本指南于1997年2月27日FDA的良好指南规范（GGP）实施前起草。本文件不为或向任何人创造或赋予任何权利，也不会对食品药品监督管理局（FDA）或公众产生约束。如果替代方法满足适用的法律法规或两者的要求，则可以使用该方法。本指导性文件将在下一版本中进行更新以纳入包括GGP标准要素。

**与器械标签相关的人为因素原则**

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# **引言**

依据政府法规和行业实践，将伴随医疗器械分发给公众的说明称为“标签”。医疗器械标签包括如何使用和维护医疗器械的说明。其也包括与理解和安全性相关的补充信息，如与风险、预防措施、警告事项、潜在不良反应等相关的信息。本报告通过为标签编写者和设计者提供了关于医疗器械标签的原理。这些原理仅适用于补充信息和与器械随附的说明册上贴的医疗器械标签。

标签中也纳入了对开具医疗器械处方或销售医疗器械的专业人士有价值的临床和实验室详细信息。“包装说明”下进一步归纳了许多这些详细信息。联邦政府按照贴标药品和医疗器械的要求对标签和包装说明书进行管理。联邦法规要求：按照特定格式来提供医疗器械的标签。21 CFR第801部分中包含了这些法规。完整准确的标签对于安全、可靠操作医疗器械（无论消费者在在家中使用还是专业人员在医院使用）至关重要。

本报告说明并拓展了一种项FDA项目的结果，该项目测试了一种广泛使用的医疗器械（Callan, Gwynne, Cardinal, & Kelly, 1990; Gwynne, Cardinal, Easterly, & Callan, 1991; Gwynne, Provo, & Callan, 1992），即软性隐形眼镜标签的有效性。该项目的一个结局是一系列使隐形眼镜标签更有助于消费者的建议。通常，大多数这些建议对医疗器械贴标（而不仅是隐形眼镜）是有价值的。此处提供的建议作为开发全部医疗器械标签的原则。

可将本报告视为**《正确书写：开发用于家庭保健治疗中使用的医疗器械的用户说明手册的建议》**的FDA小册子的相关文件。该小册子为开发从初步计划到宣传最终产品的说明手册的全部开发过程提供了指南。本报告着重于该过程的更普遍方面、潜在说明原理、人为因素和在设计医疗器械有效标签方面涉及的认知心理学。

本项目根据内容和版式／格式对医疗器械标签进行了思考。内容指的是应纳入到教材中的信息类型。

版式／格式指传递信息的方式和风格。在结合使用时，他们显著影响了医疗器械有效标签的开发。在本报告中按下述方面对内容和版式／格式进行了讨论：

|  |  |
| --- | --- |
| **内容** | **版式／格式** |
| 结构 | 语言和可读性 |
| 背景信息 | 插图和图形 |
| 程序 | 强调信息 |
| 风险沟通 | 印刷格式和易读性 |
| 补充信息 | 物理特征 |

已汇总并整合了每个**领域**中的文件设计研究、人为因素和认知心理学，从而提供有效医疗器械标签的原则。在对每个**领域**进行讨论后，均提供了项目和书籍的参考列表。本报告结尾部分的参考文献包括每个**领域**的一系列完整的参考文献。本报告第三部分对于医疗器械标签**相关**的主题（尽管不作为主要观点的中心）进行了讨论。这些主题包括**教学**理论、医疗器械标签评估方法、其它教学媒体以及针对医疗器械标签的法规、标准和指导方针。

# **内容**

## **结构**

结构指如何安排标签中彼此相关的主题。结构是如何有效了解和遵循标签的主要决定因素。通常，第一部分应包括与医疗器械目的相关的背景信息。请在此处提及与器械使用相关的任何重大危害。接下来的部分应对器械操作和维护程序进行说明。同样，通常也需要描述潜在健康风险和器械故障排除的部分。

结构要素的举例**有**主题、标题、副标题和总结。其可辅助快速定位信息、改善器械操作的维持、激励用户使用以定期贴标、并强调实施程序的顺序。诸如目录和边缘索引表等结构要素有助于帮助阅读者定位特定主体。这些要素还能提高对各步骤之间关联性的理解。

下述眼镜护理说明册的目录显示了标题和子标题的叙述主体如何传答出每部分的内容。这些主题与说明册文本中的标题和子标题逐字对应。

|  |
| --- |
| 结构举例*目录*隐形眼镜护理表 2引言 3一般预防措施 4戴上隐形眼镜 9取下隐形眼镜 17清洁和消毒 21冷（化学）消毒 26热（热量）消毒 28紧急热消毒 30酶清洁 32隐形眼镜盒清洁和消毒 33当您在戴眼镜时出现问题时，该怎么做 35 |

结构参考文献

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Mayer, R.E. (1979). Can advance organizers influence meaningful learning? ***Review* of *Educational*** Research, 37.37 1-383.

|  |
| --- |
| 关于结构的提示* 根据器械操作和维护要求来组织标签主题
* 按主题、标题和子标题将不同部分分隔开来
* 先行组织者，如目录，可通过界定标签的主要部分来辅助用户理解
 |

##

## 背景信息

背景信息由器械使用者在操作医疗器械之前因更了解的信息组成。在提供如何操作并维护器械的程序之前，在标签的开头提供背景信息，并把它放在一个单独的部分。这可避免背景信息造成用户在操作器械时**分心**。背景信息包括下述要素：

|  |  |
| --- | --- |
| * 器械的预期使用目的
 | * 器械组件
 |
| * 一般警告信息
 | * 器械使用条件
 |
| * 供应品和材料
 | * 用户准备
 |

器械的预期用途

描述器械的使用目的、使用器械人员的医疗需求、以及器械适应症。解释应如何在保健专业人员的指导下，利用器械提供的信息来监控或治疗医疗条件。

器械组件

详细描述器械组件及其功能，因此，器械用户可了解器械的操作原理。提供器械插图，清晰标识每个组件及其文本描述。强调用户需要在使用器械前熟悉器械组件。

如果为电子器械或机械器械，对全部主要器械特征和操作做出解释，如：

|  |  |
| --- | --- |
| * 操作模式
 | * 电池装载和测试
 |
| * 显示信息
 | * 清洁和维护
 |
| * 控制驱动
 | * 校准
 |

一般警告事项

警告事项是**使**器械使用者了解器械使用可能引起重度不良健康结局的声明。一般警告事项包括器械操作前需要的重要信息。一般警告事项举例有，如果出现特定症状，需要停止使用器械。在标签的靠前位置**声明**关于器械使用的警告事项。（相反，在合理的程序章节中声明警告事项，放在其所适用的步骤之前。）讨论与不合规使用器械相关的危害**和**在解释测试结果时容易出现的误区。避免使用技术术语，以便非专业使用者能够理解警告事项。以特殊格式来提供能够引起注意的警告事项。本报告的描述／格式部分对几种可能的警告事项格式进行了讨论。

器械使用条件

声明安全可靠操作医疗器械所需的条件。讨论任何可能破坏器械操作的条件，如温度或湿度过高。否则，使用者可能在引起错误器械操作或不准确测试结果的条件下对器械进行操作。请对储存条件进行讨论，并强调可能损坏器械的条件。适用时，提供关于器械或其合理供应品的特殊操作。

供应品和材料

描述并阐明器械操作或维护所需的全部供应品和材料。指定全部所需材料的数量、规格和类型（无论是否作为器械附属品）。

用户准备

使用一些医疗器械进行的测试要求在测试前或在测试过程中摄取或不摄取特定物品。确保标签中清楚声明了该要求。

背景信息参考文献

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|  |
| --- |
| 背景信息提示* 提供关于器械使用目的的基本信息
* 提供关于如何使用器械的一般信息
* 声明一般警告事项和预防措施
* 列出并阐明使用器械所需的供应品
 |

## 程序

程序是告知用户如何操作或维护医疗器械的一系列步骤。请使用简短的句子和常见的词语陈述步骤；否则，可能出现用户错误。程序可能伴有原理或指导用户操作的进一步说明。例如，关于器械操作可能误区的提示可能帮助用户避免错误。紧跟在相关步骤后面简要提供本信息。

预说明声明

在标签的开头部分提供声明以强调使用器械之前仔细阅读全部说明的需求。此时，诸如客户援助电话号码等参考文献来源也是有帮助的。

逐步说明

可能将程序分类为一系列简短的、不连续步骤，而不是一个长篇段落。这使器械用户在更早期实施纠正措施，同时参考标签。每个程序可能包括下述信息：

* 应执行程序的条件
* 所需的供应品和设备
* 时间关键步骤的计时要求
* 影响器械用户或测试结果的因素
* 阐明所需文本和插图的例子

下述举例源于模型眼镜护理说明册：

|  |
| --- |
| 说明举例步骤5-将隐性眼镜戴在您的眼睛上将隐形眼镜放在您食指指尖。利用同一只手的中指压住下眼睑，眼睛向上看。将隐性眼镜放在眼白下部。向下看，并放开隐性眼镜。随后，隐形眼镜应自己移动到中心位置。 |

阅读并解释**结果**

纳入应如何阅读和解释测试结果的说明。下述要素对于本描述至关重要。

关于阅读结果的警告说明。明确声明可能影响测试结果阅读的任何条件。这些条件举例包括反应计时和读取结果时的温度和光照条件。

读取结果。充分描述获得测试结果的程序。如果需要进行数学计算，提供例子。

解释结果。解释全部可能结果的意义。解释结果时考虑到对模棱两可的结果和测试局限性的适当处理至关重要。声明可接受结果的范围，以检测无效结果。

对结果采取行动。说明指定结果后应采取的行动。举例包括通过保健专业人员来寻求建议或通过再测试来确认测试结果。使用户了解获得无效结果的概率、与采取措施相关的危害以及检测方法。

**程序参考文献**

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Hartley, J. (1990). Is this text any use? Methods for evaluating text. In J.R. Wilson and E. N. Corlett (Eds.), ***Evaluation*** of human ***work: A practical ergonomics methodology (***pp. 248-270). London: Taylor & Francis.

Wieringa, D., Moore, C., & Barnes, V. (1993) Procedure Writing, Principles and Practices. Columbus: Battelle Press.

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| 程序提示* 强调医疗器械使用中所涉及的措施和技术。
* 指出所需步骤和必要的测试条件。
* 指出必要的供应品和材料。
* 不得利用过多的证明和原理来稀释步骤。
 |

## **风险沟通**

风险沟通告知器械用户与操作器械的潜在危害和如何降低危害相关的信息。国家研究委员会（1989年）确认了对于医疗器械标签至关重要的几种风险沟通内容领域。这些包括因使用器械、出现危害效果和影响器械使用的环境因素所引起的有害效果。这些领域考虑了许多因素，包括器械操作特点和要求、用户群体特征、器械使用注意事项、以及与器械使用相关的危害效应的类型和发生率。

**风险沟通参考文献**

National Research Council (1989). ***Improving risk communication.*** Washington, ***D.C.:*** National Academy Press.

Ryan, J.P. (1991). ***Design of warning labels and instructions.*** New York: ***Van*** Nostrand Reinhold.

Wogalter, M. S., Allison, S. T., & McKenna, N. A. (1989). Effects of cost and social influence on warning compliance. Hum Factors, 31, 133- **14.0.**

Wogalter, M. S., Godfrey, S. S., Fontenelle, G. A.. Desaulniers, D. R., Rothstein, P. R., & Laughery, K. R. (1987). Effectiveness of warnings. Human Factors, 29,599-612.

Young, S.L., & Wogalter, M.S. (1988). Memory of instruction manual warnings: Effects of pictorial icons and conspicuous print. In Proceedings of the Human Factors Society, 32nd Annual Meeting (pp. 905-909). Santa Monica, CA: Human Factors Society.

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| **风险沟通提示*** 不得最小化与医疗器械相关的危害效果。
* 纳入已知危害效果的发生率。
* 提供危害效果的补救措施或参考合理权威。
* 描述影响操作者和器械的环境因素。
 |

## **补充信息**

补充信息包括器械用户在使用器械过程中发现的有用信息。其可能包括与器械相关的信息、记录测试结果的方法和器械用户遵循的治疗或监控方案的描述。**通常**，最好利用表格而不是文本来提供补充信息。这有助于器械使用者快速容易地定位信息的具体项目。

**器械信息**

列出完整的商标名称、型号和器械制造日期。包括器械制造商和分销商的名称、地址和电话号码，因此，器械用户可获得与器械相的关更详细信息。

**测试结果记录**

许多器械在延长的时间段内，在一系列测试中对某种物理或生物化学过程进行了检测。在这些情况下，请纳入记录日期、时间和每项测试结果的表格。保健专业人员在诊断和治疗时可使用本记录。

下述举例来源于模型隐形眼镜护理说明册。其阐述了器械用户通常认为有价值的补充信息类型。

|  |
| --- |
| **补充信息举例** |
| 隐形眼镜拥有者姓名 街道 城市／州／邮编 电话 隐形眼镜说明  | 隐形眼镜护理医生姓名 街道 城市／州／邮编 电话 处方日期  |
| 隐形眼镜 | 类型 | 规格 | 直径 | 底部 | 曲率 |
| 右眼 |  |  |  |  |  |
| 左眼 |  |  |  |  |  |
| 预约安排日期 时间 日期 时间 日期 时间 日期 时间  | 隐形眼镜制造商电话号码 消毒系统类型（勾选一项）冷（化学）热（热量） |

|  |
| --- |
| **补充信息提示*** 提供与器械相关的具体、完整的确认信息
* 纳入器械制造商的名称、地址和电话号码
* 为记录针对患者及其健康保健方案（如向一名保健专业人员就诊）的信息提供充分空间。
 |

# **描述／格式**

## **语言和可读性**

语言是传达信息的正确、简洁和清楚的词汇使用。可读性是理解文本的相对轻松程度。对于医疗器械标签而言，良好的语言和可读性相当于简单、直接和清楚的陈述说明。其最小化了阅读困难，并尽可能使大多数阅读者了解标签。

每个程序应由简单、常见的词汇书写的简短、清楚的句子构成。将程序分成几个短小段落而不是使用少数长段落；这提高了理解和阅读速度。请使用主动语态而不是被动语态。不要利用较长的理由和原理来稀释程序；程序步骤中的证明和原理会引起阅读者的注意。最小化技术术语、复音词和复杂表达。

可读性评估了说明的可读程度，也通常被医疗器械标签作者忽视。可读性措施取决于书写风格（词语使用、句子特征）而不是内容。对标签进行编写，使其可读性依赖于下述使用者组的阅读等级水平。六年级水平是可读性的良好目标。大多数器械使用者可理解在该等级书写的标签。

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| **语言和可读性提示*** 书写简短、直接的句子
* 使用肯定的主动语态
* 使用简短、简单、常见的非技术词语
* 将可读性维持在不超过六年级水平
 |

## **插图和图形**

插图和图形由照片、图纸、动画、表格和图形组成。它们应通过增加文本描述来简化医疗器械操作。插图和图形通常比词语更容易记忆。同样，它们降低了阅读者对文本的依赖程度，对于阅读能力较差者存在绝对优势。

在大多数情况下，不要纳入对文本进行重复性说明的插图。然而，可利用它们来显示难以通过口头方式表达的器械操作方面。将插图和图形插入到相关文本旁边。这样，读者的眼睛能够在同一页中的文本和附图之间转换。应特别注意，保证插图与相关文本说明准确相关。

插图应清楚、简单和整洁。每个插图应仅传递一个想法；这可减少使用者错误。照片准确传递了目标外观并显示了其三维视图。线图强调了具体细节和目标维度（Bailey, 1989）。

通常优先选择彩色插图而不是黑白插图。鉴于其生动的文字且更为醒目，这些插图能更好地吸引读者的注意力（Marcus，1992年）。作为本项目部分内容的研究发现了颜色插图的强烈主观优选。通过这种优先选择能够将更多的注意力集中到带有彩色插图的说明上。但是，在同一时间内，在颜色使用和改善任务性能之间未建立明确关联，尽管结合其他技术的颜色使用确实促进了对任何特点的记忆（例如，Young &Wogalter, 1988）。

下述作为模型隐形眼镜护理手册部分内容开发的流程图显示了插图在医疗器械标签中的效果。流程图是对程序进行描述的图形方法。其能清楚概述软性隐形眼镜的清洁和消毒过程中涉及的整套程序。是已熟悉隐形眼镜护理程序的有经验用户的有价值的记忆辅助工具。



***隐形眼镜日常护理***

**酶清洁**

遵循酶清洁说明

清洁和消毒隐形眼镜

**热（热量）消毒**

在盒中充入生理盐水溶液

将隐形眼镜盒放入消毒装置中

开始消毒

戴隐形眼镜前冲洗眼镜

**隐形眼镜盒的清洁和消毒**

煮沸一锅自来水

将空的隐形眼镜盒和盖子放在沸水中至少煮10分钟\*

风干盒和盖

\*参见第xx页上关于隐形眼镜盒的预防措施。

**清洁和消毒**

洗手

将隐形眼镜放在手掌中

使用清洁溶液

擦拭隐形眼镜两侧20秒

利用生理盐水冲洗隐形眼镜

将隐形眼镜放到隐形眼镜盒中

对隐形眼镜进行消毒

**冷（化学）消毒**

在盒中充入消毒溶液

浸没隐形眼镜4小时

戴隐形眼镜前冲洗眼镜

‡根据隐形眼镜护理系统的不同，准确词汇可能存在差异。

***每周隐形眼镜护理***

**图形举例\***

**插图和图形参考文献**

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| **插图和图形提示*** 使用插图和图形来增加和阐明文本
* 仅在每个插图中描述一个步骤
* 使插图和图形位于相关文本旁
* 保证插图清楚、整洁
* 使用实际照片
* 使用线图来描述细节
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## **突出内容**

突出内容通过引起视觉注意强调了医疗器械操作的重要方面。突出技术包括使用的颜色、粗字体、下划线、背面印刷、各种字形、文本边框线、抵消边界和背景、以及空白处。强调内容缓解了视觉压力、强调了关键点、并将文本的部分和子部分进行了分离。应在标签的规定部分中始终进行强调。注意不要过度强调，否则，将降低其影响。

空格

在段落之间使用空格来改善文件外观、使其便于阅读、并强调主要程序之间的分隔。注意不要在文本线之间使用过多的空格。各线之间存在的空格太多会影响阅读速度、理解和可读性。过多空格也会增加打印成本并增加不必要的说明长度。另一方面，如果各线之间的空格太多，对于许多阅读者而言（特别是视力不好的阅读者），线将模糊不清。空格不够的标签通常看起来难以辨认且难以阅读。也可使用空格来界定一套说明中的不同部分。作者想要强调的标签部分能够引起读者注意。例如，空格能够以一定方式使阅读者了解说明的特定内容。眼会扫过作者打算让阅读者忽略的内容，而集中到与如何操作或维护医疗器械相关的重要说明。

加边框线和加粗

诸如加边框线和加粗等突出技巧能够强调关键信息。下述为本项目中的模型隐形眼镜说明册中的举例：

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| **警告事项**与隐形眼镜和眼镜护理液相关的问题可能造成眼睛严重损伤和失明。若眼部持续存在任何不适、流泪、视力变化或发红等症状，请立即联系您的医生或就诊。 |

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| **突出内容提示*** 在各段和边缘以及边界之间留出充分的空格
* 使用不均匀边界或背景
* 利用黑体字、斜体字、颜色和反面印刷来强调重要步骤
* 栏目标题和子标题清楚阐述标签的结构
* 加边框强调了警告信息和其它关键信息
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## 排印和易读性

排印是该类型印刷材料的排列、类型和一般外观。其包含不同的印刷特征，包括字体、字号和字样。正确排印增加了文件易读性、减轻了疲劳、最大化了信息传达并帮助器械用户定位理想信息（Simpson &Casey. 1988）。

可读性决定了在器械操作条件下能够正确阅读材料的轻松程度。特别是当由因年龄或身体原因而出现视力下降的人员对器械进行操作时，这是医疗器械标签的重要因素。易读性与印刷特征密切相关。例如，字号、字型和线宽倾向于通过相互作用来影响文件**易读性**。

**字号**

为标签使用足够大的字号以便于用户轻松阅读。由于许多医疗器械用户是老年人，字号是医疗器械标签的一个尤为重要的特征。

9号和更小字号可能使阅读者跳过材料或造成用眼疲劳。

10号字号是一般阅读者（而不是老年阅读者）能够接受的最小字号。

12号字号是保留空格需求和提供清楚说明之间的最佳平衡点。12号字号也是对于视觉受损人员和老年人的最佳整体字号。

14号字号适用于视觉受损阅读者和老年人。

如果确有必要使用18号字，应尽量少用。

**字体**

大多数字体的易读性相同，但尽管新罗马字体可能最不容易使人感到疲劳（Simpson & Casey, 1988）。衬线字体与无衬线字体相比，更容易阅读。（衬线字体是结束字母主要笔画的一种精美的水平线）。在可能的情况下使用衬线字体。利用不同字体打印的标签抑制了阅读速度。在整个文件中使用一致的通用字体。尽量减少多种字体的使用。

**行长度**

长线是针对在诸如本报告等标准尺寸字母纸张上印刷的非教学性、叙事性写作规范。

针对以12号字号在说明书打印的最佳行长是4.0±1.25英寸。行较长，会使眼睛扫描整个长度，并更容易串行，因此，更容易造成视觉疲劳。这是医疗器械特别重要的注意事项，而必须按正确顺序对每个操作程序步骤进行操作。

行较短（小于2.5英寸），要求眼睛在阅读单个句子的同时频繁来回移动，因此，会减慢阅读速度。应减少或消除短行的使用。

**全部大写字母和斜体字**

全部利用大写字母印刷的文本干扰了易读性，同时占据了更多空间。由于字母形状差别不大，因此，也降低了阅读速度（多达20%，TINKER, 1963）。同样，使用斜体字也会降低阅读速度，因此，尽量减少其应用。

但是，如果审慎使用，全部大写字母和斜体字可能强调重要文本。

在模型隐形眼镜护理手册中对合理使用全部大写字母的情况做出了下述举例：

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| **全部大写字母举例**本手册解释了如何护理您的软性隐形眼镜。**从头到尾仔细阅读本手册。**保存该手册以便于回答关于您隐形眼镜护理的问题。在阅读本本手册后，如果您存在更多关于护理和戴软性隐形眼镜的问题，拨打电话或向您的眼部护理医生就诊。 |

右边缘不齐文本与对齐右边缘文本相比更便于阅读标签。由于右侧轮廓有助于在各线之间进行区分，因此，阅读者能够追踪位置。眼镜不必针对各词之间的不同间距做出调整（如右对齐行）。比例间距在单词中的各个字母之间产生了统一空间。

白色背景下的黑色版本是印刷对比的通用标准。尽量减少连字符的使用；其要求阅读者记住之前行的最后一个字。视力有限或记忆力不佳者通常难以找到最后一个字。

排印和**易读性参考文件**

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| 排印和易读性提示* 使用合理字号（12pt，是最佳的最通用字号）
* 为文本使用衬线字体，为主题和标题使用无衬线字体
* 比例间距是便于阅读的关键因素
* 维持较高的打印-背景对比度
* 维持足够短的线长，以便于阅读
* 倾向使用右边不齐行排版
* 尽量减少使用连字符，特别针对较短单词
* 审慎使用全部由大写字母和斜体字组成的单词
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## 物理特征

标签的物理特征影响其易用性和主观吸引力。文件应紧凑、便于理解并在实际器械操作条件下轻松使用。这些因素对阅读、理解、遵循和保留标签的程度存在影响。两个因素对医疗器械标签的物理特征存在影响：

（a）将如何使用文件和（b）更新要求。

当不操作器械时，通常可使用诸如技术手册等文件。这些文件具有通用的书本长度并应具有相应的尺寸。在操作医疗器械的同时，使用其它文件，如操作者手册和快速参考指南等。其设计必须便于访问和使用，并具有更小的格式。

更新文件涉及增加或删除页。环形带是符合这些要求的理想方法。对于不修改的文件，应优先使用螺旋装订（Simpson & Casey, 1988）。全部文件在不利用辅助设备帮助的情况下应平铺，因此，使用者能够利用双手操作器械。

进行消光加工的纸张比光面纸更好，光面纸会向眼睛进行漫反射。纸张应足够重，以防止透印。

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| 物理特征提示* 采用允许一同显示文本和图形的方向
* 根据目的来调整大小
* 使用适用于更新要求的绑定类型
* 保证文件平铺
* 纸张应进行消光加工且无透过
 |

# **相关主题**

## 教学理论

已针对教人进行操作的理论基础进行了许多研究。这些理论的具体细节不在本报告的范围之内。由于其影响对本报告中医疗器械标签原理的说明，因此，提及教学理论是适当的。下述所列的参考文献与医疗器械最相关。文献目录中所含的文章与适用于标签设计、开发和评估的更多理论主题相关。

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## 医疗器械标签评估

已获得FDA批准的医疗器械标签应进行上市前测试和评估。预测试涉及从针对标签不同特征的拟定用户组成员中系统采集的数据。预测试能够确认标签的明确优点和缺点。使用预测试调查结果以在器械上市前对标签进行改良。

标签的预测试应集中在下述一个或多个领域：用户理解、用户性能、可接受性、以及可信性。着重于预期用户组的特征，使标签发挥最大效果。许多医疗器械标签的主要缺点是未考虑到目标用户。因此，用户可能通常误解或无法理解标签。

可采用几种方法来预先测试医疗器械标签，包括典型人群谈话、深度个体谈话、调查问卷和可读性测试。在通常情况下，必须利用这些方法的一些组合来尽可能开发最有效的标签。所附的参考文献列表包括阐述如何使用这些方法来评估、评价和改善医疗器械标签的典型文章和专章。

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## 其它教学媒体

本报告涉及一种专门作为教导人们操作医疗器械方法的打印标签。至今为止，关于媒体不同于标签的教学价值的研究关注度较低。但是初步调查结果是值得注意的。例如，本项目用户观察研究的参与者优先选择个人示范和录像带而不是印刷商标。并且，教学套装与任何教学媒体相比，产生了更好的一致性能。因此，尽管印刷材料在教人如何操作医疗器械方面发挥了重要作用，其它媒体也值得调查。下述参考文献列表为媒体研究而不是印刷标签研究提供了样本。

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## 法规、标准和指导方针

法规、标准和指导方针有助于保证以一种安全和有效的方式来设计、制造和使用医疗器械。法规是构成的权威机构规定的规则、限制条件和控制。标准为材料、方法或规范确认了特定的、基本要求”。与法规一样，使用标准不需要修正。通过共识来制定指导性原则，并为一般操作规范、程序或材料的标准进行说明。指导性方针至少对这三类惯例进行了约束，并且，可能被作为符合特别要求的书面文件或经修改的文件。

法规、标准和指南参考文献

United States, Code of Federal Regulations, Title 21 Food and Drug Administration, DHHS, Part 801, Labeling, Subpart C, Labeling requirements for over-the-counter devices.

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