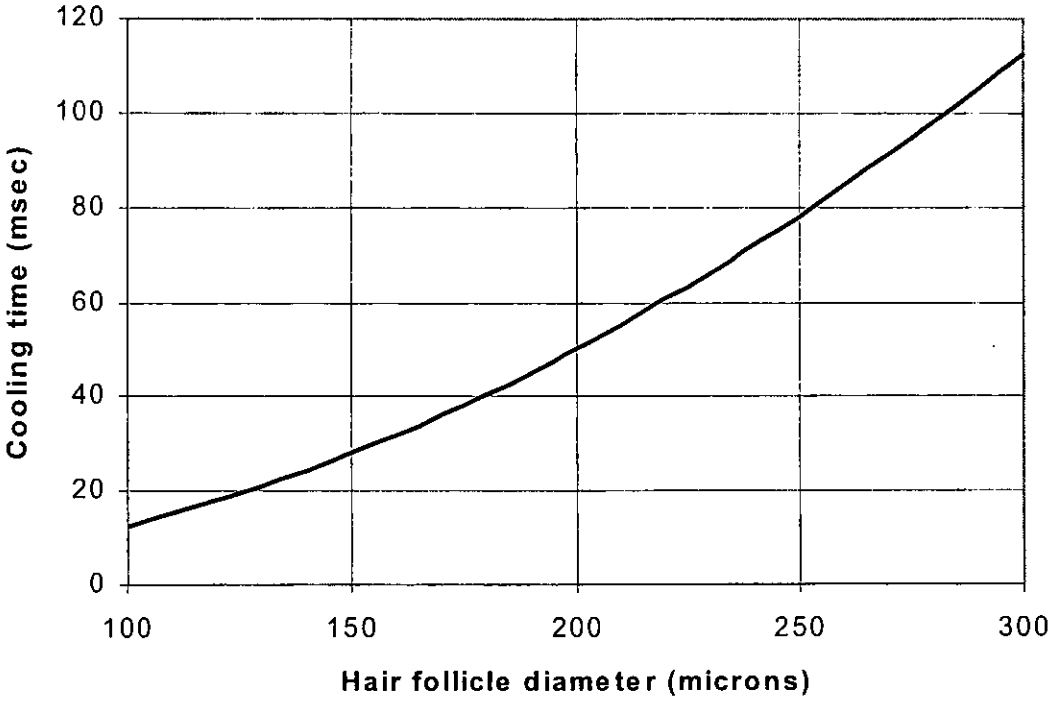

Figure 4 Cooling time of a hair follicle vs. its diameter

Safety

(b) (4)

Summary

It was shown that the choice of the proper optical energy parameters (b) (4) (b) (4) is necessary to achieve safe and effective hair removal on all potential Flash N' Go users.

The optimal range of parameters for safe and effective hair removal as is implemented with the Flash N' Go device are summarized below:

Spectrum	475-1200nm
Fluence	3-5 J /cm^2
Spot size	2x3 cm^2

References

1. R. Rox Anderson, "Laser-tissue Interactions", in Cutaneous Laser Surgery by Mitchel P. Goldman and R.E. Fitzpatrick (1994, Mosby p.9)
2. G. Lask, S. Eckhouse, M. Slatkine, A. Waldman, M. Kreindel, V. Gotfried, "The role of laser and intense light sources in photo-epilation: comparative evaluation". Cutaneous Laser Therapy, 1999, 1:3-13.
3. Svaasand, L.T. Norvang, E.J. Fiskerstrand, E.K.S. Stopps, M.W. Bearns, J.S. Nelson, "Tissue Parameters determining the Visual Appearance of Normal Skin and Port-wine stains". Lasers in Medical Science 1995, 10:55-65
4. R.R. Anderson, J.A. Parrish, "The Optics of Human Skin." Journal of Investigative Dermatology 1981, 77:13-19
5. M.G.C. Van Gemert, A.J. Welch. Time constant in thermal laser medicine. Lasers Surg. Med., 1989, 9405-21

Chapter 2 Device Description

Flash N' Go hair removal system is basically a low power IPL system. The device has two filtered Xenon flash lamps that are mounted inside of a hand held applicator which is connected to a main console with a cord. The on-off switch is located on the main console, along with a switch to set the desired energy level, as well as a set of LEDs that indicate the system's operation mode. A trigger push-button is located on the applicator to emit light pulse.(b) (4)

1. (b) (4)
2.

Device specifications:

Wavelengths range	475-1200 nm
Energy density	3- 5 J/cm^2
Spot size	2*3 cm^2
Pulse repetition rate	0.3 Hz
Weight	Console 1.5 Kg (3 lbs) Applicator .25 Kg (1 lbs)

Control

The control of the system is carried out through a combination of hardware controls and a real-time controller that monitors the status and parameters of the device subsystems. The micro controller translates the treatment parameters selected by the user into electrical signals that generate the proper energy out of the Applicator.

The interface of the real-time controller with the operator is carried out through a control panel that shows the status of the system and is also used to select the treatment parameters.

The control functions and the structure of the hardware element of the control system are shown in ***Figure 1.***

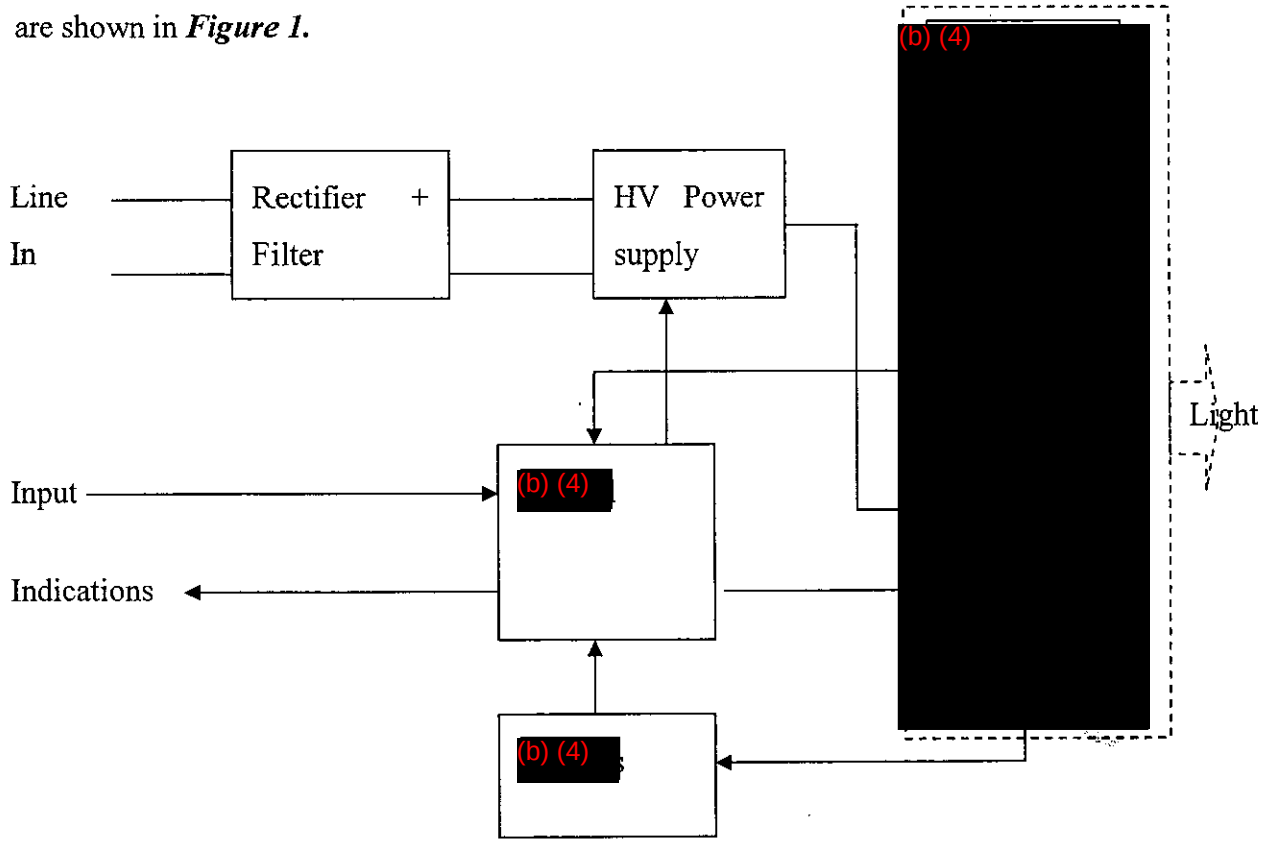

Figure 1. Control system structure and functional relationship.

Turn on and turn off sequence

A push–button switch on the front panel is used to turn the machine on by the user. The controller gets its power from the power line through an isolation transformer. Check sum of the software is carried out whenever the device turns on. By turning the mains switch off, the user immediately disconnects the system from the power line and the system is turned off. Whenever the treatment mode is initiated by the user through the user interface, the controller initiates the new power.

Control during treatment

(b) (4)

[redacted]

Safety function monitoring

(b) (4)

[redacted]

During the entire time that the machine is on, the operational functionality of the cooling system is checked and in the event that there is a problem with this subsystem- the system stops its operation until the safety mode is over. (b) (4) [redacted] (b) (4) [redacted] in the applicator, and in the event of over- heating beyond a predetermined point, the systems stops its operation until the safety mode is over.

Quality System Specification

KEMA

CERTIFICATE

Number: 2109191

The management system of:

Home Skinovations Ltd.

4 Hacharoshet street
P.O. Box 7028
44640 Kfar Saba
Israel

including the implementation meets the requirements of the standard:

ISO 13485:2003

Scope:
Design, manufacture, marketing and sales of home use skin treatment devices

The file that forms the basis of this certificate:
2109191-QUA

This certificate is valid until: December 1, 2010

Issued for the first time: December 10, 2007

KEMA Quality B.V.

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Certification Manager

MGMT.SYS.
RvAC 013

Chapter 3: Substantial equivalence

The Flash N' Go is substantially equivalent (SE) to the following devices:

- ABC hair removal system, Indication for use: "The ABC hair removal system is an over the counter device intended for adjunctive use with shaving for hair removal sustained with periodic treatments". Manufactured by Palomar Medical Technologies Inc. and subject of K060839.
- Spectra hair removal laser system, Indication for use: The Spectra hair removal laser system is an over the counter device intended for adjunctive use with shaving for hair removal sustained with poeriodic treatments. Manufactured by SpectraGenics, Inc. and subject of K053527.
- Silk'n, Indication for use: The Silk'n is intended for removal of unwanted hair by using selective photothermal treatment. The device is generally indicated for dermatological use. The Silk'n is specifically indicated for patient removal of unwanted hair by using selective photothremal treatment under the direction of a physician, after training by a healthcare professional. Manufactured by Home Skinovations Ltd. and subject of K072906.

Labeling and promotional material of the substantially equivalent devices are presented in Appendices 5-1, 5-2, 5-3 of this chapter.

Substantial equivalence is demonstrated according to the criteria outlined in the 510(k) "Substantial Equivalence" Decision Making Process, as published in the FDA 510(k) Guidance (FDA 90-4158).

A comparison table of the subject and predicate devices is included in this discussion.

Intended use equivalence

The Flash N' Go device is an over the counter device intended for the removal of unwanted hair.

The Flash N' Go employs pulses of low energy light to achieve delayed hair growth.

This intended use is similar to the intended use of the Silk'n with respect to the clinical result: "The Silk'n Photoepilation system is intended for removal of unwanted hair by using a selective photothermal treatment. The device is generally indicated for dermatological use. The Silk'n is specifically indicated for patient removal of unwanted hair by using a selective photothermal treatment under the direction of a physician, after training by healthcare professional". (b) (4)

(b) (4)

The Flash N' Go intended use is similar to the ABC and the Spectra devices as an over the counter device: "the ABC hair removal system is an over the counter device intended for adjunctive use with shaving for hair removal sustained with periodic treatments". (b) (4)

(b) (4).

Technological equivalence

The Flash N' Go has technological characteristics that are substantially equivalent to predicate devices. (b) (4). ABC and Spectra devices are laseres at 810 nm with maximum energy density of 12 J/cm^2, and 20 J/cm^2.

No new types of safety or effectiveness questions are raised and differences in the technological characteristics between the Flash N' Go and the predicate devices can be assessed for their effects on safety and effectiveness.

A comparison is provided in the table below:

Technological Characteristic	**Flash N' Go**	Silk'n	Spectra	ABC device	Comments
Nature and Source of Energy Imparted to Patient	Pulsed light via external applicator	Pulsed light via external applicator	Pulsed Diode laser	Pulse Diode Laser	All devices use optical energy as the power source for hair removal treatment

Wavelength range (nm)	475-1200	475-1200	810	810	All devices use Visible / Near IR Wavelengths range to achieve reduced hair growth
Maximum Light Energy (J/cm^2)	(b)	(b)	20	12	Same energy like the Silk'n

Safety and Effectiveness equivalence

The Flash N' Go does not present any new safety and effectiveness issues as compared with the predicate devices.

(b) (4)

As far as effectiveness, (b) (4)

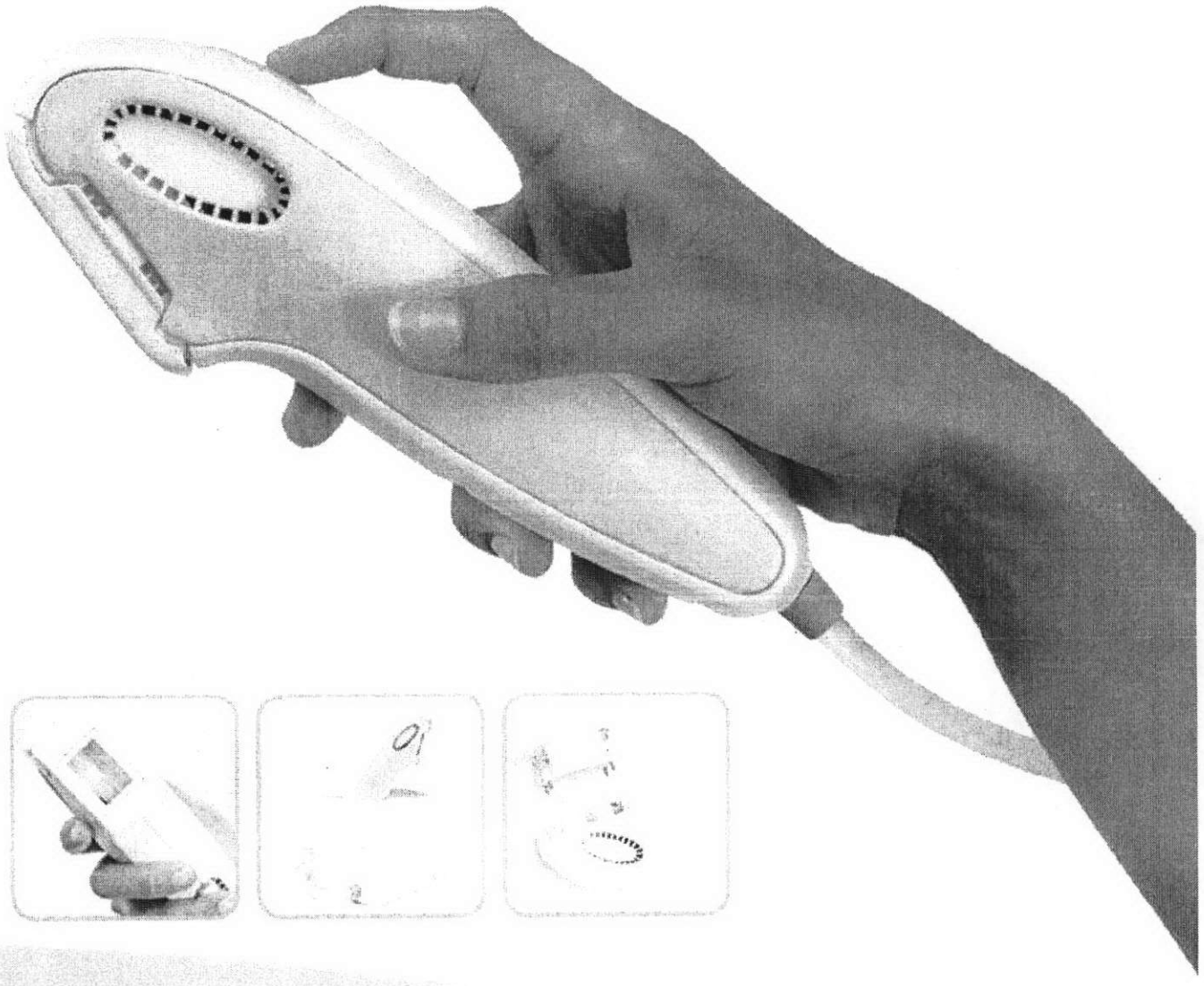
(b) (4)

In light of the results, we conclude that the Flash N' Go device is safe and effective as an over the counter device indicated for the removal of unwanted hair.

Flash N' Go™

Personal Hair Removal at Home

with Home Pulsed Light™



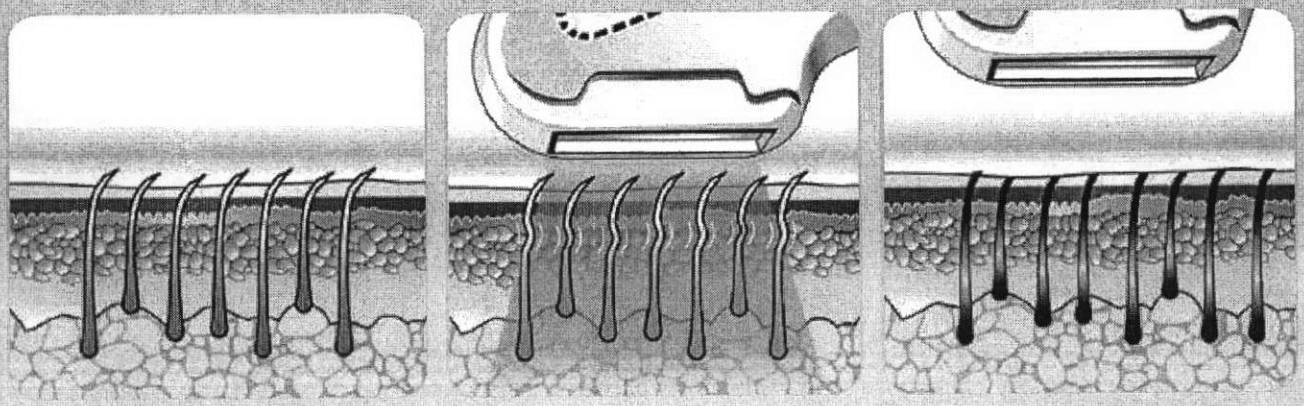
Flash N' Go™ is a physician recommended and innovative light-based device for hair removal in the privacy of your home. Safe, easy to use and cost effective, Flash N' Go™ achieves marked clinical results while offering personal convenience.

THE HPL™ INNOVATION

The Flash N' Go™ device utilizes the highly sophisticated and new **Home Pulsed Light™** (**HPL™**) technology, developed by Home Skinovations Ltd. especially for safe use at home.

HPL™ Epilation is based on the theory of selective photothermolysis in which **optical** energy is used to disable hair growth. Epilation with Home Skinovations' proprietary HPL™ technology is further benefited by a unique **acoustic** effect that enhances the normal process of epilation by photothermolysis.

To safely achieve the desired clinical results the hair shaft needs to selectively absorb HPL™ light energy and transform it into heat. Melanin is the pigment in the hair shaft that is responsible for the absorption of light, which generates the heat at the follicle. Selectivity is achieved when the HPL™ optical energy delivered to the tissue is mostly absorbed by pigment in the hair shaft, while the epidermis and the surrounding tissue remain cool. Additionally HPL™ technology creates an acoustic effect that enhances the overall hair removal result. Together the optical and acoustic effects of HPL™ technology are what enable the Flash N' Go™ device to be safely used by patients for home based hair removal.



- Before using Flash N' Go™
- During Flash N' Go™ pulse
- After Flash N' Go™ application

Flash N' Go™ ADVANTAGES

Physician Recommended

Tested over 12 months in a multi-center clinical study involving over 150 female patients.

Small and Portable

Flash N' Go™ is about the size of a hairdryer and it runs off of regular electric power. so treatment can be done anywhere, anytime and non-stop for as long as necessary.

Safe

When used according to instructions, hair removal with Flash N' Go™ is safe and with minimal discomfort compared to waxing or laser.

Easy to Use

Flash N' Go™ is easy to set up, and treatments are simple, clean and very quick.

Cost Effective

Using Flash N' Go™ will save you money when compared to extended use of professional laser treatments, waxing or shaving.

Marked clinical Results

Although small and portable, the HPL™ technology in Flash N' Go™ captures all the clinical benefits of light-based hair removal.

TECHNICAL SPECIFICATIONS

Spot size	2cm x 3cm [6cm2]
Speed	1 pulse every 3.5 second: 1.7 cm2/sec
Technology	Home Pulsed Light™
Max Energy Level	5 J
Wavelength	475-1200 nm
Charging time / Power source	Continuous operation
Time needed to treat lower legs	30 minutes
Operation and safety	Safety sensor tip enables maximum safety & control. Easy to use.

CONTACT INFORMATION

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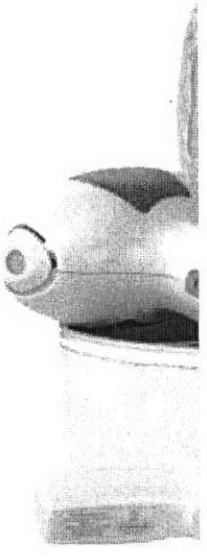
COMING SOON

Smooth, sleek, silky skin at the touch of a button



The TRIA Personal Laser Hair Removal System is the first FDA-cleared laser hair removal product on the market that delivers clinical results in the privacy, comfort, and convenience of your own home.

Kit Includes:

- TRIA laser handpiece
- TRIA Skin Sensor
- Battery charger
- *Instructions for Use* booklet
- Instructional DVD
- Warranty card
- Storage case

Benefits:

- No more endless shaving
- No more painful waxing
- No more inconvenient office appointments
- Laser hair removal in the privacy, comfort, and convenience of your own home
- Beautiful, smooth skin that looks and feels as though the hair was never there

Price: $995.00 (shipping & handling included)

To buy the TRIA System:
Call: 1-877-321-TRIA (8742) or
Email us at clientservices@triabeauty.com

Want to experience the TRIA laser in person?

Click here to find a TRIA MD near you.

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Silk'n

Helping physicians enhance
and maximize their hair removal business

HomeSkinovations

Flash N' Go User manual

Print date: February 2008

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Table of Contents

1. Before You Start

Before using Flash N' Go™ for the first time, please read this User Manual in its entirety. Pay particular attention to sections on device use procedures, device operation, and after-use procedures.

We recommend you re-familiarize yourself with this User Manual before each use of Flash N' Go™.

Flash N' Go™ is a powerful electrical device. As such, it should be used with special attention to safety.

Please read all warnings and safety precautions before use, and strictly follow them when using Flash N' Go™

1.1. What is Flash N' Go™?

Flash N' Go™ is a light-based device for long-term hair removal designed for home-use.

1.2. Flash N' Go™ intended use

Flash N' Go™ is intended for removal of unwanted hair.

Flash N' Go™ may be used to remove unwanted body hair. Ideal body areas for Flash N' Go™ use includes the underarms, bikini line, arms and legs.

2. Safety with Flash N' Go™

2.1. With Flash N' Go™ Safety Comes First

- **HPL™ technology in Flash N' Go™ - Superior safety with lower energy level**

  Home Pulsed Light™ technology is able to achieve long-term hair removal results at a fraction of the energy level used in other light-based hair removal equipment. The low energy used in Flash N' Go™ reduces its potential to cause harm or complications, and contributes to your overall safety.

- **Flash N' Go™ protects your eyes**

  The Flash N' Go™ *APPLICATOR* has a **built-in safety feature** for eye protection. It has been designed so that a light pulse can not be emitted when the *APPLICATOR*

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is facing open air. The safety switch is activated only when the *APPLICATOR TIP* is in full contact with the tissue and pressed.

- **Flash N' Go™ protects your skin**

  Flash N' Go™ comes with a *SKIN COLOR SENSOR* enabling use only on lighter skin complexions to ensure skin safety.

  Furthermore, the 2X3cm² *OPTICAL LENS* through which pulses of light are delivered is recessed inside the *LAMP CARTRIDGE* at the *APPLICATOR TIP*. This enables Flash N' Go™ to protect your skin by avoiding direct contact between the *OPTICAL LENS* and the skin.

2.2. *Is Flash N' Go™ for you?*

Important Safety Information – Read Before Use!

Flash N' Go™ is not designed for everyone. Please read and consider the information in the following section before use. For further information and personalized advice you may also visit www.silkn.com or your local Flash N' Go™ domain.

If you are unsure if Flash N' Go™ is safe for you to use, please ask your doctor or dermatologist!

- **DO NOT USE Flash N' Go™ on naturally dark skin complexion!**

Flash N' Go™ removes unwanted hair by selectively addressing hair pigment. Varied quantities of pigment also exist in the surrounding tissue of skin. The quantity of pigment in a particular person's skin, which is manifested by their skin complexion, determines the degree of risk they are exposed to using Flash N' Go™.

Treating dark skin with Flash N' Go™ can result in adverse effects such as burns, blisters, and skin color changes (hyper- or hypo-pigmentation).

DO NOT USE Flash N' Go™ on naturally dark skin!

A unique *SKIN COLOR SENSOR* is embedded in Flash N' Go™ to measure the treated skin complexion at the beginning of each session and occasionally

during the session. *SKIN COLOR SENSOR* ensures that pulse will be emitted on suitable skin tones.

- **DO NOT USE Flash N' Go™ on tanned skin or after recent sun exposure!**

Tanned skin particularly following sun exposure, contains large quantities of the pigment Melanin. This applies to all skin types and complexions, including those which don't seem to tan quickly. The presence of large quantities of Melanin exposes the skin to higher risk when using Flash N' Go™.

Using Flash N' Go™ on skin that has been recently exposed to sunlight can result in adverse effects such as burns, blisters, and skin color changes (hyper- or hypo-pigmentation).

DO NOT USE Flash N' Go™ on tanned skin or after recent sun exposure! Such use can cause serious burns or skin injury. Avoid exposure to the sun for 4 weeks before your Flash N' Go™ treatment!

The unique Flash N' Go™ *SKIN COLOR SENSOR* will also help you avoid treating sun exposed skin.

- **Flash N' Go™ is not recommended for use on the face or neck**

Unlike body hair, most of women's potential facial hair remains inactive and hidden, while only a fraction of it grows and surfaces. Exposing facial hair to the light pulses of Flash N' Go™ may remove apparent hair but simultaneously stimulate unwanted growth of hidden hair.

Using Flash N' Go™ to remove facial hair may cause serious eye injury and may stimulate facial hair growth.

Flash N' Go™ is not recommended for use on the face or neck.

- **NOTE! Flash N' Go™ is not effective on light hair**

The Flash N' Go™ device is not effective on naturally white, grey, blond and red body hair. If your body hair is of these colors, Flash N' Go™ will not work on you.

2.3. *When to avoid using Flash N' Go™?*

Certain conditions may prevent the use of Flash N' Go™ temporarily. **DO NOT USE Flash N' Go™** if any of the following currently apply to you:

- If you are pregnant or nursing (lactating).
- If you were exposed to strong sunlight or an artificial tanning machine during the past 28 days.
- If you have a tattoo or permanent makeup on the area to be treated.
- If you have dark brown or black spots, such as large freckles, birth marks, moles or warts on the area to be treated.
- If you have eczema, psoriasis, lesions, open wounds or active infections, such as cold sore in the area to be treated. Wait for the effected area to heal before using Flash N' Go™.
- If you have a history of kelodial scar formation, a known sensitivity to light (photosensitivity) or are taking medication that makes the skin more sensitive to light, including non-steroidal anti-inflammatory agents, (e.g., aspirins, ibuprofens, acetaminophen), tetracyclines, phenothiazines, thiazide, diuretics, sulfonyluraes, sulfonamides, DTIC, fluorouracil, vinblastine, griseofulvin, Alpha-Hydroxi Acids (AHAs), Beta-Hydroxi Acids (BHAs), Retin-A®, Accutane® and/or topical retinoids.
- If you have abnormal skin conditions caused by diabetes, for example, or other systemic or metabolic diseases
- If you are currently or have recently been treated with Alpha-Hydroxi Acids (AHAs), Beta-Hydroxi Acids (BHAs), Retin-A®, topical retinoids or azelaic acid.
- If you have been treated with Accutane® (isotretinoin) within the past 6 months.
- If you have been on a steroid regimen within the past 3 months.
- If you have a history of herpes outbreaks in the area of treatment, unless you have consulted your physician and received preventative treatment before using Flash N' Go™.
- If you suffer from epilepsy.
- If you have an active implant, such as a pacemaker, incontinence device, insulin pump, etc.
- If you have a disease related to photosensitivity, such as porphyria, polymorphic light eruption, solar urticaria, lupus, etc.
- If you have a history of skin cancer or areas of potential skin malignancies.
- If you have received radiation therapy or chemotherapy treatments within the past 3 months.
- If you have any other condition which in your physician's opinion would make it unsafe for you to be treated.

If you are unsure if Flash N' Go™ is safe for you to use, please consult with your doctor or dermatologist.

2.4. *Precautions – How to use Flash N' Go™ Safely*

- **Choose your energy levels CAREFULLY!**
  Energy level refers to the intensity of the light pulse that is projected on your skin during use, from the lowest level (-) to the highest level (+). *INDICATOR LIGHTS* on the *CONTROL PANEL* illustrate the energy level at which the machine is set. As the energy level increases, so do the results of Flash N' Go as well as the risk of side effects (see "Possible Side Effects" below).

  Always begin your first use of Flash N' Go™ at the lowest energy setting (one light at "-")!

  Only if you experience little or no discomfort during and after use of Flash N' Go™ at the lowest energy setting, raise the energy level by one *INDICATOR LIGHT* the next time you use Flash N' Go™, and so on for each subsequent hair removal session.

  For detailed instructions on energy level setting see "Energy Level" box in section 4.4 - "Treating with Flash N' Go™ for the first time".

- **Avoid adverse effects!**
  Do not treat the same area of skin more than once per hair removal session!
  Try to avoid overlapping pulses!
  If your skin blisters or burns, **STOP USE IMMEDIATELY!**

- **Avoid complications after use of Flash N' Go™!**
  Do not expose treated areas of skin to the sun. Be sure to carefully protect the treated skin with sunscreen, throughout the hair removal period and for at least 2 weeks following the last hair removal session.

- Always shave the area to be treated and make sure that the skin is clean and dry before using the Flash N' Go™.
- Cover birthmarks and tattoos before Flash N' Go™ application.
- Cover dark brown or black spots, such as large freckles, birth marks, moles or warts before Flash N' Go™ application.
- Never look directly at the light coming from the Flash N' Go™ *APPLICATOR* and *LAMP CARTRIDGE*..
- Do not use Flash N' Go™ on nipples and genitals (male or female).
- Do not use Flash N' Go™ on any body site where you might later want hair.
- Do not use Flash N' Go™ for any purpose other than hair removal.
- Never point the Flash N' Go™ *APPLICATOR* in an attempt to emit a light pulse into open space. Always make sure that the *APPLICATOR* is pointed at, and in full contact with the skin during application.
- Remove the Flash N' Go™ *APPLICATOR* from the skin if either the skin or the *APPLICATOR* is too hot.
- Never use flammable liquids such as alcohol (including perfumes, sanitizers, or other applications containing alcohol) or acetone to clean the skin before using Flash N' Go™.
- Use of Flash N' Go™ may cause temporary pigmentation changes (See "Possible Side Effects" below).

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- Keep this device out of the reach of children. Do not use Flash N' Go™ on children or allow children to use it.

2.5. *Reducing the risk of injury*

As with any electrical device, certain precautions must be taken in order to ensure your safety when using Flash N' Go™.

- **Keep Flash N' Go™ away from water!**
  Flash N' Go™ is an electrical device. As such it should always be kept away from water.
  Do not place or store Flash N' Go™ where it can fall or be pushed into a tub, sink or any other vessel containing water. Do not place in, or drop into water or any other liquid.
  This may cause severe electrocution.
  Do not use Flash N' Go™ while bathing.
  Do not use Flash N' Go™ if it becomes damp or wet.
  Do not reach for Flash N' Go™ if it has fallen into water.
  Unplug Flash N' Go™ immediately if it has fallen into water.

Keep Flash N' Go™ away from water!

- **Never open Flash N' Go™!**
  Do not attempt to open or repair your Flash N' Go™ device. Opening Flash N' Go™ may expose you to dangerous electrical components and to pulsed light energy, either of which may cause serious bodily damage and/or permanent eye injury.

Do not attempt to open or repair your Flash N' Go™ device. Only authorized Flash N' Go™ repair centers are permitted to perform repairs.

- Trying to open Flash N' Go™ may also damage the device and will void your warranty.
  Please contact Flash N' Go™ Customer Service if you have a broken or damaged device in need of repair.

- Use Flash N' Go™ only for its intended use and as described in its manual.
- Flash N' Go™ should never be left unattended when plugged into an outlet.
- Do not operate Flash N' Go™ if it has a damaged cord or plug and keep the power cord away from heated surfaces.
- Do not use Flash N' Go™ if you see or smell smoke when it is in use.

- Do not use Flash N' Go™ if it is not working properly or if it appears damaged.
- Do not use Flash N' Go™ if the fan vent in its *APPLICATOR* is cracked, coming off or missing.
- Do not use Flash N' Go™ if the *SKIN COLOR SENSOR* in its *APPLICATOR* is cracked, or broken.
- Do not use Flash N' Go™ if the outer shell is cracked or is coming apart.
- Do not use Flash N' Go™ with a damaged *DISPOSABLE LAMP CARTRIDGE*, or if its *OPTICAL LENS* is cracked, chipped or missing
- Always unplug Flash N' Go™ from the electrical outlet immediately after use.
- Unplug Flash N' Go™ before cleaning.
- Do not use Flash N' Go™ with any attachments or accessories not recommended by Home Skinovations Ltd.

2.6. Possible Side Effects using Flash N' Go™

When used according to the instructions, side effects and complications associated with use of Flash N' Go™ are uncommon. However every cosmetic procedure, including those designed for home use, involves some degree of risk. Therefore it is important that you understand and accept the risks and complications that can occur with pulsed light hair removal systems designed for home use.

- **Minor Skin Discomfort**
  Although home pulsed light hair removal is generally very well-tolerated, most users do feel some mild discomfort during use, usually described as being a mild stinging sensation on the treated skin areas. The stinging sensation usually lasts during the time of the application itself or for a few minutes thereafter. Anything beyond this minor discomfort is abnormal and means that either you should not continue to use Flash N' Go™ because you are unable to tolerate the hair removal application, or that the energy level setting is too high.

- **Skin Redness**
  Your skin may become red right after using Flash N' Go™ or within 24 hours of using Flash N' Go™. Redness generally clears up within 24 hours. See your doctor if redness does not go away within 2 to 3 days.

- **Increased Sensitivity of the Skin**
  The skin of the treated area is more sensitive so you may encounter dryness or flaking of the skin.

- **Skin Wounds and Burns**
  Very rarely, burns or wounds to the skin can occur following the application. The burn or wound can require a few weeks to heal and, extremely rarely, may leave a noticeable permanent scar.

- **Scarring**
  Although very rare, permanent scarring may occur. Usually when scarring occurs it is in the form of a flat and white lesion on the skin (hypotrophic). However, it can be large and red (hypertrophic) or large and extend beyond the margins of the injury itself (keloid). Subsequent aesthetic treatments may be required to improve the appearance of the scar.

- **Pigment Changes**

Flash N' Go™ targets the hair shaft, in particular the pigmented cells in the hair follicle and the hair follicle itself. Nevertheless there is risk of temporary hyperpigmentation (increased pigment or brown discoloration) or hypopigmentation (whitening) to the surrounding skin. This risk of changes in skin pigmentation is higher for people with darker skin tones.
Usually discoloration or changes to skin pigment are temporary and permanent hyperpigmentation or hypopigmentation rarely occur.

- **Excessive Redness and Swelling**
  In rare cases treated skin may become very red and swollen. This is more common in sensitive areas of the body. The redness and swelling should subside within 2 to 7 days and should be treated with frequent applications of ice. Gentle cleansing is OK, but one should avoid exposure to sun.

- **Infection**
  Infection of the skin is exceedingly rare but is still a possible risk following a skin burn or wound caused by Flash N' Go™.

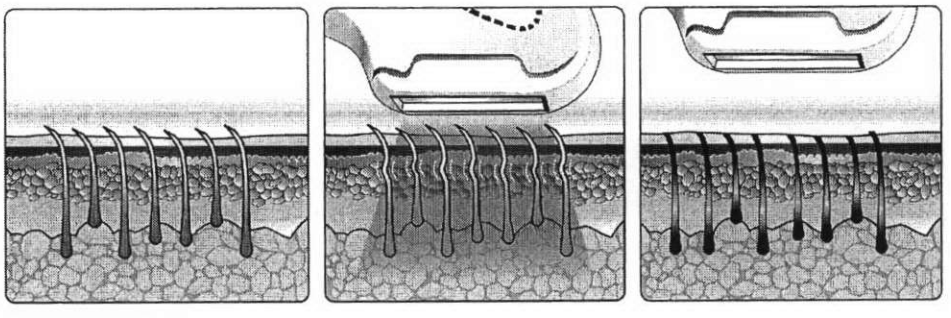
- **Bruising**
  Very rarely, use of Flash N' Go™ may cause blue-purple bruising that can last 5 to 10 days. As the bruising fades, there may be a rust-brown discoloration of the skin (hyperpigmentation) that can be permanent.

3. Long Term Hair Removal the Flash N' Go™ Way

Flash N' Go™ is a personal light-based device for long-term hair removal. The process of laser and light-based hair removal is well known and established. It has been proven in clinical use around the world for over 15 years as a safe and effective way to achieve long-term hair reduction.

3.1. How does light remove hair?

Light-based hair removal is based on the theory of selective photothermolysis in which optical energy is used to disable hair growth. In order to achieve such thermal effect the hair shaft needs to selectively absorb light energy and transform it into heat. This selectivity is achieved when optical energy that is delivered to the tissue is mostly absorbed by hair shaft pigment, while the skin and the surrounding tissue stays cool. Melanin is the pigment in the hair shaft that is responsible for the absorption of the light, which generates the heat that eventually disables hair growth. Therefore the more melanin present in the hair (i.e. the darker the hair) the more light that can be absorbed and the more effective light can be at removing hair.

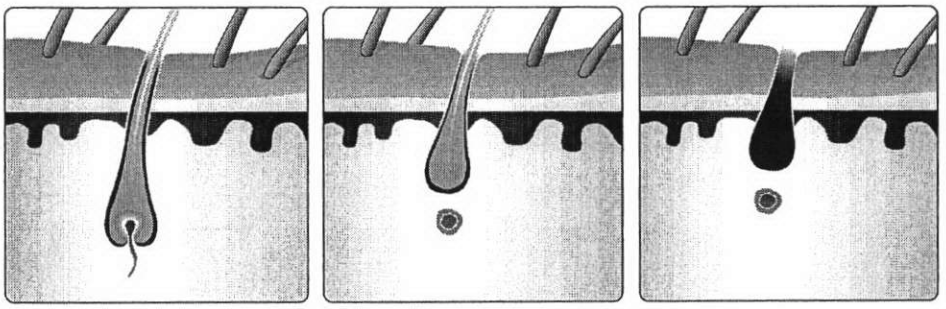


Before Flash N' Go™ Application **During Flash N' Go™ Pulse** **After Flash N' Go™ Application**

3.2. How does the hair growth cycle impact light-based hair removal?

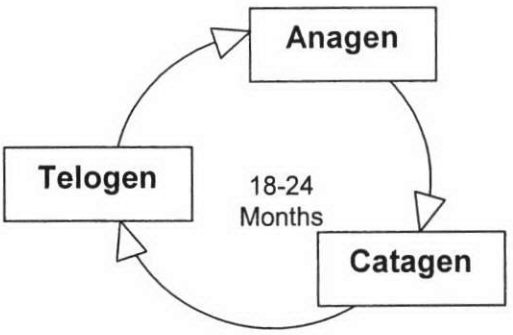
Every hair in our body goes through the three phases of the hair growth cycle: Anagen, Catagen and Telogen. These phases have an important impact on how the process of light-based hair removal works.

Anagen is the hair growth phase while Catagen and Telogen, both are resting phases.



Anagen–Growth phase **Catagen–Resting phase** **Telogen–Resting phase**

The time it takes to complete a full hair growth cycle varies from person to person and the location of the hair on the body, but is typically 18-24 months. At any given moment the majority of the hair follicles in any skin area are in the resting phases. These resting hairs cannot be affected by Flash N' Go™. However, hairs in the growing Anagen phase will respond to Flash N' Go™ applications. It is important to understand that it may take a full hair growth cycle to realize complete hair removal results with Flash N' Go™.



3.3. What is different about Home Pulsed Light™ technology in Flash N' Go™?

Flash N' Go™ utilizes the patent pending Home Pulsed Light™ technology (HPL™) developed by the scientists at Home Skinovations exclusively for safe and effective removal of unwanted hair at home. The technology allows for Flash N' Go™ to be small, portable and easy to operate compared to other similar systems. And like other light and laser systems HPL™ uses light energy to target melanin pigment in the hair.

3.4. Plan your Flash N' Go™ hair removal for best results

A typical full hair growth cycle may take 18-24 months. During this time multiple Flash N' Go™ sessions may be required in order to achieve long term hair removal.

The efficiency of hair removal varies from person to person according to body area, hair color, and how Flash N' Go™ is used.

Typical Flash N' Go™ hair removal plan during a full hair growth cycle:

- The first **3-4 hair removal sessions** with Flash N' Go™ will be approximately **two weeks apart**.
- Hair removal **sessions 5-7** with Flash N' Go™ will be approximately **four weeks apart**.
- After that you will typically use Flash N' Go™ again **from time to time** if and when needed, until long-term results are achieved.

Typical maintenance with Flash N' Go™ after achieving long-term hair removal:

Due to hormonal or other physiological changes dormant hair follicles may become active. Maintenance hair removal sessions with Flash N' Go™ may be required from time to time.

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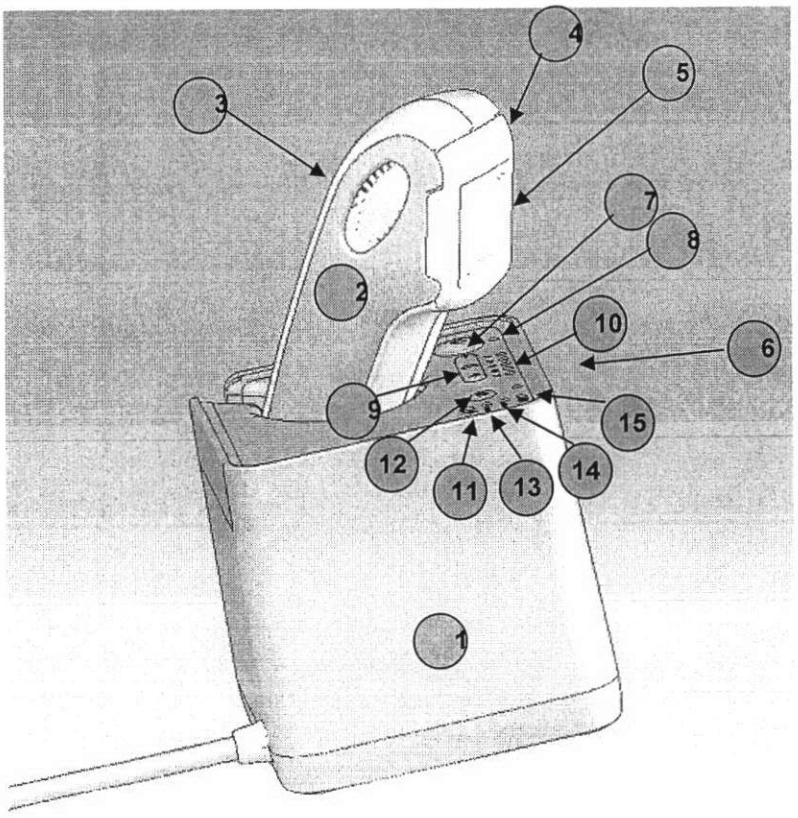
4. First Steps with Flash N' Go™

4.1. Flash N' Go™ device description

Your Flash N' Go™ consists of a ***BASE UNIT*** and an ***APPLICATOR.***

On the ***BASE UNIT*** you can find the Flash N' Go™ ***CONTROL PANEL*** including ***POWER ON/OFF SWITCH*** and ***POWER INDICATOR LIGHT***, the ***ENERGY LEVEL SETTING BUTTONS*** and ***ENERGY LEVEL INDICATOR LIGHTS,*** the ***AUDIO ON/OFF SWITCH, READY INDICATOR, SYSTEM WARNING INDICATOR LIGHT*** and ***CARTRIDGE 90%*** and ***100% USAGE INDICATOR LIGHTS.***

On the Flash N' Go™ ***APPLICATOR*** you can find the ***PULSE BUTTON***. The ***DISPOSABLE LAMP CARTRIDGE*** is located at the ***APPLICATOR TIP.***



1. BASE UNIT
2. APPLICATOR
3. PULSE BUTTON
4. DISPOSABLE LAMP CARTRIDGE
5. *SKIN COLOR SENSOR*
6. CONTROL PANEL
7. POWER ON/OFF SWITCH
8. POWER INDICATOR LIGHT
9. ENERGY LEVEL SETTING BUTTONS
10. ENERGY LEVEL INDICATOR LIGHTS
11. READY INDICATOR LIGHT
12. AUDIO ON/OFF SWITCH
13. CARTRIDGE 90% USAGE INDICATOR LIGHT
14. CARTRIDGE 100% USAGE INDICATOR LIGHT
15. SYSTEM WARNING INDICATOR LIGHT

4.2. Package contents

Upon opening the Flash N' Go™ package, you will find the following parts:

- Flash N' Go™ *BASE UNIT* and *APPLICATOR*
- An AC cord
- A second *DISPOSABLE LAMP CARTRIDGE*
- This User's Manual and a Quick Start Guide leaflet
- An Instructional DVD

4.3. Flash N' Go™ Setup

1. Remove Flash N' Go™ *BASE UNIT*, *APPLICATOR* and other components from box.
2. Insert the *APPLICATOR* into its cradle in the Flash N' Go™ *BASE UNIT*.
3. Verify that the *DISPOSABLE LAMP CARTRIDGE* is inserted correctly into the *APPLICATOR*.
4. Plug the power cord into the Flash N' Go™ *BASE UNIT* socket.
5. Plug the other end of the power cord into an electrical outlet.

Your Flash N' Go™ is now ready to start.

4.4. Treating with Flash N' Go™ for the first time

The skin should be **shaved**, **clean**, **dry** and **free** of any powders, antiperspirants or deodorants.

1. Press the *POWER ON/OFF SWITCH* to turn Flash N' Go™ on.
2. Shortly after pressing the *POWER ON/OFF SWITCH*, the *READY INDICATOR LIGHT* will turn on, accompanied by a beep, to indicate that your Flash N' Go™ is ready for its first pulse.
3. Your Flash N' Go™ is automatically set to the lowest energy level.

Energy Level

Energy level determines the intensity of the Flash N' Go™ light pulse delivered to your skin, from the lowest level (-) to the highest level (+). Corresponding *INDICATOR LIGHTS* on the *CONTROL PANEL* represent the increases in energy. As energy level increases, so does hair removal results as well as the risk of possible side effects and complications.

Always start your first Flash N' Go™ hair removal session at the lowest energy setting.

If you experience little or no discomfort during and after the hair removal session using the lowest energy level, raise the energy level by one *INDICATOR LIGHT* at the next session, and so on for each subsequent session.

Do not raise the energy level if you experience abnormal discomfort during or after treating with Flash N' Go™ (See section 2.6 - "Possible Side Effects").
Do not raise the energy level during hair removal session even if you experience no discomfort. Discomfort may also appear some time after the session.

Whenever Flash N' Go™ is turned on its energy level will automatically be reset to the lowest energy level. Only one *ENERGY LEVEL INDICATOR LIGHT* will be on.

To set the energy level, press the *ENERGY LEVEL SETTING BUTTONS* using "-" or "+" to respectively decrease or increase the energy level. The number of *ENERGY LEVEL INDICATOR LIGHTS* will coincide with the change in energy level.

For your safety, when using Flash N' Go™ for the very first time, the system is automatically set to deliver the first 50 pulses at the lowest energy level, and the

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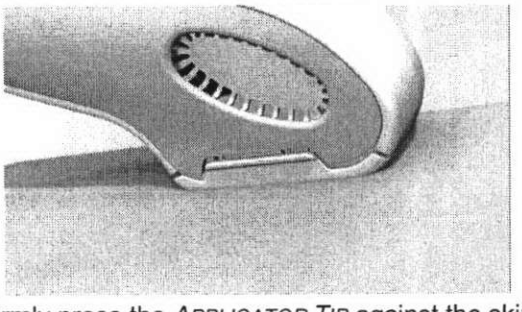
next 200 pulses at up to level 3.

To cancel these safety settings press and hold the "+" and "-" *ENERGY LEVEL SETTING BUTTONS* simultaneously until you hear 2 consecutive "beep" sounds.
To **restore** these safety settings press and hold the "+" and "-" *ENERGY LEVEL SETTING BUTTONS* simultaneously until you hear 3 consecutive "beep" sounds.

4. Using firm pressure, apply the *APPLICATOR TIP* to the skin. Be sure that the skin area you are about to treat is spread evenly and smoothly, and that the *APPLICATOR TIP* is in full contact with the skin.



Firmly press the *APPLICATOR TIP* against the skin

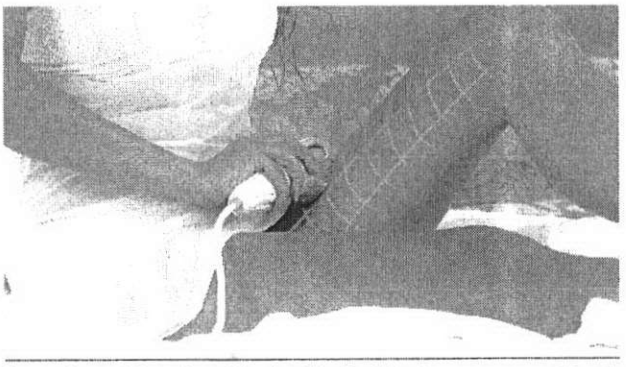
5. Press the *PULSE BUTTON* to emit a pulse. The *SKIN COLOR SENSOR* will briefly measure your skin tone. If the measured skin tone is light enough, the first pulse will immediately be emitted. You will see a flash of light and hear a subtle pop-like sound. This is a normal light pulse of Flash N' Go™.
   If the measured skin tone is too dark for Flash N' Go application, the 5 green energy level LED will blink for 3 seconds. *SKIN TONE SENSOR* will measure again in your next attempt to emit a pulse.

Note: As this intense pulse may be disturbing to your eyes, it is recommended to close them shortly before pressing the *PULSE BUTTON*.

6. After emitting a pulse, remove the *APPLICATOR TIP* from the skin. Flash N' Go™ will recharge for the next pulse.
7. After approx. 3.5 seconds the *READY INDICATOR LIGHT* will turn on again, accompanied by a beep, to indicate that your Flash N' Go™ is ready for another pulse.
8. Continue to administer pulses until the desired skin area is fully treated.

Covering skin areas

Flash N' Go™ pulses should be administered in rows, starting at one end of each row and progressing sequentially towards the other end. This technique allows better control of skin coverage, and helps you avoid treating the same area more than once or overlapping skin areas



When applied to the skin, the Flash N' Go™ *APPLICATOR TIP* is designed to create temporary pressure marks on the treated area. These visible marks can be used for proper positioning of the next pulse.

Try to avoid overlapping pulses!

Do not treat the same area of skin more than once per hair removal session!

If your skin blisters or burns, STOP USE IMMEDIATELY!

4.5. What to Expect when treating with Flash N' Go™?

For many people, using Flash N' Go™ may be their first experience with a light-based device designed for home use. Flash N' Go™ is simple to use, and hair removal sessions go by quickly. During a Flash N' Go™ session it is **normal** to experience and feel:

- **A Flash of Light** – The bright light of Flash N' Go™ will not harm the eyes when applied to non-facial sites, and special eye-protection is not needed when using Flash N' Go™.
- **A Fan Noise** – The cooling fan in Flash N' Go™ makes noise similar to a hairdryer. This is normal.
- **A Pop Sound with Each Pulse** – When a pulse of HPL™ light is activated, it is normal to hear a subtle pop sound simultaneously with the flash of light.
- **Moderate Pressure of the *APPLICATOR*** – This is necessary and helpful for placement of adjacent pulses of light, and is part of the unique safety feature of Flash N' Go™.
- **A Sensation of Warmth and Tingling** – During each pulse of light it is normal to feel a mild sensation of warmth and tingling from the light energy. Remember it is important to always use low energy settings for initial hair removal sessions. You may feel some warmth for up to an hour after your Flash N' Go™ session.
- **Some Mild Red or Pink Color** – During and just after your Flash N' Go™ session it is not uncommon to see some very mild, pink-like color of the skin. This is usually most noticeable around the hairs themselves. However if you see full redness of the skin, blistering or burns stop use of Flash N' Go™ immediately.

4.6. After treating with Flash N' Go™

- When Flash N' Go™ session has been completed turn Flash N' Go™ off by pressing the *POWER ON/OFF SWITCH*. (Be sure to remember the last energy level setting you used, as it will not be restored when turning Flash N' Go™ on again.)
- Unplug the power cord from the electrical outlet.
- After each hair removal session it is recommended that you clean your Flash N' Go™ device, especially the *APPLICATOR TIP* (See section 5.1: "Cleaning Flash N' Go™").
- After cleaning, it is recommended to store your Flash N' Go™ device in its original box, and keep it away from water.

Skin care following hair removal session

Do not expose treated areas of skin to the sun. Be sure to carefully protect the treated skin with sunscreen, throughout the hair removal period and for at least 2 weeks following the last Flash N' Go™ session.

Side effects and complications

Some patients may experience pigmentation changes resulting from treating with Flash N' Go™. These effects, if they occur, are generally mild and transient.

In case you experience any complication (See section 2.6 Possible Side Effects using Flash N' Go™) ***please contact your physician immediately.***

5. Maintenance of Flash N' Go™

5.1. Cleaning Flash N' Go™

After each hair removal session, it is recommended to clean your Flash N' Go™ device, and especially the *APPLICATOR TIP*.

- Unplug Flash N' Go™ before cleaning.
- Use a dry, clean cloth and a specially formulated cleaner for electronic equipment to gently wipe Flash N' Go™ surface, and especially the *APPLICATOR TIP*.
  Never immerse Flash N' Go™ or any of its parts in water!

5.2. Replacing the LAMP CARTRIDGE

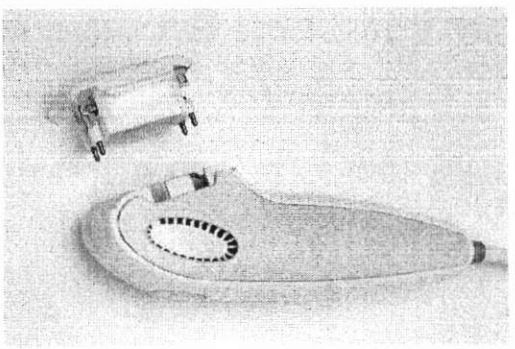
The Flash N' Go™ *DISPOSABLE LAMP CARTRIDGE* can fire 750 light pulses that would typically cover 2 Legs, Arms, Under arms, and Bikini line. Pulse intensity is determined only according to the energy level setting of the device. There is no decrease of energy during the usable lifetime of the *LAMP CARTRIDGE*.

When a *DISPOSABLE LAMP CARTRIDGE* has reached 90% of its possible lifetime the *CARTRIDGE 90% USAGE INDICATOR LIGHT* on the *CONTROL PANEL* will be activated, indicating that the *DISPOSABLE LAMP CARTRIDGE* should soon be replaced.

Once all 750 pulses in a *DISPOSABLE LAMP CARTRIDGE* have been used the *CARTRIDGE 100% USAGE INDICATOR LIGHT* will be activated, indicating that further pulses can not be emitted.

In order to continue the hair removal session, it will now be necessary to replace the *DISPOSABLE LAMP CARTRIDGE*.

Note: A *DISPOSABLE LAMP CARTRIDGE* should also be replaced if large spots appear inside it or if its *LENS* is broken.



To replace a *DISPOSABLE LAMP CARTRIDGE*:

1. Press the *POWER ON/OFF SWITCH* to turn Flash N' Go™ off.
2. Unplug the power cord from the electrical outlet.
3. Grasp the used *DISPOSABLE LAMP CARTRIDGE* on both sides, pull it out of the

socket and discard with normal trash.

4. Unwrap a new *DISPOSABLE LAMP CARTRIDGE*.
5. Line up the holes in the *APPLICATOR* socket with the metal and plastic hinges in the new *DISPOSABLE LAMP CARTRIDGE,* and push it gently into place.

If correctly installed, the *DISPOSABLE LAMP CARTRIDGE* will spring back when pushed in and released.

6. Troubleshooting

6.1. *"My Flash N' Go™ does not start."*

- Make sure the power cord is properly connected to the Flash N' Go™ device.
- Make sure the power cord is plugged into an electrical outlet on the wall.

6.2. *"A light pulse is not emitted when I press the PULSE SWITCH."*

- Make sure that you have good contact with the skin and that the *APPLICATOR TIP* is evenly and firmly pressed to the skin. For your safety, the *PULSE BUTTON* will activate a pulse only if the *APPLICATOR TIP* is firmly pressed against the skin.
- Skin color sensor stopped the light pulse, your skin may be to dark for using the Flash N' Go. Try to apply Flash N' Go™ again.
- Check the *CARTRIDGE 100% USAGE INDICATOR*. If it is on, disconnect Flash N' Go™ and replace the *DISPOSABLE LAMP CARTRIDGE*.
- Make sure that the *READY INDICATOR* is on.
    a. If within 10 seconds the *READY INDICATOR* remains off turn Flash N' Go™ off and back on by pressing the *POWER ON/OFF SWITCH* twice.
    b. If the problem persists, contact your local Flash N' Go™ Customer Service Center.
- Check the *SYSTEM WARNING INDICATOR LIGHT*.
    c. If the light is on turn Flash N' Go™ off and back on by pressing the *POWER ON/OFF SWITCH* twice.
    d. If the problem persists, contact your local Flash N' Go™ Customer Service Center.

If these problems persist, contact your local Flash N' Go™ Customer Service Center.

Do not attempt to open or repair your Flash N' Go™ device. Only authorized Flash N' Go™ repair centers are permitted to perform repairs.

Opening Flash N' Go™ may expose you to dangerous electrical components and to pulsed light energy, either of which may cause serious bodily damage and/or permanent eye injury.

Trying to open Flash N' Go™ may also damage the device and will void your warranty.

Please contact Flash N' Go™ Customer Service if you have a broken or damaged device in need or repair.

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7. Customer Service

For more information about Flash N' Go™ please enter www.silkn.com.

If your Flash N' Go™ is broken, damaged, in need of repair, or for any other Flash N' Go™ user assistance, please contact Flash N' Go™ Customer Service:
1-877-DO-SILKN / 1-877-367-4556
contact@silkn.com

8. Frequently Asked Questions

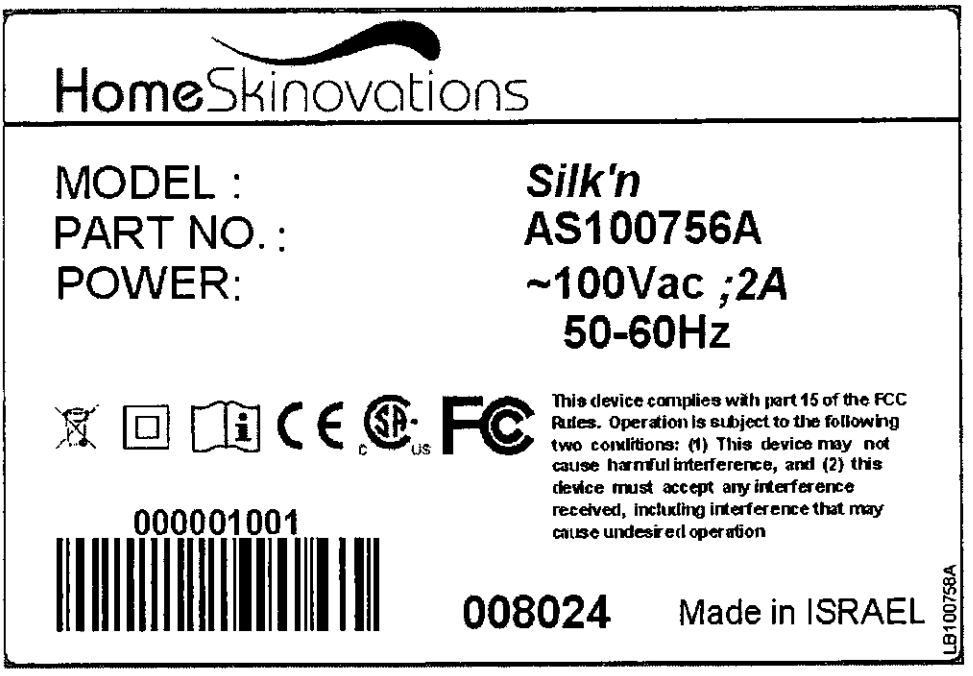
1. ***Does Flash N' Go™ really work?***
   Yes. In clinical trials held by physicians, Flash N' Go™ was proven to safely achieve long-term hair removal results.
2. ***Where on my body can I use Flash N' Go™?***
   The Flash N' Go™ device has been designed for body hair removal anywhere below the neck. The most common areas treated with Flash N' Go™ are: legs, underarms, arms and bikini line. It is not recommended to use Flash N' Go™ on the face. Flash N' Go™ is not suitable for everyone. We recommend that you read all the Flash N' Go™ warnings and contraindications in this User's Manual.
3. ***How long does a Flash N' Go™ treatment session take?***
   The time can vary depending on the area of the body treated. A full leg can take up to 30 minutes, or two underarms could take 10 minutes. Because Flash N' Go™ runs on regular electric power it can be used for as long as needed to complete a full hair removal session of the desired body part(s).
4. ***Is Flash N' Go™ safe?***
   Flash N' Go™ has been designed with your safety in mind, and tested and approved by top dermatologists and plastic surgeons to meet their safety standards for a home-use device. But like any skin product or electronic device, one must use according to the operating instructions and user precautions.
5. ***Will Flash N' Go™ hurt?***
   When used properly most users of Flash N' Go™ report feeling a slight sensation of heat at the time of the pulse of light. Users with thicker and darker hairs may feel slightly more discomfort, but this discomfort subsides once the hair removal session is completed. For your convenience Flash N' Go™ has five setting levels that can be used according to your sensitivity.
6. ***How often should I use Flash N' Go™?***
   Hair removal sessions with Flash N' Go™ should be spaced every two weeks for the first three to four sessions. After that hair removal sessions should be done if hairs have grown back, until the desired results are achieved.
7. ***Is Flash N' Go™ effective on white, grey or blonde hairs?***
   Flash N' Go™ works best on darker hair types, or hair that contains more melanin. Melanin is the pigment that gives hair and skin their color, and will absorb light energy. Black and dark brown respond the best, although brown and light brown hairs will also respond but typically require more hair removal sessions. Red may show some response. White, grey or blonde hairs usually don't respond to Flash N' Go™ though some users have noted results after multiple hair removal sessions.
8. ***Can I use Flash N' Go™ on brown or black skin***
   Do not use Flash N' Go™ on naturally dark skin complexion! Flash N' Go™ removes unwanted hair by selectively addressing hair pigment. Varied quantities of pigment also exist in the surrounding tissue of skin. The quantity of pigment in a particular person's skin, which is manifested by their skin complexion, determines the degree of risk they are exposed to using Flash N' Go™. Treating dark skin with Flash N' Go™ can result in adverse effects such as burns, blisters, and skin color changes (hyper- or hypo-pigmentation).
9. ***When will I see results from Flash N' Go™?***
   As with any light-based or laser hair removal device, results are not immediate, and in fact you may not think anything happened at all. Hair may sometimes appear to be growing back after a hair removal session, but typically after two weeks many of these hairs will simply fall out. Additionally hairs grow in three different stages and only hairs in an active growth stage will be affected by Flash N' Go™. This is one of the main reasons that multiple sessions are required to achieve the desired result.

10. ***Can a man use Flash N' Go™?***
    Though designed exclusively for women, Flash N' Go™ may be suitable for use by men. However, hairs on men, typically those on the chest, will require more hair removal sessions than that of women to get the desired results. As with women, using Flash N' Go™ on men's facial hair such as beard and mustache, is not recommended.
11. ***Why is my hair growing, even though I treated it a week ago?***
    It is quite common for hair to appear as if it is still growing up to two weeks after a hair removal session with Flash N' Go™. This process is known as "ejection" and at around two-weeks you'll see that these hairs simply fall out or slide out with a slight tug. (We don't however recommend pulling on the hairs – just let them come out naturally.) It is also possible that some hairs, due to missed application or different stages of growth, were not affected by Flash N' Go™. These hairs will be treated in follow-up sessions, and hence the reason multiple hair removal sessions are needed to get the best result with Flash N' Go™.
12. ***I've heard that some hairs grow back lighter and finer after light based hair removal?***
    This phenomenon is well documented amongst aestheticians and doctors using light and laser devices for hair removal. It is possible that some hairs will grow back lighter and finer after hair removal with Flash N' Go™. Usually these hairs are a fraction of what was originally there, and continued use may have a desirable effect on them.
13. ***Why can't I treat myself if I have an "active" suntan?***
    Do not use Flash N' Go™ on tanned skin or after sun exposure! Tanned skin and particularly following sun exposure, contains large quantities of the pigment Melanin. This applies to all skin types and complexions, including those which don't seem to tan quickly. The presence of large quantities of Melanin exposes the skin to higher risk of adverse effects when using Flash N' Go™ including burns, blisters, and skin color changes (hyper- or hypo-pigmentation).
14. ***Is long-term use of Flash N' Go™ dangerous for my skin?***
    The use of light and laser energy in aesthetic medicine has been well documented for over 15 years in professional peer-reviewed journals, and by well respected institutions like the Mayo Clinic. These journals and institutions have not reported any side-effects or damage from long-term use of light and laser device.
15. **Can I use Flash N' Go™ to remove my chin hair or elsewhere on my face?**
    It is not recommended to use Flash N' Go™ on the face or neck. Unlike body hair, most of women's potential facial hair remains inactive and hidden, while only a fraction of it grows and surfaces. Exposing facial hair to the light pulses of Flash N' Go™ may remove apparent hair but simultaneously stimulate unwanted growth of hidden hair. In addition, using Flash N' Go™ to remove facial hair may cause serious eye injury.
16. ***How long should I wait to treat with Flash N' Go™ after unprotected exposure to the sun?***
    One should wait 4 weeks before using Flash N' Go™ after unprotected exposure to the sun. However, if there is ever any uncertainty about sun exposure please contact your physician or Home Skinovations customer support.
17. ***Should I do anything before using Flash N' Go™?***
    Before any Flash N' Go™ session it is important to avoid sun exposure on the treated area for at least four weeks. A high level UV Sun Screen (SPF 50+) will help, as will clothing covering the treated area. The area to be treated should also be cleaned with mild soap and water, and the hairs shaved down to skin level.
18. ***How should I care for the treatment area after using Flash N' Go™?***
    The area treated with Flash N' Go™ can be cleaned and maintained with standard skin care products. Special care must be taken to avoid unprotected sun exposure. Strong sunscreens (50+ SPF) and covering clothing are suitable for protection from the sun.
19. ***Should I pull the hairs out after treatment?***
    No, let the hairs gradually fall out on their own. This may take up to 2 weeks.

9. Specifications

Spot size	2cm x 3cm [6cm^2]
Speed	1 pulse every 3.5 second: 1.7 cm^2/sec
Technology	New Home Pulsed Light™
Max Energy Level	Max 5J/cm^2
Wavelength	475-1200nm
Charging time / Power source	Continuous operation
Electrical requirements	100-240VAC, 2A
Time needed to treat lower legs	30 minutes
Operation and Safety	*SKIN COLOR SENSOR* seamlessly ensures use only on appropriate skin types. Safety sensor Tip enables self-trigger for maximum safety & control. Easy to use on all body parts.
package size	Height 9 inch, Width 9 inch, Depth 5.2 inch
System weight	4 pounds

10. Labeling



Class II equipment

Degree of protection against electric shock: type BF applied part

WEEE - Waste Electrical and Electronic Equipment

CE Mark

Follow operating instructions

This device comply with part 15 of the (FCC) Federal Communications Commission.

CSA Mark for USA and Canada

Degree of protection against ingress water: ordinary

This device is not suitable for use in the presence of flammable anesthetic mixture with air or with Oxygen or Nitrous Oxide.

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HomeSkinovations

EC Declaration of Conformity

We Home Skinovations Ltd. declare under our sole responsibility that the home Skin treatment products

Brand Name:	***Home Skinovations***
Model Name:	***Flash N' Go, Disposable Lamp Cartridge***
Models Number	**AS100001E,AS100674B,AS100756A**

are fully in conformity with the essential requirements of Council Directive 89/336/EEC and 73/23/EEC amended by Directives 93/68/EEC.

This declaration is based on the full compliance of the products with the following European standards:

EMC:	**EN 61000-3-2:2000; (A2:2005),** **EN 61000-3-3:1995; (A1:2001)** **EN 55014-1:2000; (A2:2002),** **EN55014-2:1997; (A1:2001)**
Electrical safety:	**EN 60335-1:2002; (A1:2004; A12:2006),** **EN 60335-2-23:2003,** **EN 60335-2-27:2003**
Human Exposure to electromagnetic field radiated	**EN 50364:2001**

Manufacturer:

Home Skinovations Ltd.
Apolo Building, Shaar Yokneam,
POB 533, Yokneam 20692, ISRAEL
Tel: +972-4-9097470
Fax: +972-4-9097471

Authorized Representative:

Home Skinovations GMBH
Dr. Kurt Huber Str. 6
D-82031 Grünwald, GERMANY
Tel. +49-89-64919530
Fax +49-89-64919531

Signed:

Gabi Lavi
General Manager
Yokneam, February 4, 2008

Signed:

Dr. Amir Waldman
VP Regulatory & Clinical Affairs
Yokneam, February 4, 2008

For Information: On the basis of this declaration, these products and packaging will bear the following mark:

CE

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Flash N' Go™ is a **physician recommended** and innovative light-based device for hair removal in the **privacy of your home**. **Safe**, **easy to use** and **cost effective**, Flash N' Go™ achieves **marked clinical results** while offering personal convenience.

Flash N' Go™ utilizes the highly sophisticated and new **Home Pulsed Light™** (**HPL™**) technology developed by **Home Skinovations Ltd.**

Home Skinovations Ltd.
Apolo Building.
Soltam Industrial Zone.
Yokneam, 20692, Israel

Flash N' Go - Risk Analysis Report

DO1008941

Approved By	Name	Signature	Date
[redacted]	(b) (4)		

Home Skinovations Ltd.
Apolo Building.
Soltam Industrial Zone.
Yokneam, 20692, Israel

Revisions

Rev.	Description	Approval	Signature	Date
[redacted]				

Home Skinovations Ltd.
Apolo Building.
Soltam Industrial Zone.
Yokneam, 20692, Israel

Contents

Home Skinovations Ltd.
Apolo Building.
Soltam Industrial Zone.
Yokneam, 20692, Israel

1 Introduction

1.1 Purpose

This document is used to evaluate the risk associated with the *Flash N' Go* system.

1.2 Scope

This Hazard Analysis report applies to the Flash N' Go system.

1.3 Overview

This document describes the safety hazards associated with the Flash N' Go. It also describes the possible consequences of these hazards, their probability of occurrence, the Risk Level, how they will be mitigated and how and where that mitigation will be implemented.

1.4 Applicable Standards

ISO14971: Dec 2000
IEC 60601-1:1998
EN 60601-1-4

1.5 Product Short Description

The Flash N' Go is intended to be used for home use hair removal applications. It's based on Optical radiation.

1.6 Core team

Dr. Amir Waldman	VP QA & Reguationn
Gabi Lavi	General. Manager
Emil	Software Engineer
Suhair Francis-Najjar	Software Consultants

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2 Risk Method

Levels of Risk:

Rating	Risk Level Definitions
Negligible	Nuisance only / Cosmetic in nature / User Inconvenience / Will not cause personal injury or herm
Minor	Loss of efficacy but patient safety not compromised / Will not cause personal injury or harm
Moderate	Non-functional or poor functional performance of device requiring additional medical intervention to compensate /Injury to patient or user requiring no or minor medical intervention to compensate
Major	Incapacitating / Serious injury or death

Methods of Control:

Level	Methods of control
1	Inherent safe design
2	Manufacturing control
3	Adequate USER information

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Risk levels:

	Negligible(1)	Minor(2)	Moderate(3)	Major (4)
Adequate USER information (3)	IV	III	II	I
Manufacturing control (2)	IV	III	III	II
Inherent safe design (1)	IV	IV	IV	III

RISK IV: Acceptable Risk
RISK III: Medium risk
RISK II: High Risk.
RISK I: Very High Risk, Intolerable risk

Mitigation Strategy (methods of Control):

	Mitigation Strategy	Description
(1)	Inherent Safety by Design	This strategy includes system functionality and features that have been especially incorporated to alleviate safety hazards.
(2)	Manufacturing Control, ATP, Preventive Maintenance	This includes protective measures in the device itself/ in the manufacturing process, and testing
(3)	Information needed for	This includes the provision of adequate user information, training, and labeling

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3 Risk Analysis

3.1 Chemical Hazards

Cause Of the Hazard		Level of Risk	Method of Control	Risk Level	Risk Reduction Method	New Level of Risk	New Risk Level	V&V
3.1.1	Hazard due to the presence of dangerous gases.	*Moderate*	(1)(3)	IV	No gases are used, or generated during normal operation	*Minor*	IV	
3.1.2	Hazard due to the presence of dangerous liquids.	*Moderate*	(1)(3)	IV	The only liquid is sealed in approved electrical capacitors	*Minor*	IV	
3.1.3	Hazards of Implosion and Explosion (Electrolytic Capacitors)	*Moderate*	(1)	II	The Electrolytic Capacitors are the only components thought to be at risk of exploding. The Flash N' Go enclosure is believed to be stronger than needed to contain any ejected parts	*Negligible*	IV	
3.1.4	Hazard due to the use of solid materials	*Moderate*	(1)	II	All solid materials such as metals, plastics, terminal strips, PCB etc. are common materials are proven safe by long use or approved by UL (U94-0) No materials known to generate dangerous vapours or gases when heated or burned.	*Negligible*	IV	

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3.2 Mechanical Hazards

Cause Of the Hazard		Level of Risk	Method of Control	Risk Level	Risk Reduction Method	New Level of Risk	New Risk Level	V&V
3.2.1	Sharp edge	*Minor*	(1)	III	Mechanical hazards have been avoided and minimized by construction and good engineering practice and testing according to EN60601-1.	*Negligible*	IV	
3.2.2	Accidental mechanical damage	*Minor*		III		*Minor*	III	
3.2.3	Moving parts (The only used moving part are Fans)	*Minor*	(1)(3)		Fan is protected with grid. User not allowed opening covers.	*Negligible*	IV	
3.2.4	Vibration	*Minor*	(1)	III	Vibration absorbed by mounts.	*Negligible*	IV	
3.2.5	Mechanical shock	*Minor*	(1)	III	The unit complies with EN60601-1 Standard Clause 24 requirements	*Negligible*	IV	

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3.3 Fire Hazards

Cause Of the Hazard		Level of Risk	Method of Control	Risk Level	Risk Reduction Method	New Level of Risk	New Risk Level	V&V
3.3.1	Electrical Fire Hazards	*Moderate*	(1)(2)	II	Electrical fire hazards are avoided and minimized by construction and type testing according EN60601-1, and good engineering practice such as: Proper selection fuses, thermal fuses, type and wires size (UL listed). Operating all electrical components within their ratings. Protection of wires from sharp edges. All electrical components (IC, Capacitors, Transformers, resistor, etc) were choosing so it operates below its rated (Temperature, Current, Voltage, etc). To verify this Home Skinovations engineers has selected the components that are hot, and tested them with thermocouple during testing of design verification.	*Minor*	III	
3.3.2	Ignition of thermo-plastics	*Moderate*	(1)(2)	II	All thermo-plastic materials used in unit have the adequate flame protection according to UL94	*Minor*	III	

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Cause Of the Hazard		Level of Risk	Method of Control	Risk Level	Risk Reduction Method	New Level of Risk	New Risk Level	V&V
3.3.3	Ignition of Transformer Windings	*Moderate*	(1)	II	Use of a thermal switch in the transformer	*Minor*	III	
3.3.4	Other Fire Hazards, Working beam (inside the applicator)	*Moderate*	(1)	II	If something flammable intrudes into the air paths of the working beam, it could be ignited. The probability for if to happen is very small because of two reasons: 1) The air paths is very narrow, 2) The air paths is covered by plastic parts and it unlikely that something will intrudes into the air paths. Never the less if something can be ignited it's the parts are self-extinguishing.	*Minor*	III	
3.3.5	Fires when the device is not in use	*Moderate*	(1)(3)	IV	The user manual instruct the user to shut down the system when it not in used, and to unplug the line cord, in this position it is believed to be impossible for fire to start in the Flash N' Go, if the Flash N' Go is plugged in but the switch is off, it's unlikely that fire can be start.	*Minor*	IV	

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3.4 Environmental Hazards

Cause Of the Hazard		Level of Risk	Method of Control	Risk Level	Risk Reduction Method	New Level of Risk	New Risk Level	V&V
3.4.1	Storage or operation outside prescribed environmental conditions	*Minor*	(3)	IV	System to be used in home under normal room environmental condition	*Negligible*	IV	
3.4.2	Contamination due to waste procedure and/or disposal	*Minor*	(3)	IV	Cleaning procedure are defined in the User Manual prior to using the system	*Negligible*	IV	
3.4.3	Inadequate supply of power Restriction of cooling	*Minor*	(1)(2)	III	Self test and status poling detects power instability	*Negligible*	IV	
3.4.4	Incompatibility with other devices (by radiation and conducting lines)	*Minor*	(1)	III	Tested for compatibility with RFI interference, Tested were done per EN 60601-1-2	*Negligible*	IV	

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3.5 Biological Hazard

Cause Of the Hazard		Level of Risk	Method of Control	Risk Level	Risk Reduction Method	New Level of Risk	New Risk Level	V&V
3.5.1	Bio-burden/ contamination (applicator parts)	*Moderate*	(1)	II	The parts in contact with the patient comply with bio-compatibility requirements of EN 30993-1 Standard	*Negligible*	IV	
3.5.2	Bio incompatibility (and Inability to maintain hygienic safety)	*Moderate*	(1)(3)	IV		*Negligible*	IV	
3.5.3	toxicity	*Moderate*	(1)	II	The parts in contact with the user comply with bio-compatibility requirements of EN 30993-1 Standard	*Negligible*	IV	
3.5.4	allergenicity	*Moderate*	(1)	II	No metal parts are in contact with the user	*Negligible*	IV	
3.5.5	(Cross) Infection	*Moderate*	(1)(3)	IV		*Moderated*	IV	

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3.6 Electrical Hazards

Cause Of the Hazard		Level of Risk	Method of Control	Risk Level	Risk Reduction Method	New Level of Risk	New Risk Level	V&V
3.6.1	Electrical Shock Hazards in normal use.	*Major*	(1)(2)	I	Shock hazards are avoided and minimized by construction and production testing in accordance with EN60601-1, good engineering and good manufacturing practices.	*Minor*	III	
3.6.2	Unstable electrical supply	*Minor*	(1)	III	Self-test is done after power electronics is initiated. Power on does not turned on automatically, system is turned on in Stand By mode Pooling of electrical parameters every 100[ms]	*Negligible*	IV	
3.6.3	Heat due electrical short	*Minor*	(1)	III	See "*Electrical Fire Hazards*"	*Negligible*	IV	
3.6.4	Mechanical force causing electrical short	*Minor*	(1)	III	Electrical short by mechanical force are avoided and minimized by construction and production testing in accordance with EN60601-1, good engineering and good manufacturing practices	*Negligible*	IV	
3.6.5	Electrostatic phenomena (Electrostatic charge build-up)	*Minor*	(1)	III	Flash N' Go is complies with electrostatic discharge requirements of EN 60601-1-2 Standard	*Negligible*	IV	

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3.7 Electromagnetic Hazards

Cause Of the Hazard		Level of Risk	Method of Control	Risk Level	Risk Reduction Method	New Level of Risk	New Risk Level	V&V
3.7.1	Emission s of electromagnetic interference	*Moderate*	(1)	II	The Flash N' Go is designed, built and tested to conform to: 1) EN 60601-1-2 (EN55011 Conducted) 2) EN 60601-1-2 (EN55011 Radiated) 3) CFR 47 Part 15 Class B	*Minor*	III	
3.7.2	Susceptibility to electromagnetic interference	*Moderate*	(1)	II	The Flash N' Go is designed, built and tested to conform to: 4) EN 61000-4-2 (ESD) 5) EN 61000-4-4 (Radiated Susceptibility) 6) EN 61000-4-4 (Electrical fast Transients) 7) EN 61000-4-5 (Surge) 8) EN 61000-4-5 (Conducted RF) 9) EN 61000-4-8 (Power frequency Magnetic Field) 10) EN 61000-4-11 (Voltage dips and interrupts)	*Minor*	III	
3.7.3	Human exposure to electromagnetic fields radiated	*Moderate*	(1)	II	The Flash N' Go is designed, built and tested to conform to: EN 50364:2001	*Minor*	III	

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3.8 Software Hazards

Cause Of the Hazard		Level of Risk	Method of Control	Risk Level	Risk Reduction Method	New Level of Risk	New Risk Level	V&V
3.8.1	Firmware Code corruption (total code corruption).	*Minor*	(1)	III	MCU load firmware software; but watchdog reset the MCU.	*Minor*	III	SW V&V 9.4.1
3.8.2	Firmware Code corruption (errors in a few bytes)	*Minor*	(1)	III	MCU load firmware but software checks CRC and error led turn on.	*Minor*	III	SW V&V 9.2.1, 9.2.2
3.8.3	Omission – the system produce no flow at a time when one would be expected	*Minor*	(1)	III	Hardware watchdog expires, the watchdog de-energizes the system.	*Minor*	III	SW V&V 9.4.4
3.8.4	Commission – the system produces a flow when a perfect system would not have	*Minor*	(1)	III	Watchdog uses logical program flow monitoring, the watchdog de-energizes the system.	*Minor*	III	SW V&V 9.4.4
3.8.5	The software fire pulses before attachment to the skin	*Moderate*	(1)	IV	Hardware control pulse activation only when three conditions are met: 1. HP push button. 2. Cartridge switch is pressed. 3. A software pulse is enabled.	*Minor*	IV	SW V&V 9.4.2
3.8.6	Buttons are not functioning	*Negligible*	(1)	IV	Design reviews ; and production test	*Negligible*	IV	
3.8.7	Error in downloading the software	*Minor*	(1)	III	Verification test in production	*Minor*	III	SW V&V 9.1.5

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Cause Of the Hazard		Level of Risk	Method of Control	Risk Level	Risk Reduction Method	New Level of Risk	New Risk Level	V&V
3.8.8	Software failure in Monitoring the HW status	*Minor*	(1)	III	Continuous monitoring of the correct behaviour of the hardware, by high rate scanning the signals of all the sensors; detection of errors as soon as they occur and shutting down the system.	*Minor*	III	SW V&V 9.3.1, 9.3.2, 9.3.3
3.8.9	User Confusion on the status of the system	*Minor*	(1)	III	Error indication shall have explanation in the operation manual.	*Minor*	III	Operation manual
3.8.10	Software does not indicate if the Tip was replaced during treatment.	*Minor*	(1),(3)	IV	Software routinely displays indication if Tip is disconnected Tip removal is forbidden during system power on.	*Minor*	IV	SW V&V 9.4.3
3.8.11	Late – a flow is produced after it should	*Minor*	(1)	III	Hardware watchdog expires, the watchdog de-energizes the system.	*Minor*	III	Watchdog
3.8.12	Value (d) – Reading data with error from RFID Tag	*Minor*	(1)	III	CRC protocol and checksum to check communication error	*Minor*	III	SW V&V 9.1.6
3.8.13	Value (u) – a flow contains a value that is incorrect, but in a way which the recipient cannot detect.	*Minor*	(1)	III	Code review for error handling strategy in software.	*Minor*	III	Code review

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3.9 System Malfunction Hazards

Cause Of the Hazard		Level of Risk	Method of Control	Risk Level	Risk Reduction Method	New Level of Risk	New Risk Level	V&V
3.9.1	Power delivery is not as displayed: a. Damage of light source. b. Line voltage problems, c. Software fault.	*Moderate*	(1)(2)	III		*Moderate*	III	
3.9.2	Optical power is higher by 20% of nominal.	*Moderate*	(1)(2)	III	Capacitor voltage are monitored by the system, and if fault are detected the system stops charger power supply	*Minor*	III	
3.9.3	Acoustic pressure	*Moderate*	(1)	II	Closed console design, rubber buttons for vibrating modules.	*Negligible*	IV	
3.9.4	Inadequate performance characteristics for the intended use	*Moderate*	(1)(3)	II	Applicator lifetime is limited.	*Moderate*	IV	
3.9.5	System is not working as desired (Specifications do not meet the application.).	*Moderate*	(3)	IV	Specification is validated with the clinical data as an on going process.	*Minor*	IV	
3.9.6	Loss of mechanical integrity (poor mechanical design or lack of QC)	*Minor*	(1)	II	The machine was designed by competent mechanical engineers and manufactured by high quality shops. QC checks each module and the whole machine in the critical points of the manufacturing process.	*Negligible*	IV	

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Cause Of the Hazard		Level of Risk	Method of Control	Risk Level	Risk Reduction Method	New Level of Risk	New Risk Level	V&V
3.9.7	Inadequate packaging	*Minor*	(1)	III	Packaging procedures were written and controlled by the QC personnel. All packaging are specially treated and disinfected against termites, fungus and fire according to the Israeli standard IS262	*Negligible*	IV	
3.9.8	Liquid spillage	*Minor*	(1)	III	The upper side of the system is sealed to prevent spillage of liquids. The enclosure provides a protection of IP20 according to IEC529, degrees of protection provided by enclosures	*Negligible*	IV	
3.9.9	Skin color malfunction	*Moderate*	(1)	IV	Ladling including user manual and instructional DVD are clearly stating that the device should be used on light skin completion, (skin color chart is included)	*Minor*	IV	

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3.10 Clinical Hazards

Cause Of the Hazard		Level of Risk	Method of Control	Risk Level	Risk Reduction Method	New Level of Risk	New Risk Level	V&V
3.10.1	Tissue Hazards	*Moderate*	(1)(3)	II	Flash N' Go is intended to be used non-invasively, as hair removal. The hazard of cutting major blood vessels, or major nerves, or perforating bowel witch are present for cutting instruments, are not presents. [redacted] (b) (4)	*Minor*	IV	

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Cause Of the Hazard		Level of Risk	Method of Control	Risk Level	Risk Reduction Method	New Level of Risk	New Risk Level	V&V
					c. The Flash N' Go emits a visual warning that it is in Ready mode. [redacted] (b) (4)			
3.10.2	Eye Hazards (Aiming directly into the eye)	*Major*	(1)(3)	II		*Minor*	III	
3.10.3	Excessive or Insufficient Output Power from pulsed light applicator	*Moderate*	(1)(3)	II	Each applicator is assembled by imbedded power meter. the light output power is adjusted to be ±10% of the correct value.	*Minor*	IV	
3.10.4	Treatment is unintentionally interrupted (Unstable electrical supply)	*Moderate*	(1)(3)	II	Self-test is done after power electronics is initiated. Power does not turned on automatically, system is turned on in Stand By mode [redacted] (b) (4)	*Minor*	IV	

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3.11 Other Hazards

Cause Of the Hazard		Level of Risk	Method of Control	Risk Level	Risk Reduction Method	New Level of Risk	New Risk Level	V&V
3.11.1	Human-Machine Interface	*Moderate*	(3)	IV	Considerable thought has been devoted to making the interface natural and simple. The read-out device is a set of LEDs, with good brightness. In addition, an audible emission tone alerts the user of an emission in process. All Human-machine requirements of EN60601-1 have been met.	*Negligible*	IV	

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3.12 Specific Hazards of EN60601-1, Sub-Clause 52.2; 52.4.1 prohibits

Cause Of the Hazard		Level of Risk	Method of Control	Risk Level	Risk Reduction Method	New Level of Risk	New Risk Level	V&V
3.12.1	Emission of flames, molten metal, and poisonous or ignitable gas	*Moderate*	(1)(2)	III	The Flash N' Go will not do this, These matters have been addressed in ***Fire Hazards***, and they were the subjects of various abnormal tests during the EN60601-1 Safety Tests.	*Negligible*	IV	
3.12.2	Excessive deformation of covers	*Moderate*	(1)(2)	III	The strength of the Flash N' Go covers was evaluated by the ITL engineers for EN60601-1	*Negligible*	IV	
3.12.3	Excessive temperatures	*Moderate*	(1)(2)	III	The temperature was measured during Normal and Abnormal tests made by Home Skinovations and ITL inspecting engineer for the EN60601-1 safety tests.	*Negligible*	IV	
3.12.4	System is used not according inclusion criteria	*Moderate*	(3)	II	Intended use is described in user manual..	*Negligible*		
3.12.5	System is used in contraindicated cases	*Major*	(3)	I	Contraindications are described in user manual.	*Moderate*	IV	
3.12.6	Wrong treatment parameters are used	*Moderate*	(3)	II	Energy produced by the system is limited and can not exceed the preset significantly. User manual describe the treatment procedure to avoid significant damage	*Negligible*	IV	

4 Information supplied by the manufacturer

Hazard Event	Risk Reduction Method	Risk Level
Manufacturer not identified	Manufacturer Identified in the User Manual	*Negligible*
Lack of safety information in the instructions manual	Safety instructions are defined in the User Manual	*Negligible*
Use of symbols non harmonized	Use of symbol according to EN980	*Negligible*
Intended use not obvious for user	Intended use is defined in the User Manual	*Negligible*
Lack of check-list following installation	User Manual	*Negligible*
Lack of preventive maintenance instructions to keep the device safe	Preventive maintenance instruction are defined in the User Manual	*Negligible*

4.1 Contraindications

- Pacemaker or internal defibrillator or metallic implants in the treatment area.
- Current or History of cancer, especially skin cancer, or pre-malignant moles.
- Pregnancy and nursing.
- Any active infection in the treatment area, such as sores, psoriasis, eczema and rash as well as very dry and fragile skin.
- Diseases which may be stimulated by light at the wavelengths used, such as AIDS and HIV, or use of immunosuppressive medications.
- Poorly controlled endocrine disorders such as diabetes.
- History of bleeding coagulopathies, or use of anticoagulants.
- Excessively tanned skin from sun, sun-beds or tanning creams.

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4.2 Precautions: (treat with caution if patient has any of following risk factors)

- Use of medication and herbs known to induce photosensitivity to light exposure at the wavelengths used, such as Isotretinoin (Accutane)., tetracyclines, or St. John's Wort.
- Medical Conditions that impair healing.
- In case of preventive Aspirin, treat with care or stop a few days before and after treatment.

4.3 Possible Side Effects

- Pain
- Skin redness (Erythema)
- Damage to natural skin texture (crust, blister, burn)
- Change of pigmentation (hyper- and hypo-pigmentation)
- Scarring
- Excessive Swelling (Edema)
- Fragile skin
- Bruising

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5 Risk Estimation of Hazards Associated to the Flash N' Go

Through hazard analysis, we determined that electric shock and eye/tissue burns and system used in contraindicated cases are the three significant hazards present with the Flash N' Go. Neither of the hazards identified has been determined to be unacceptably high.

The risk of electric shock hazard is considered to be LOW. It is mostly limited to Service personnel because the only hazardous live parts are contained within the Flash N' Go console; witch would require removal of the side cover while the system is turned on at the Key Switch.

The risks of eye/tissue burn hazards are considered to be MODERATE because the user could be harmed by such a hazard if they do not take adequate measures to protect against said hazards. Adequate measures are defined in the User Manual Safety section.

5.1 CONCLUSION

No known hazards have been identified. The hazard prevention features does not limit the product efficiency and defined specification

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Flash N' Go - Software System Test Plan and Results

DO1008951

	Role	Name	Signature	Date
(b) (4)	[redacted]			

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Revisions

Rev.	Page	Description	Approval	Date
(b) (4)				

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Table of Contents

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1. Introduction

1.1 Purpose

A system test plan for the Flash N' Goshould support the following:

To detail the activities required to prepare for and conduct the system test.

To communicate to all responsible parties the tasks that they are to perform and schedule to be followed in performing the tasks.

To define the source of information used to prepare the plan.

To define the test tools and environment needed to conduct the system test

1.2 Scope

This test plan covers a full systems test of the Flash N' GoDevice. This includes operate and user procedures, as well as programs. In addition to comprehensively testing firmware functionality, hardware interfaces, performance, load test, download procedure, integrity, recovery and usability.

Ideal system testing presumes that all components have been previously, successfully, integrated.

1.3 Definitions

Term	Definition
STP	System Test Plan

1.4 References

Document	Revision	Location
Software requirement specification		
Software verification and validation plan		
Software test strategy		

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2. Test Plan Type & Attribute Refinement

2.1 Test Plan Type

This test plan is functional, stress, performance, safety, testing used to verify the Flash N' Go SW release.

2.2 Level

System Level

2.3 Objective

The objectives of the system test plan are:
1. Functional testing: testing based on a comparison of a component's actual behavior with its specified behavior without regard to the component's implementation.
2. Performance testing: tests that explore the consistency of a system with its performance objectives such as response time or throughput
3. Stress testing - testing in which a system is subjected to unrealistically harsh inputs or load with inadequate resources with the intention of breaking it
4. Recovery testing - testing that explores how well the system meets it objectives in recovering from programming errors, hardware failures, and data errors.
5. Safety testing – aims at showing that an unsafe state cannot be reached although that state could be invalid (traceable to hazard analysis document)
6. Regression testing – it assumed that several iterations of the system test will be done in order to test program modifications made during the system period. A regression test will be performed for each new version of the system to detect unexpected impact resulting from program modifications. The regression test will be done by running all of the tests on a new version that were run on the previous version and then comparing the results.

2.4 Approach

Testing methods used to achieve the objective of this test plan:
Black box technique: Data-Flow testing.
Black box technique: Domain testing & boundary value analysis.

The developer will assist in developing the test cases; this will help ensure that the tests represent the production use of the system.

2.5 Readiness Criteria

The Unit and Integration testing shall have been passed and completed successfully.
The software is stable (means a reliable software with no major issues).
The SW Packages under test have been collected under a system test build in configuration management.
All test Hardware and environments must be in place, and free for system test use.
ALL Human resources must be assigned and in place

2.6 Input Work Products

The input work product used for the system test plan is the:

Software requirements specification documents – refer to DHF.
Software Detailed Design documents – refer to DHF.
Software System Verification and Validation Plan – refer to DHF

2.7 Test Environment

The tests require a system with the software fully installed and the options (hardware and software) available.

2.7.1 Hardware

Flash N' Go device consists of a Base unit and an Applicator.

2.7.2 Software

Software version: 1.0.0

2.7.3 Security

NA.

2.7.4 Tools

2.7.4.1 Error reporting Tools

An Excel file named: bugsreport.xls.

2.7.4.2 Publications

NA.

2.8 Roles & Responsibilities

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2.8.1 Test Plan generation

Functional test plan is generated by the system engineer.

Test Procedures for safety related components shall be defined by a system engineer and a team regulatory& quality member.

2.8.2 Test Execution

Test Procedures shall be executed by a team member not directly involved in the design and implementation of the component.

2.8.2.1 Test Phases and Cycles

There will be two main stages of testing for the Software during system testing:

System Testing

Acceptance Testing

2.8.2.1.1 System Testing Cycles

The main thrust of the approach is to intensively test the SW in two releases, thus raising approximately 80% of errors in this period. With the majority of these errors fixed, standard and/or frequently used actions will be tested to prove individual elements and total system processing. Regression testing of outstanding errors will be performed on an ongoing basis.

When all errors (which potentially impact overall processing) are fixed, an additional set of test cases are processed to ensure the system works in an integrated manner. It is intended that Release Flash N' GoSW 1.2.0 be the final proving of the system as a single application. There should be no severity 1 or 2 errors outstanding prior to the start of Release.

Revision number	Creation date	System Test Cycle
Flash N' Go1.0.0	Jul 27; 2008	First Cycle
Flash N' Go1.0.0	Jul 27; 2008	Second Cycle

2.8.2.1.2 Acceptance Testing Cycles

The main thrust of the approach is to test the usability of the device after approval of the system test.

2.8.2.2 Software Delivery

During System Test the release of new versions of the software will be co-ordinates between the Development SW engineer and the Development System engineer. However, unless it concerns a fix to a very serious error, new versions should only be released when agreed targets have been reached (i.e. the next version contains fixes to X or more numbers of bugs).

Notes:

It is intended that 80% of the functionality will have been tested in full prior to the Phase 3 Release.
All the functionality must be present in the Phase 2 Release. No previously undelivered functionality will be accepted for testing after Phase 2.

2.9 Formal Reviewing

There will be several formal review points before and during system test, including the review of this document. This is a vital element in achieving a quality product.

- Design Documentation - Requirements Specification & Functional Specification
- System Test Plans & Test conditions.
- System Test results
- Post system test review.

3. Test Items

All items that makeup the software Flash N' Go device will be tested during the system test. The versions to be tested will be downloaded to the device

4. Features to be tested

- Resets and Initialization
- Set energy level
- Pulse handler
- Monitor the Capacitor s voltage.
- Hardware checks.

5. Features not to be tested

NA

6. Tester Skills

The following staff is needed to carry out this testing project:

System engineer: he provides the overall management of the testing and technical testing expertise.

SW engineer: he transmits the system to be tested and responds to the system test Incident reports he does any program debugging that required. It also supplies the version control.

All the staff must be trained to perform the test.

7. Safety Issues

Safety issues have been analyzed. This test plan takes into account this analyze and all the tests associated to a safety issue are noted "safety related" in the title refer to risk analysis management file.

8. Test Termination Criteria

This test plan terminates normally if the execution of each test procedures results in a passed condition. The test plan may be terminated abnormally under the following conditions:

- Upon reaching a "Fail" condition on for any test case within a test procedure, the tester may terminate the test procedure.
- Upon reaching a failed condition in one test procedure, the tester may continue testing if the preconditions of subsequent test procedures can be satisfied. Otherwise, the tester may terminate execution of the test plan.

If the preconditions of a test procedure cannot be satisfied, the tester may proceed to execute subsequent test procedure as long as the preconditions of those procedures can be satisfied. Otherwise, the tester may terminate execution of the test plan."

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9. Test Procedures

9.1 Verify Interfaces

9.1.1 Verify User Interfaces

ID	*Action*	*Expected result*	*Test result*	*Comments and Recommendations*
General actions				
1	(b) (4)			
2				
3				
4				
5				

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9.1.2 Verify Self test

ID	Action	Expected result	Test result	Comments and Recommendations
1	Disconnect Power Supply Switch (disconnect R21)	-----	-----	
2	(b) (4) [redacted]			

9.1.3 Verify Polling

ID	Action	Expected result	Test result	Comments and Recommendations
1	Turn off the system and install new valid cartridge	-----	-----	
2	Turn on the system and set to energy level (1), wait for Ready Led to turn ON	-----	-----	
3	(b) (4) [redacted]			

(b) (4) [redacted]

ID	Action	Expected result	Test result	Comments and Recommendations
1	(b) (4) [redacted]			
2				

9.1.5 Verify firmware download process

ID	Action	Expected result	Test result	Comments and Recommendations
1	(b) (4)			
2				
3				
4				

(b) (4)

ID	Action	Expected result	Test result	Comments and Recommendations
1	(b) (4)			
2				

9.2 *Verify Functionality*

9.2.1 Verify system initialization

ID	Action	Expected result	Test result	Comments and Recommendations
1	(b) (4)			
2				

9.2.2 Verify system initialized with corrupted firmware

ID	Action	Expected result	Test result	Comments and Recommendations
1	(b) (4)			
2				

9.2.3 Verify system set energy level (general actions)

ID	Action	Expected result	Test result	Comments and Recommendations
	General actions			
1	(b) (4)			
2				
3				
4	(b) (4)			
5				
6				

9.2.4 Verify system set energy level (Treatment)

ID	*Action*	*Expected result*	*Test result*	*Comments and Recommendations*
	Treatment Mode			
1	(b) (4)			
2				
3				
4				
5				
6				
7				
8				
9				
10				

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ID	*Action*	*Expected result*	*Test result*	*Comments and Recommendations*
11	(b) (4) [redacted]			
12				
13				
14				
15				

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9.2.5 Verify system calibration energy level

ID	*Action*	*Expected result*	*Test result*	*Comments and Recommendations*
1	(b) (4)			
2				
3				
4				
5				
6				
7				
8				
9				

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10	(b) (4) [redacted]
11	
12	

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9.2.6 Verify new system level limitation

ID	Action	Expected result	Test result	Comments and Recommendations
1	(b) (4)			
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				

10	(b) (4)	
11		
12		

9.2.7 (b) (4)

ID	*Action*	*Expected result*	*Test result*	*Comments and Recommendations*
1	(b) (4)			
2				
3				
4				
5				
6				
3				
4				(b) (4)

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9.3 Verify System Recovery

9.3.1 (b) (4)

ID	Action	Expected result	Test result	Comments and Recommendations
1	(b) (4)			
2				

9.3.2 (b) (4)

ID	Action	Expected result	Test result	Comments and Recommendations
1	(b) (4)			
2				

9.3.3 (b) (4)

ID	Action	Expected result	Test result	Comments and Recommendations
1	(b) (4)			
2				

9.3.4 (b) (4)

ID	Action	Expected result	Test result	Comments and Recommendations
1	(b) (4)			
2				
3				

		apart		
4	(b) (4)			
5				
6				(b) (4)

9.3.5 (b) (4)

ID	*Action*	*Expected result*	*Test result*	*Comments and Recommendations*
1	(b) (4)			
2				
3				
4				

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9.3.6 Verify system ignores wrong energy level calibration value

ID	Action	Expected result	Test result	Comments and Recommendations
1	(b) (4)			
2				
3				
4				
5				
6				
7				
8				

i

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9.3.7 Verify system response to miss-matched color

ID	*Action*	*Expected result*	*Test result*	*Comments and Recommendations*
1	(b) (4)			
2				
3				
4				
5				
6				
5				
4				(b) (4)

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9.4 Verify Safety

9.4.1 (b) (4)

ID	Action	Expected result	Test result	Comments and Recommendations
1	(b) (4)			

9.4.2 (b) (4)

ID	Action	Expected result	Test result	Comments and Recommendations
1	(b) (4)			
2				
3				

9.4.3 (b) (4)

ID	Action	Expected result	Test result	Comments and Recommendations
1	(b) (4)			
2				
3				

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9.4.4 (b) (4)

ID	*Action*	*Expected result*	*Test result*	*Comments and Recommendations*
1	(b) (4)	-----	----	
2		(b) (4)	(b) (4)	

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10. Test Plan Results Summary

ID	*Action*	*Expected result*	*Test result*	*Comments and Recommendations*
1	(b) (4) [redacted]			

Tester Name: _____

Date: _____ Signature: _____

Comments: _____

Approved by: _____

Date: _____ Signature: _____

Comments: _____

Appendix 7 – Clinical Results

Background

(b) (4) [redacted]

(b) (4) [redacted] In this clinical study we demonstrated that the Flash N' Go is safe for all users. (b) (4) [redacted]

(b) (4) [redacted]

Name and Intended Use of Device

Device Name: Flash N' Go

Common: Pulsed Light Device

Intended Use: The Flash N' Go is intended for removal of unwanted hair.

Description of Experiment

Tests were carried out on (b) users with a variety of skin types, (b) (4) and on a variety of body locations. (b) (4) [redacted]

(b) (4) [redacted] No adverse effects were noted on all of the (b) users. (b) (4) [redacted]

(b) (4) [redacted]

Results

(b) (4) [redacted]

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(b) (4)

(b) (4)

(b) (4)

(b) (4)

Conclusion

The Flash N' Go device (b) (4) is safe for use on all skin colors. (b)

(b) (4)

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

PREMARKET NOTIFICATION TRUTHFUL AND ACCURACY STATMENT

(As required by 21 CFR 807.87(j))

I certify that in my capacity as VP of Regulatory Affairs of Home Skinovations Ltd., I believe, to the best of my knowledge that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

Amir Waldman

August 10, 2008

Dr. Amir Waldman

510(k) Number (if known)_____.

Device Name Flash N' Go

Indications For Use:

The Flash N' Go is an over the counter device intended for the removal of unwanted hair.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over The Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Performance & clinical data:

The device complies with the following U.S. Food and Drug Administration performance standards: 21CRF § 1040.10 & 1040.11. Clinical safety data was collected in a prospective safety study.

Substantial Equivalence:

The Flash N' Go system is substantial equivalent to its predicate devices. The data in this 510k submission demonstrate that the Flash N' Go system has identical output as the Silk'n, and shares the similar intended use as other predicate devices. Therefore is substantial equivalent to its predicate devices. Details are provided in chapter 3: Substantial equivalent of this submission.

Based upon an analysis of the overall performance characteristic for the device, Home Skinovations Ltd. believes that no significant differences exit. Therefore the Flash N' go should raise no new issues of safety or effectiveness.

August 10, 2008

Date

Dr. Amir Waldman,
VP Regulatory Affairs
Home Skiovations Ltd.

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Home SkinovationsLtd.
Flash N' Go

This summary of safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

Submitter's information

Name:	Home Skinovations Ltd.
Address:	Apolo building, POB 533, Yokneam 20692, Israel
Contact:	Dr. Amir Waldman VP Regulatory Affairs

Device information

Trade/Proprietary name:	Flash N' Go
Common/Usual name:	Light based hair removal device
Classification name:	Laser surgical instrument for use in general and plastic surgery and in dermatology (21CRF §878.4810)
Product code:	GEX

Predicate devices

- ABC hair removal system, (K060839)
  Palomar Medical Technologies Inc.
- Spectra hair removal laser system, (K053527).
  SpectraGenics, Inc.
- Silk'n, (K072906).
  Home Skinovations Ltd.

Intended use:

The Flash N' Go is intended for removal of unwanted hair.

Device Description:

The Flash N' Go hair removal system is composed of a base unit and hand held applicator. Details are provided in the chapter 1: Device description, of this submission.

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Karem S. Burney

Subject: 510(k) Number K103184

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☒ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		✓
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			✓
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓ ✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)			✓
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			✓
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			✓
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.*

Regulation Number	Class*	Product Code
878.4810	II	OHT

(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: _____ GSDB 11/10/10
(Branch Chief) (Branch Code) (Date)

Final Review: _____
(Division Director) (Date)

11/10/10

DEPARTMENT OF HEALTH AND HUMAN SERVICES **M E M O R A N D U M**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K103184

Date: November 9, 2010
To: The Record
From: Kareem S. Burney, M.S.

Office: ODE
Division: DSORD

510(k) Holder: Home Skinovations LTD
Device Name: Slilk'N Flash N Go
Contact: Amir Waldman
Phone: 972 547 404616 (Israel)
Fax:
Email:

I. Purpose and Submission Summary

The 510(k) holder would like to introduce the Silk'N Flash N Go into interstate commerce.

III. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement		X	
510(k) Summary or 510(k) Statement	X		
Standards Form			X

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?	X		

- The Flash N go hair removal system is pulsed light system composed of a base unit and hand help applicator.

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II. Indications for Use

Flash N Go is also intended for permanent reduction in hair regrowth defined as a long-term, stable reduction in hair counts following a treatment regime.

This device is for over the counter use.

III. Predicate Device Comparison

Flash N' Go (K082298)

TRIA Hair Removal System (K090820)

EpiLight and PhotoDem HR K991935

The sponsor has provided a substantial equivalence table. The Flash N Go for this device has a similar wavelength, energy as the Flash N Go (K082298) The wavelength is 475-1200nm and a energy of 5 J/cm2. The indication for K082298 is just for the removal of unwanted hair. **Because these devices are similar the sponsor should also provide the spot size and pulse repetition rate. This information is not in the submission.**

The TRIA has a wavelength of 810nm and energy of 20 J/cm2. The indication is intended for the adjunctive use with shaving fo rhair ermoval sustained with periodic treatments and for permanent reduction in hair regrowth defined as a long term stable reduction in hair counts following a treatment regime.

The EpiLight/PhotoDerm has a wavelength range of 645-1200nm and energy of 45 J/cm. The indication is for the removal of unwanted hair. To stable long-term or permanent hair reduction in skin types I – V through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as a long-term stable reduction in the number of hairs regrowing after a treatment regime.

IV. Labeling

The sponsor states that the only change to the labeling compared to previously cleared Flash N Go is the new indication for use.

The sponsor has made some changes to the instruction for use such as providing a device description, information about the package contents an disposable lamp cartridge. This information was in the instruction for use but the sponsor moved it up to the front of the instruction for use.

After reviewing the instruction for use for both the current submission and K082298's instruction for use. The instruction for use is the same as K082298. The sponsor will not have to provide usability study, label comprehension on this instruction for use. The sponsor will have to provide the box labeling.

However there are some inconsitencies with the labeling. On page 19 the sponsor states that the cleaning section is 5.1 when it is actually 11.1.

The sponsor put in the labeling that the clincial data is based on 1,3, and 18 month follow up data.

8

V. Sterilization/Shelf Life/Reuse

The sponsor states that the sterilization information is the same as the K082298. Here is the infomation from the K082298 submission:

Cleaning instructions have been included in the instruction for use. The cleaning instructions are as folows: " Unplug Flash N Go before cleaning. Use a dry clean cloth and specially formulated cleaner for electronic equipment to gently wipe Flash N Go surface and especially the Applicator tip. Never immerse Flash N G or any of its parts in water.

VI. Biocompatibility

The sponsor states that the biocompatibility information is the same as the K082298. Here is the infomation from the K082298 submission:

The aperture comes in contact with the patient. The materials that are in direct contact with the skin are identical to the Silk'N K072096. Sponsor has stated that parts in contact with the patient but needs to state whether this device complies the requirement of ISO 10993 or EN 30993-1.

VII. Software

The sponsor has staed that the software is the same as the predicate device K082298. The software is a moderate level of concern. Please refer to K082298 for information about the software.

Version:		
Level of Concern: Moderate		
	Yes	**No**
Software description:		
Device Hazard Analysis:		
Software Requirements Specifications:		
Architecture Design Chart:		
Design Specifications:		
Traceability Analysis/Matrix:		
Development:		
Verification & Validation Testing:		
Revision level history:		
Unresolved anomalies:		

VIII. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

The EC Declaration of Conformity showing that is in full compliance with the following standards have been provided: EN 61000-3-2:2000; EN 61000-3-3:1995; EN 55014-1:2000; EN 55014-2: 1997; EN 60335-1:2002; EN 60335-2-23:2003; EN 60335-2-27:2003; and EN 50364:2001

IX. Performance Testing – Bench

X. Performance Testing – Animal

XI. Performance Testing – Clinical

The sponsor stated that they carried out clinical trials to verify the safety and effectiveness of the Silk'N Flash and Go.

(b) (4)

The treatment test spot is as follows:

1) In the area to be treated hairs should be trimmed to 3/32 inch length, (1-2mm) or shaved 3 days prior to the treatment.
2) Clean the skin from trimmed haris.
3) Hold the applicator to ensure that the light output window is clean.
4) Switch on the system and set the energy level.
5) Place the Applicator on the treatment area and apply slight pressure. Press the trigger switch to emit light pulse.
6) Move the applicator to the next spot to ensure full coverage of the area to be treated.
7) Repeat the test spot procedure.for 3 pulses.
8) If side effects are noted after 15 minutes, reduce the energy level by one level to lower setting.
9) Transient Erythema and follicular redness are normal reactions as well as smell of burned hair.
10) If no side effects are noted after 15 minutes, complete the treatment to cover entire area to be treated.

Post Treatment Care:
Apply moisturizer after the treatment.
Use high factor sunscreen and protect the treated area from sunlight for at least 2 days after the treatment. Tanning after a treatment may cause hyper-pigmentation.

Repetitive Treatments:

(b) (4)

[redacted]

Complications:
If an unanticipated adverse event occurs at any time during or after the use of the system, the Investigator must report it to the sponsor. A serious adverse event or complication directly attributable to the use of the System will be reported to the Sponsor as soon as possible within twenty-four (24) hours or sooner.

Data Analysis:
Hair loss at each follow up session will be calculated as the ratio of the number of hairs after the treatment compared with the hair count prior to treatment. Hair count will be preformed by the investigator.

This is the protocol from K072906. The orginal submission for the Flash N' Go:

1. In the area to be treated, hairs should be trimmed to 3/32 inch length, (1-2 mm), or shaved 3 days prior to the treatment.
2. Clean the skin from the trimmed hairs.
3. Hold the applicator and ensure that the light output window is clean.
4. Switch on the system and set the energy level.
5. Place the Applicator on the treatment area and apply slight pressure. Press the trigger switch to emit light pulse.
6. Move the applicator to the next spot to ensure full coverage of the area to be treated.
7. Repeat the test spot procedure for 3 pulses.
8. If side effects are noted after 15.minutes, reduce the energy level by one level to lower setting.
9. Transient Erythema and follicular redness are normal reactions as well as smell of burned hairs.
10. If no side effects are noted after 15 minutes, complete the treatment to cover entire area to be treated.

Post Treatment Care:
Apply moisturizer after the treatment.
Use high factor sunscreen and protect the treated area from sunlight for at least 2 days after the treatment. Tanning after a treatment may cause hyper-pigmentation.

(b) (4)

[redacted]

Complications:

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If an unanticipated adverse event occurs at any time during or after the use of the system, the Investigator must report it to the sponsor. A serious adverse event or complication directly attributable to the use of the System will be reported to the Sponsor as soon as possible within twenty-four (24) hours or sooner.

Data Analysis:
Hair loss at each follow up session will be calculated as the ratio of the number of hairs after the treatment compared with the hair count prior to treatment. Hair count will be preformed by the investigator.

(b) (4)

[redacted]

The sponsor stated that the only adverse event was edema, peri follicular, edema and light erythama which were resolved in 60 minutes. No other side effects were noted by the sponsor.

(b) (4)

[redacted]

XII. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?			If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?			If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?			If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

Note: See http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

2. Explain why there is or is not a new effect or safety or effectiveness issue:

3. Describe the new technological characteristics:

4. Explain how new characteristics could or could not affect safety or effectiveness:

5. Explain how descriptive characteristics are not precise enough:

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

7. Explain why existing scientific methods can not be used:

8. Explain what performance data is needed:

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XIII. Deficiencies

XIV. Contact History

XV. Recommendation

I find no safety and effective issues with the changes presented in 510(k) K103184. Therefore, I find the proposed device to be substantially equivalent to the predicate.

(b) (4)

[redacted]

XII. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	✓		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?	✓		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?	✓	✓	If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?	✓		If **NO** = Request Data
9. Data Demonstrate Equivalence?	✓		Final Decision: SE

Note: See http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

2. Explain why there is or is not a new effect or safety or effectiveness issue:

3. Describe the new technological characteristics:

4. Explain how new characteristics could or could not affect safety or effectiveness:

5. Explain how descriptive characteristics are not precise enough:

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

7. Explain why existing scientific methods can not be used:

8. Explain what performance data is needed:

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XIII. Deficiencies

XIV. Contact History

XV. Recommendation

I find no safety and effective issues with the changes presented in 510(k) K103184. Therefore, I find the proposed device to be substantially equivalent to the predicate.

Regulation Number: 878.4810
Regulation Name: Laser Instrument, Surgical, Powered
Regulatory Class: II
Product Code: OHT

Kareem S. Burns
Reviewer

11/9/10
Date

Neil R. Ogden
Branch Chief

11/10/10
Date

Burney, Kareem

From: Amir Waldman [amirw@silkn.com]
Sent: Tuesday, November 09, 2010 8:40 AM
To: Burney, Kareem
Subject: RE: FDA review of Flash N Go (K103184)

The number of treatment in the current study was 6.
On the K082298/K072906 the number of treatment was 3.
Amir

From: Burney, Kareem [mailto:Kareem.Burney@fda.hhs.gov]
Sent: Tuesday, November 09, 2010 3:04 PM
To: 'Amir Waldman'
Subject: RE: FDA review of Flash N Go (K103184)

Amir,
I was looking at your clinical data and I have a question.What was the total number of treatments done in this study? Can you compare this to the total number of treatment done in the study for K082298/K072906? Thanks.

Kareem S. Burney , M.S.
Biomedical Engineer
Division of Surgical, Orthopedic and Restorative Devices
U.S. Food and Drug Administration
WO66-1439
10903 New Hampshire Ave
Silver Spring, MD 20993
Phone # (301)796-6388
E-mail:kareem.burney@fda.hhs.gov

From: Amir Waldman [mailto:amirw@silkn.com]
Sent: Monday, November 08, 2010 3:10 AM
To: Burney, Kareem
Subject: RE: FDA review of Flash N Go (K103184)

Chapter 2 on page 4 Flash N GO intended use changed to :

2. Flash N' Go™ Intended Use

Flash N' Go™ is intended for removal of unwanted hair. Flash N' Go™ is also intended to effect long term, or permanent hair reduction. Permanent hair reduction is defined as a long-term stable reduction in the number of hairs re-growing after a treatment regime.

Flash N' Go™ may be used to remove unwanted body hair. Ideal body areas for Flash N' Go™ use includes the underarms, bikini line, arms and legs.

(b) (4) [redacted]

(b) (4) [redacted]

Amir

From: Burney, Kareem [mailto:Kareem.Burney@fda.hhs.gov]
Sent: Friday, November 05, 2010 4:49 PM
To: 'Amir Waldman'
Subject: RE: FDA review of Flash N Go (K103184)

(b) (4) [redacted]

Kareem S. Burney , M.S.
Biomedical Engineer
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From: Amir Waldman [mailto:amirw@silkn.com]
Sent: Friday, November 05, 2010 1:39 AM
To: Burney, Kareem
Subject: RE: FDA review of Flash N Go (K103184)

Mr. Burney,

Attached is chapter 2 clinical information in a pdf format, is this OK or you prefer that I'll send printed color copy?
Sorry for not putting the detailed terms but here they are:

(b) (4) [redacted]

Amir

From: Burney, Kareem [mailto:Kareem.Burney@fda.hhs.gov]
Sent: Thursday, November 04, 2010 4:52 PM
To: 'Amir Waldman'
Subject: RE: FDA review of Flash N Go (K103184)

(b) (4) [redacted]

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From: Amir Waldman [mailto:amirw@silkn.com]
Sent: Wednesday, November 03, 2010 2:08 PM
To: Burney, Kareem
Subject: RE: FDA review of Flash N Go (K103184)

Yes,
(b) (4) [redacted]

Amir Waldman
Home Skinovations Ltd.

From: Burney, Kareem [mailto:Kareem.Burney@fda.hhs.gov]
Sent: Wednesday, November 03, 2010 7:59 PM
To: 'Amir Waldman'
Subject: RE: FDA review of Flash N Go (K103184)

(b) (4) [redacted]

Kareem S. Burney , M.S.
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From: Amir Waldman [mailto:amirw@silkn.com]
Sent: Wednesday, November 03, 2010 1:25 PM
To: Burney, Kareem
Subject: RE: FDA review of Flash N Go (K103184)

(b) (4) [redacted]

Amir

From: Burney, Kareem [mailto:Kareem.Burney@fda.hhs.gov]
Sent: Wednesday, November 03, 2010 6:52 PM
To: 'amirw@silkn.com'
Subject: FDA review of Flash N Go (K103184)

Amir,
I have done look at some of this submission and I have the following questions. Are the patient contact materials and sterilization information the same as K082298? What we mean by sterilization is whether there are sterilization information or the device can be cleaned like K082298.

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Standard Operating Procedures for 510(k) Summaries

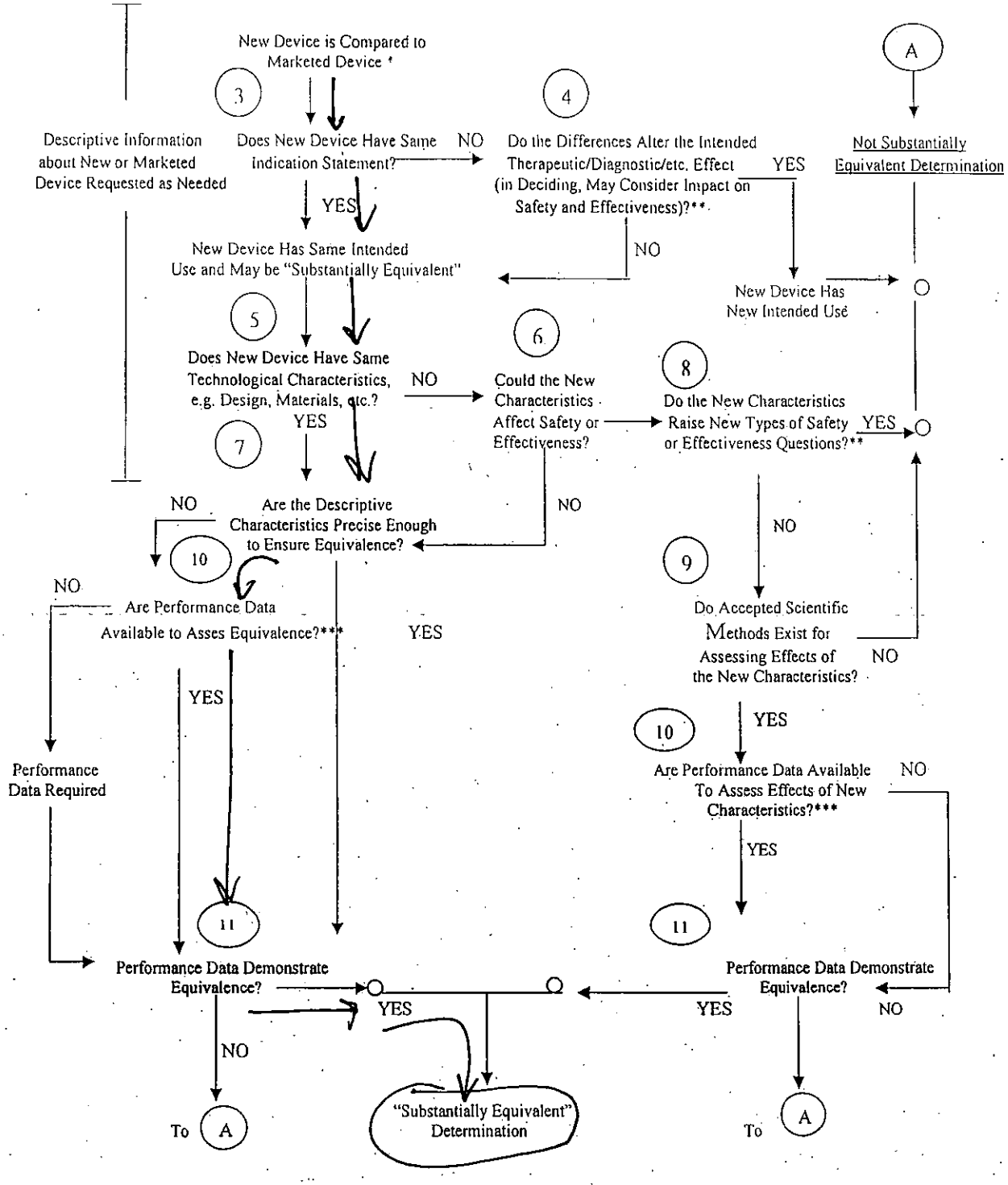
1) If a 510(k) submitter decides to submit a 510(k) summary, as per 21 CFR 807.87(h), they need to follow the content requirements as per 21 CFR 807.92.
2) If during the review of the 510(k), the submitter decides to switch to a 510(k) statement, as per 21 CFR 807.87(h), they may do so while the 510(k) is under review. They must follow 21 CFR 807.93 for a 510(k) statement.
3) The 510(k) summary is written by the 510(k) submitter, but FDA will agree with the content prior to clearing any 510(k).
4) The 510(k) summary needs to agree with the final classification decision of FDA, e.g., the predicate classification needs to match the FDA classification decision. The submitter may need to revise the summary while the 510(k) is under review. In other words, the 510(k) summary will need to reflect the predicate(s) and decision made by FDA. The submitter will then need to revise the summary while the 510(k) is under review.
5) The IFU provided in the 510(k) summary needs to match the IFU statement that is determined to be substantially equivalent
6) The 510(k) summary should reflect all the testing done by the 510(k) submitter to demonstrate substantial equivalence. This may include testing that FDA did/would not require to demonstrate substantial equivalence, but would include all testing that FDA does/would require to demonstrate substantial equivalence.
7) If the 510(k) summary is deficient, the deficiency(ies) may be put in an AI letter or handled through interactive review.
8) The 510(k) may not be found to be substantially equivalent until the 510(k) summary meets the regulatory requirements of 21 CFR 807.92.
9) If, after interactions, a 510(k) submitter does not revise the 510(k) summary as requested and we disagree with their rationale, the 510(k) may be found not substantially equivalent for lack of required data/information.
10) Neither the 510(k) summary, nor 510(k) statement, are needed if the decision is other than SE.
11) The 510(k) summary will go on FDA's website approximately the 5th of the month following any SE decision.

510(k) **SUM**MARY REQUIREMENTS CHECKLIST
21 CFR 807.92

All 510(k) summaries shall contain the following information:		Y	N	N/A
1	The submitter's name, address, telephone number, a contact person, and the	✓		

	date the summary was prepared			
2	The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name	✓		
3	An identification of the legally marketed device(s) to which the submitter claims equivalence.	✓		
4	A description of the device that is the subject of the 510(k), including an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device (e.g., device design, material used, and physical properties)	✓		
5	A statement of the indications for use of the device that is the subject of the 510(k), including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is indicated. Or, if the indication statements are different from those of the legally marketed device(s) identified in paragraph (3) of this section, an explanation as to why the differences are not critical to the intended therapeutic, diagnostic, prosthetic, surgical or other use of the device, and why the differences do not affect the safety and effectiveness of the device when used as indicated.	✓		
6	If the device has the same technological characteristics (i.e., design, material, chemical composition, energy source, etc.) as the predicate device(s) identified in paragraph(3) of this section, a summary of the technological characteristics of the new device in comparison to those of the predicate device(s). Or, if the device has different technological characteristics from the predicate device(s), a summary of how the technological characteristics of the device compare to a legally marketed device(s) identified in paragraph (3) of this section.	✓		
510(k) summaries for those 510(k)s in which a determination of substantial equivalence is also based on an assessment of performance data shall contain the following information				
7	A brief discussion of the nonclinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence			
8	A summary discussion of the clinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety or effectiveness data obtained from the testing, with specific reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence. (There can not be any patient identifier information in the summary.)			
9	The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs at least as safely and effectively as the legally marketed device identified in paragraph(3) of this section.			

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



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