Test Report issued under the responsibility of:
签发试验报告的责任：

IEC 62366
Medical devices
Application of usability engineering to medical devices
医疗器械--医疗器械可用性工程学的应用

Report Reference No. ..... :
报告编号
Date of issue ..... :
签发日期
Total number of pages .....
总页数

CB Testing Laboratory ..... :
CB测试实验室
Address ..... :
地址

Applicant's name ..... :
申请人
Address ..... :
地址

Test specification:
测验规格
Standard ..... : IEC 62366:2007(ed.1)
标准
Test procedure ..... : CB
试验方法
Non-standard test method…….: N/A
非标测试方法

Test Report Form No. ..... : IEC62366A
测验报告编号
Test Report Form Originator ..... : TÜV Rheinland Product Safety GmbH
报告格式创始人
Master TRF ..... : Dated 2008-07
TRF硕士

Test item description ..... :

测试项目描述

Trade Mark ..... :

商标

Manufacturer ..... :

制造商

Model/Type reference ..... :

参考型号/类型

Ratings ..... :

评级

Testing procedure and testing location:

测试程序和测试位置：

☐ **CB Testing Laboratory**:

CB测试实验室

Testing location/ address ..... :

测试位置/地址

☐ **Associated CB Test Laboratory:**

相关的CB测试实验室

Testing location/ address ..... :

测试位置/地址

Tested by (name + signature) ..... :

由（姓名+签名）进行测试

Approved by (+ signature)..... :

批准（+签名）

☐ Testing procedure: TMP

检验程序：TMP

Tested by (name + signature) ..... :

由（姓名+签名）进行测试

Approved by (+ signature)..... :

批准（+签名）

Testing location/ address ..... :

测试位置/地址

☐ Testing procedure: WMT

测试程序：WMT

Tested by (name + signature) ..... :

由（姓名+签名）进行测试

Witnessed by (+ signature) ..... :

证明人（+签名）

Approved by (+ signature)..... :

批准（+签名）

Testing location/ address ..... :

测试位置/地址

☐ Testing procedure: SMT

测试程序：SMT

Tested by (name + signature) ..... :

由（姓名+签名）进行测试

Approved by (+ signature)..... :

证明人（+签名）

Supervised by (+ signature) ..... :

监督人（+签名）

Testing location/ address ..... :

测试位置/地址

☐ Testing procedure: RMT

测试程序：RMT

Tested by (name + signature) ..... :

由（姓名+签名）进行测试

Approved by (+ signature)..... :

证明人（+签名）

Supervised by (+ signature) ..... :

监督人（+签名）

Testing location/ address ..... :

测试位置/地址

Summary of testing: **总结**	
Tests performed (name of test and test clause): 测试的执行（测试名称以及条款）	**Testing location:** 测试位置
Summary of compliance with National Differences: 总结符合不同国家的差异性	

Copy of marking plate

标识板的副本

Test item particulars..... :
测试项目的细节

Classification of installation and use……:
安装和使用的分类

Supply connection ……:
电源连接

Context of Use ……...:
使用环境

Abbreviations used in the report:
报告中使用的缩写

- Usability Engineering:	UE	- Risk analysis:	RA
可用性工程	UE	风险分析	RA
- User interface:	UI	- Risk management:	RM
用户界面	UI	风险管理	RM
- Primary operating function:	POF		
主要操作功能	POF		

Possible test case verdicts:
可能性测试案例的决定（经过试验、检验或体验发表的决定）

- test case does not apply to the test object..... : N/A
不适用于测试对象的测试用例
- test object does meet the requirement ..... : Pass (P)
测试对象是否符合要求
- test object does not meet the requirement ..... : Fail (F)
测试对象不符合要求

Testing:
测试

Date of receipt of test items.....:
收到测试项目的日期

Date(s) of performance of tests.....:
性能测试的日期

General remarks:
结论

The test results presented in this report relate only to the object tested.

本报告中的测试结果仅涉及本次测试的对象

This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory.

未经开证测试实验室的书面批准,本报告不得转载。除了在全没有的签字的书面批准。

"(see Enclosure #)" refers to additional information appended to the report.

“（参见附件＃）”是指附加到报告中的其他信息。

"(see appended table)" refers to a table appended to the report.

“（见所附的表）”是指附加到报告中的表。

Throughout this report, a point (coma) is used as the decimal separator.

本报告中，一个点（昏迷）作为小数分隔符。

List of test equipment must be kept on file and available for review.

测试设备清单必须存档并供审查。

This Test Report contains the general safety requirements as related to the usability of Medical Equipment.

此报告包含相关可用性医疗设备的一般安全要求。

General product information:

产品常规信息

IEC 62366			
Clause	Requirement + Test	Result - Remark	Verdict
4	**GENERAL REQUIREMENTS** **一般要求（原理）**		
4.1	General Requirements 一般要求		
4.1.1	USABILITY ENGINEERING PROCESS 可用性工程过程		
	Has the MANUFACTURER established, documented and maintained a USABILITY ENGINEERING PROCESS to provide SAFETY for the PATIENT, USER and others related to USABILITY for the product? 制造商建立,记录并维护可用性工程过程,为病人提供安全、用户和其他与可用性相关的产品?		
	Does the PROCESS addressed USER INTERACtions with the MEDICAL DEVICE according to the ACCOMPANYING DOCUMENT including, but not limited to transport, storage, installation, operation, maintenance, repair and disposal? 该过程是否按照附属文档告知用户如何使用医疗设备。可用性工程过程包括，但不限于：运输，储存，安装，操作，维护，维修和处置？		
4.1.2	RESIDUAL RISK 剩余风险		
	Are RESIDUAL RISKS associated with USABILITY of the MEDICAL DEVICE presumed to be acceptable, unless there is OBJECTIVE EVIDENCE to the contrary and documented? 残余风险与医疗设备的可用性被认为是可以接受的,除非有相反的客观证据和记录?		
4.1.3	Information for SAFETY 信息安全		
	MANUFACTURER subject the information for safety used as a RISK CONTROL to the USABILITY ENGINEERING PROCESS (e.g., warnings or limitation of use in the ACCOMPANYING DOCUMENTS, marking, etc.) in the UE file and Accompanying documents. 安全信息用作风险控制措施，制造商应该把安全信息（如风险控制、警告或限制使用所附文件，问题文件中的标记等）和相应的文档归入可用性工程过程。		

IEC 62366			
Clause	Requirement + Test	Result - Remark	Verdict
	Disregarding such information for SAFETY is considered beyond any further reasonable means of RISK CONTROL 无视这些信息安全被认为是超越任何进一步的合理的风险控制手段。		
4.2	USABILITY ENGINEERING FILE 可用性工程文件		
	The results of the USABILITY ENGINEERING PROCESS are recorded in the USABILITY ENGINEERING FILE 可用性工程过程的结果记录在可用性工程文件中		
	The records and other documents that make up the USABILITY ENGINEERING FILE form part of other documents and files (e.g., a MANUFACTURER'S product design file or RISK MANAGEMENT FILE), (SEE List of documents make up the UE file) 可用性工程过程的结果应该记录在可用性工程文件中。形成可用性工程文件的记录和其他文档可以是其它文档和文件（如制造商的产品设计文件或风险管理文件）的一部分。(详见文件构成了问题列表文件)		
4.3	Scaling of the USABILITY ENGINEERING effort 可用性工程的规模		
	The USABILITY ENGINEERING PROCESS is scaled based on the significance of any modifications depending on the results of the RISK ANALYSIS and documented 在医疗器械的设计修改情况下，根据风险分析结果所确定的修改情况，可用性工程过程的规模可大可小。		
5	**USABILTY ENGINEERING PROCESS** 可用性工程过程		
5.1	Application specification 应用规范		

IEC 62366			
Clause	Requirement + Test	Result - Remark	Verdict
	Application of MEDICAL DEVICE in the USABILITY ENGINEERING FILE is specified by the MANUFACTURER and includes 制造商应该在可用性工程文件中规定医疗器械的应用说明，说明应包括	--	
	– intended medical indication (e.g., conditions(s) or disease(s) to be screened, monitored, treated, diagnosed, or prevented); 医疗指示(如条件(s)或疾病(s)筛选,监控,治疗,诊断,或预防)		
	– intended PATIENT population (e.g., age, weight, health, condition); 患者人口(如年龄、体重、健康、状况)		
	– intended part of the body or type of tissue applied to or interacted with; 使用和交互的身体部位和身体组织类型		
	– intended conditions of use (e.g.. environment including hygienic requirements, frequency of use, location, mobility); 预期使用条件(如环境包括卫生要求、使用频率、位置、移动);		
	– operating principle(s) 操作原理		
5.2	Frequently used functions 常用功能		
	Are frequently used functions that involve USER interaction with the MEDICAL DEVICE are determined and recorded in the USABILITY ENGINEERING FILE? 制造商是否确定涉及与医疗器械进行用户交互的常用功能，并将其记录在可用性工程文件中？		
5.3	Identification of HAZARDS and HAZARDOUS SITUATIONS related to USABILITY 鉴别与可用性有关的危害和危害处境		
5.3.1	Identification of characteristics to SAFETY 鉴别与安全有关的特性		
	Identification of characteristics related to SAFETY (part of a RISK ANALYSIS) that focuses on USABILITY performed according to ISO 14971:2007, 4.2. 识别与安全相关的特征(风险分析的一部分),根据ISO 14971:2007 4.2关注可用性表现		

IEC 62366			
Clause	Requirement + Test	Result - Remark	Verdict
	During the identification characteristics related to SAFETY, the following are considered: 在鉴别与安全有关的特性过程中，应考虑以下方面 – application specification, including USER PROFILE(S); and 应用规范，包括用户概况。和 –frequently used functions. 常用功能		
	Results of this identification characteristics related to SAFETY recorded in the USABILITY ENGINEERING FILE 鉴别与安全有关的特性的结果应该记录在可用性工程文件中		
5.3.2	Identification of known or foreseeable HAZARDS and HAZARDOUS SITUATIONS 鉴别已知或可预见的危害和危害处境		
	MANUFACTURER has identified known or foreseeable HAZARDS (part of a RISK ANALYSIS) related to USABILITY according to ISO 14971:2007, 4.3. 制造商应该按照IOS14971:2007 4.3.鉴别已知的和可预见的有关可用性的危害（风险分析的一部分）		
	Identification of HAZARDS considered HAZARDS to PATIENTS, USERS and other persons 危害鉴别应考虑对患者、用户和其他人员的危害		
	Reasonably foreseeable sequences or combinations of events involving the USER INTERFACE that can result in a HAZARDOUS SITUATION associated with the MEDICAL DEVICE were identified. The SEVERITY of the resulting possible HARM is determined. 应该鉴别涉及用户接口的合理可预见的事件序列和事件组合，这些事件序列和事件组合可能导致有关医疗器械的危害处境。应该确定导致可能损害的严重度。		

IEC 62366			
Clause	Requirement + Test	Result - Remark	Verdict
	During the identification of HAZARDS and HAZARDOUS SITUATIONS, the following was considered: 在鉴别危害和危害处境的过程中，应考虑以下情况： – application specification, including USERROFILE(S); 应用规范，包括用户概况 – task related requirements; 相关的任务要求 – context of use; 使用的上下文 – information on HAZARDS and HAZARDOUS SITUATIONS known for existing USER INTERFACES of MEDICAL DEVICES of a similar type, if available; 如可能，了解熟悉类型医疗器械的现有用户接口方面危害和危害处境的信息 – preliminary USE SCENARIOS; 主要使用方案 – possible USE ERRORS; 可能的使用错误 – if an incorrect mental model of the operation of the MEDICAL DEVICE can cause a USE ERROR resulting in a HAZARDOUS SITUATION; and 操作医疗器械的不正确的心理模式是否可能导致危害处境 – results of the review of the USER INTERFACE 用户接口的回顾结果		
	The results of this identification of HAZARDS, HAZARDOUS SITUATIONS and SEVERITY are recorded in the USABILITY ENGINEERING FILE. 鉴别危害、危害处境和严重度的结果，应该记录在可用性工程文件中		
5.4	PRIMARY OPERATING FUNCTIONS 主要操作功能		
	The manufacturer has determined the PRIMARY OPERATING FUNCTIONS and recorded in the USABILITY ENGINEERING FILE 制造商应确定主要操作功能，并记录在可用性工程文件中。		
	The inputs to the PRIMARY OPERATING FUNCTIONS include frequently used functions and functions related to SAFETY of the MEDICAL DEVICE 输入到主操作功能包括常用功能和功能相关的医疗设备的安全		
5.5	USABILITY SPECIFICATION 可用性说明		

IEC 62366			
Clause	Requirement + Test	Result - Remark	Verdict
	MANUFACTURER developed a USABILITY SPECIFICATION recorded in the USABILITY ENGINEERING FILE as part of the USABILITY ENGINEERING PROCESS 制造商应规定可用性说明，并记录在可用性工程文件中。作为可用性工程过程的一部分。		
	The USABILITY SPECIFICATION recorded in USABILITY ENGINEERING FILE. The USABILITY SPECIFICATION may be integrated into other specifications 可用性说明应该记录在可用性工程文件中。可用性说明可以整合到其它说明中。		
	The USABILITY SPECIFICATION includes: 可用性规范包括 – application specification; 应用规范 – PRIMARY OPERATING FUNCTIONS 主要操作功能 – HAZARDS and HAZARDOUS SITUATIONS related to the USABILITY; and 有关可用性的危害和危害处境 – known or foreseeable USE ERRORS associated with the MEDICAL DEVICE 有关医疗器械的已知的或可预见的使用错误		
	The USABILITY SPECIFICATION describes at least: 可用性说明至少应描述的内容包括：		
	– USE SCENARIOS related to the PRIMARY OPERATING FUNCTIONS EQUIPMENT, including 有关主要操作功能的使用方案，包括： – frequent Use Scenarios, and 常用方案 – reasonably foreseeable worst case USE SCENARIOS; 合理可预见最差情况使用方案		
	– USER INTERFACE requirements for the PRIMARY OPERATING FUNCTIONS EQUIPMENT including those to mitigate RISK; 主要操作功能的用户接口需求，包括减少风险的需求		

IEC 62366			
Clause	Requirement + Test	Result - Remark	Verdict
	– Requirements for determining whether PRIMARY OPERATING FUNCTIONS are easily recognizable by the USER. 确定主要操作功能是否易于被用户识别的需求。		
5.6	USABILITY VALIDATION plan 可用性确认计划		
	The MANUFACTURER has developed and maintains a USABILITY VALIDATION plan specifying: 制造商应该准备和维护可用性确认计划		
	– any method used for VALIDATION of the USABILITY of the PRIMARY OPERATING FUNCTIONS; 用于确认主要操作功能的可用性的方法		
	– the criteria for determining successful VALIDATION of the USABILITY of the PRIMARY OPERATING FUNCTIONS based on the USABILITY SPECIFICATION; and 确定成功确认基于可用性说明的主要操作功能可用性的准则		
	– the involvement of representative intended USERS 包括有代表性的用户		
	USABILITY VALIDATION performed in a laboratory setting ..... : 可用性验证在实验室环境中进行		
	USABILITY VALIDATION performed in a simulated use environment..... : 可用性验证在模拟使用环境进行		
	USABILITY VALIDATION performed in the actual use environment..... : 可用性验证在实际使用环境中进行	--	
	The USABILITY VALIDATION plan addresses: 可用性确认计划地址： – frequent Use Scenarios, and 常用方案 – reasonably foreseeable worst case USE SCENARIOS that are identified in the USABILITY SPECIFICATION 合理可预见最差使用方案		

IEC 62366			
Clause	Requirement + Test	Result - Remark	Verdict
	The USABILITY VALIDATION plan recorded in the USABILITY ENGINEERING FILE 可用性确认计划应该记录在可用性工程文件中。		
5.7	USER INTERFACE design and implementation 用户接口的设计和实现		
	MANUFACTURER designed and implemented the USER INTERFACE as described in the USABILITY SPECIFICATION utilizing, as appropriate, USABILITY ENGINEERING methods and techniques 制造商应该按可用性说明、可用性工程方法和技术中的描述设计和实现用户接口。		
5.8	USABILITY VERIFICATION 验证可用性		
	MANUFACTURER verified the implementation of the MEDICAL DEVICE USER INTERFACE design according to the USABILITY SPECIFICATION 作为医疗器械设计验证过程的一部分，制造商应按照可用性说明的要求验证医疗器械用户接口的实现		
	The results of the verification are recorded in USABILITY ENGINEERING FILE 验证的结果记录在可用性工程文件		
5.9	USABILITY VALIDATION 确认可用性		
	The MANUFACTURER has validated the USABILITY of the MEDICAL DEVICE according to the USABILITY VALIDATION plan 制造商根据可用性确认计划确认医疗设备的可用性		
	The results are recorded in the USABILITY ENGINEERING FILE 其结果应记录在可用性工程文件		

IEC 62366			
Clause	Requirement + Test	Result - Remark	Verdict
	For the acceptance criteria documented in the USABILITY VALIDATION plan that are not met: 结果应记录在可用性工程 - further USER INTERFACE design and implementation activities are performed; or 应该执行进一步的用户接口设计和实现活动，或 - if further improvement is not practicable, the MANUFACTURER may gather and review data and literature to determine if the medical benefits of the INTENDED USE outweigh the RISK arising from USABILITY problems 如果进一步的改进不能实现，制造商可以收集和回顾数据和文献，以便确定有意使用带来的医疗利益是否比可用性问题带来的风险权重更大。 To perform this step, the MANUFACTURER needs to estimate the RISK arising from USABILITY problems. 要进行这一步，制造商需要评价由可用性问题带来的风险。		
6	**ACCOMPANYING DOCUMENTS** 附属文档		
	The ACCOMPANYING DOCUMENT includes a summary of the MEDICAL DEVICE application specification 附属文档应该包括对医疗器械应用说明的概述		
	A concise description of the MEDICAL DEVICE, its operating principles, significant physical and performance characteristics and intended USER PROFILE are included in the ACCOMPANYING DOCUMENT 附属文档应该包括对医疗器械应用说明的概述，包括操作原理、显著的物理和性能特征和预期的用户概况		
	The ACCOMPANYING DOCUMENT is written at a level consistent with the intended OPERATOR PROFILE 附属文档和用户概况的相关内容应该保持一致		
	The ACCOMPANYING DOCUMENT for equipment are, optionally, provided electronically 可以提供电子的附属文档		

IEC 62366			
Clause	Requirement + Test	Result - Remark	Verdict
	USABILITY ENGINEERING PROCESS includes the information that will need to be provided as a hard copy or as markings on MEDICAL DEVICE when ACCOMPANYING DOCUMENTS are provided electronically 附属文档是电子版，可用性工程应该包括考虑需要提供硬拷贝的信息，或在医疗器械上做标记。		
7	**TRAINING AND MATERIALS FOR TRAINING** 培训和培训材料		
	The required training on the MEDICAL DEVICE for safe and effective use of PRIMARY OPERATING FUNCTIONS by the intended USER is given by: 为了让用户安全和有效地使用主要操作功能，如果需要对指定医疗器械进行培训，制造商应该按以下方式进行培训：		
	– necessary training materials provided by the manufacturer; 由制造商提供必要的培训材料;		
	– necessary training materials are available; or 确保培训所需材料可以得到		
	– the manufacturer provides TRAINING 提供培训		
	The ACCOMPANYING DOCUMENT describes the available training options 随附文档介绍的所有培训方案 (Recommendation: ACCOMPANYING DOCUMENT include the suggested duration and frequency of such training) （建议随附文档应该包括推荐的培训周期和培训频率）		
	INTENDED USE AND USER PROFILE(S) are the basis for TRAINING and TRAINING material 预期用途和用户概况应该是培训和培训材料的基础		

IEC 62366			
Clause	Requirement + Test	Result - Remark	Verdict

List of documents make up the UE file

文件构成的问题列表

4.2	Document title 文件标题	Version版本

supplementary information:

备注