

Simplicity in Labeling, especially in Home care

Several comments were made in the past with regard to simplicity in labelling, especially in Home care. Patient information (like Instructions for use) was often found to be too complex and difficult to understand for home care users (see FDA Draft Guidance Design Considerations for Devices Intended for Home Use, December 2012).

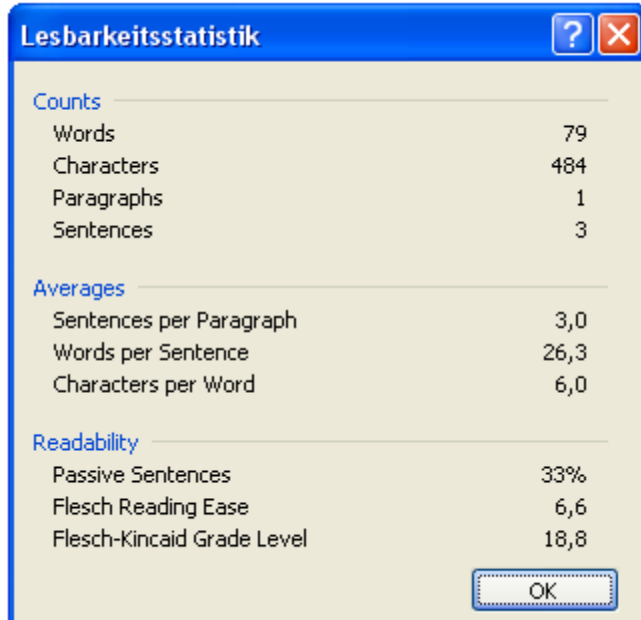
Tools are available to validate if language used in labelling is too complex or easy to understand. One tool is the “Flesch Reading Ease Test”. The test is available in off-the-shelf software.

An example is shown below:

Text without modification

This draft guidance is intended to assist manufacturers in designing and developing home use devices that comply with applicable standards of safety and effectiveness and other regulatory requirements. Home use devices are associated with unique risks created by the interactions among the user (often a layperson), the use environment, and the device. This guidance identifies several factors that manufacturers of home use devices should consider, especially during device design and development, and provides recommendations for minimizing these unique risks.

Using the Flesch reading Ease score provided in Microsoft Word, the following evaluation was done:



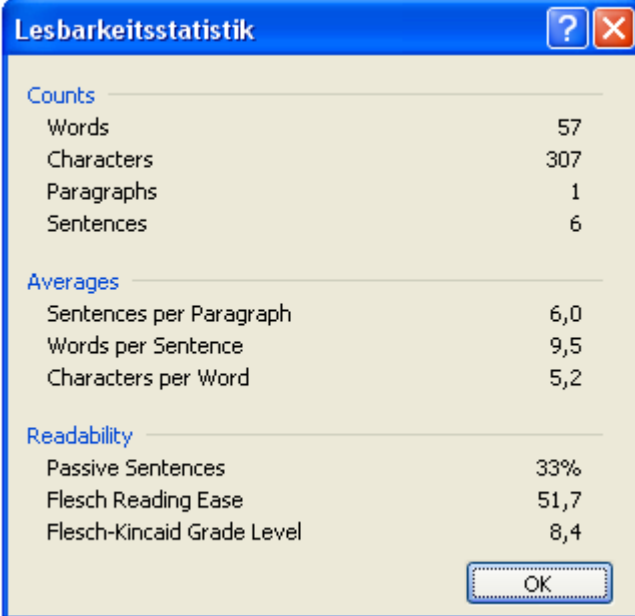
Lesbarkeitsstatistik	
Counts	
Words	79
Characters	484
Paragraphs	1
Sentences	3
Averages	
Sentences per Paragraph	3,0
Words per Sentence	26,3
Characters per Word	6,0
Readability	
Passive Sentences	33%
Flesch Reading Ease	6,6
Flesch-Kincaid Grade Level	18,8
OK	

A Flesch Reading ease score of 6.6 was achieved, which can be rated as very difficult, best understood by university graduates. This is equivalent to a Flesch-Kincaid Grade Level of 18.8.

The text evaluated above is actually from the FDA guidance and indicates that the guidance may have been written for (or by) university graduates only. It is very difficult to read.

Text after modification

This guidance is a draft. It assists in design and development of home use devices. It ensures that standards of safety and effectiveness and regulatory requirements are met. Home use devices bare unique risks. These risks are created by the interactions among the user, the use environment, and the device. This guidance provides recommendations to reduce risks.



Lesbarkeitsstatistik	
Counts	
Words	57
Characters	307
Paragraphs	1
Sentences	6
Averages	
Sentences per Paragraph	6,0
Words per Sentence	9,5
Characters per Word	5,2
Readability	
Passive Sentences	33%
Flesch Reading Ease	51,7
Flesch-Kincaid Grade Level	8,4

Re-wording and re-phrasing the text, helped to simplify the text and to increase ease of reading. The best way to improve the scoring is to shorten sentences and to reduce the number of words per sentence. By doing this, the Flesch Reading ease score was increased up to 51.7, which can be rated as medium. The Flesch-Kincaid Grade Level was reduced to 8.4., which would satisfy FDA's criteria for patient information.

References and Background:

Evaluation of the results achieved may be done by using the tables and references below.

Score	Notes
90.0–100.0	easily understood by an average 11-year-old student
60.0–70.0	easily understood by 13- to 15-year-old students
0.0–30.0	best understood by university graduates

Flesch Reading Ease Score Von ... bis unter ...	Lesbarkeit	Verständlich für
0-30	Sehr schwer	Akademiker
30-50	Schwer	
50-60	Mittelschwer	
60-70	Mittel	13-15 jährige Schüler
70-80	Mittelleicht	
80-90	Leicht	
90-100	Sehr leicht	11 jährige Schüler

<http://de.wikipedia.org/wiki/Lesbarkeitsindex>

http://en.wikipedia.org/wiki/Flesch-Kincaid_readability_test#Flesch_Reading_Ease

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm080602.pdf>

FDA recommends the following acceptance criteria:

To enhance patient comprehension, materials should be written at a 6th to 8th grade reading level, and have a reading ease score of at least 60% (60% corresponds to an 8th grade reading level).

http://www.accessdata.fda.gov/drugsatfda_docs/nda/2009/022371s000OtherR.pdf

Note: Michael provides free information. The author does not take any responsibility for contents and correctness.