

# FINAL REPORT

“Testing new symbols of sterile barrier systems for sterile medical devices to comply with new general safety and performance requirements (GSPR) of the new European medical device regulation”

Quotation no.: AS/5004/19  
 Date of report: 11.03.2019

To Mr Bernhard Schilling

+49 162 2763271

director.general@sterilebarrier.org

Delivery address THE STERILE BARRIER ASSOCIATION

4 King Square, Bridgwater, Somerset

TA6 3YF, United Kingdom

From: Fraunhofer-Institute for Process Engineering and Packaging IVV  
 Giggenhauser Str. 35  
 85354 Freising  
 Germany

Department Department of Sensory Analytics

Contact person Dr Brid Karacan Dr Jonathan Beauchamp

Phone +49 8161 491-321 +49 8161 491-214

Fax +49 8161 491-242 +49 8161 491-242

E-Mail brid.karacan@ivv.fraunhofer.de jonathan.beauchamp@ivv.fraunhofer.de

Date of order: 21.01.2019

Date of data receipt: 17.01.2019

No. of pages: 325

The results relate only to the investigated samples. The results of this report are the property of the client. However, use of the results by a third party, for publication, or duplications of excerpts of this report is subject to a written agreement from the Fraunhofer Institute for Process Engineering and Packaging IVV. This summary is part of a more extensive research report.

## 1 Introduction and executive summary

Five symbols for sterile medical devices were tested in relation to comprehensibility, usability and memory in an online survey. These symbols are intended to help healthcare workers (e.g. nurses) to distinguish between protective packaging layers without microbial barrier and sterile barrier systems of packaged sterile medical devices. The objective of this project was to validate the symbols for inclusion in EN ISO 15223-1 'Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements'

This report outlines the work conducted on testing the new symbols of sterile barrier systems and presents the outcomes of the study. Specifically, the data in this report comprise survey results from 342 participants for comprehension and usability testing and 129 participants for memory testing from Europe, Asia, USA and Australia. In the current report, the total sample will be described as well as each sample per language group.

The results of the previous interim report (04.02.2019) offered indications of the final outcome of the project. On the basis of these preliminary results minor adjustments were made with regard to the formulation of the multiple-choice questions of symbol 1 and 3. The current report also includes the results of this modified survey.

The dates of the interim report and the final report have been aligned with the standardization ballot of CEN/CLC/JTC3 for a new work item proposal for amendment of EN 15223-1:2016 and with the date of the next meeting of ISO TC210/WG3 to discuss the revision of ISO 15223-1: 2016.

The acceptance criteria for a symbol to be considered validated was set to a minimum of 50% correct answers while results above 65% would allow the conclusion that the symbols are easily understandable (Table 1c). A summary of the final results is illustrated in Table 1a/b. All symbols passed the acceptance criteria.


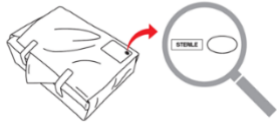

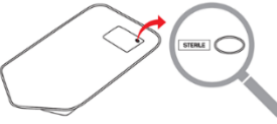



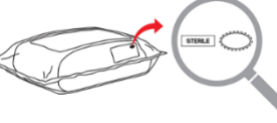

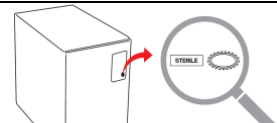
It should be noted that the relatively poor understanding of symbol 1 and 3 for comprehension and usability testing seems to be related to a lack of clarity of the original survey questions.

The results of the modified survey confirmed this postulated hypothesis (for a comparison of the original and modified version, see Table 1d-g). In the modified version, the functionality of the answers was emphasized more strongly by adding the same text modules that participants had previously encountered. This approach enabled a conscious processing of what had previously been learned.

The data from memory testing further demonstrates that participants remembered well the meaning of solid and dotted lines, which is the basis for a good comprehension of the symbols as demonstrated by the data in the memory testing.


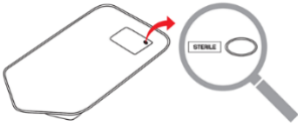

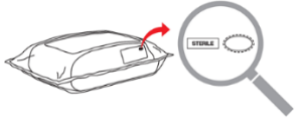
**It can be concluded that all proposed symbols have been successfully validated fully meeting the acceptance criteria. It can further be concluded that participants learn the meaning of symbols quickly and remember them well leading to excellent results in terms of usability.**

**Table 1a.** Summary of results. Comprehension and usability testing ( $n = 342$  (main survey);  $n = 61$  (modified survey)).

	Comprehension testing		Usability testing		
Symbol description	Symbol	correct answer f (%)		1. correct answer f (%)	2. correct answer f (%)
<b>Symbol 1</b> Single sterile barrier system		56 (92%) [183 (54%)]*		44 (72%) [214 (63%)]	47 (77%) [173 (51%)]
<b>Symbol 2</b> Double sterile barrier system		315 (92%)		208 (61%)	246 (72%)
<b>Symbol 3</b> Single sterile barrier system with protective packaging inside		49 (80%) [126 (37%)]		44 (72%) [210 (61%)]	45 (74%) [203 (59%)]
<b>Symbol 4</b> Single sterile barrier system inside protective packaging		298 (87%)		202 (59%)	259 (76%)
<b>Symbol 5</b> Double sterile barrier system inside protective packaging		286 (84%)		255 (75%)	256 (75%)

Note. Pass/fail criteria defined by ISO 27185:2012(E), clause C.4. a) 66 % to 100 % correct: validated as easily understandable by the survey group; b) 50 % to 65 % correct: validated as somewhat understandable by the survey group; c) Below 50 % correct: poor understanding; requires re-evaluation of design for better understanding by the user group, or indicates a necessity to learn a symbol's meaning. \*For symbol 1 and 3, the results from the modified English survey ( $n = 61$ ) are shown, while the results from the total survey for those symbols are put in brackets.

**Table 1b.** Summary of results. Memory testing ( $n = 129$ ).

	Memory testing				
	Comprehension		Usability		
Symbol description	Symbol	correct answer f (%)		1. correct answer f (%)	2. correct answer f (%)
<b>Symbol 2</b> Double sterile barrier system		124 (96%)		74 (57%)	100 (78%)
<b>Symbol 4</b> Single sterile barrier system inside protective packaging		120 (93%)		81 (63%)	108 (84%)


Note. Pass/fail criteria defined by ISO 27185:2012(E), clause C.4. **a) 66 % to 100 % correct: validated as easily understandable** by the survey group; **b) 50 % to 65 % correct: validated as somewhat understandable** by the survey group; **c) Below 50 % correct: poor understanding**; requires re-evaluation of design for better understanding by the user group, or indicates a necessity to learn a symbol's meaning.

**Table 1c.** Description of acceptance criteria and color code.

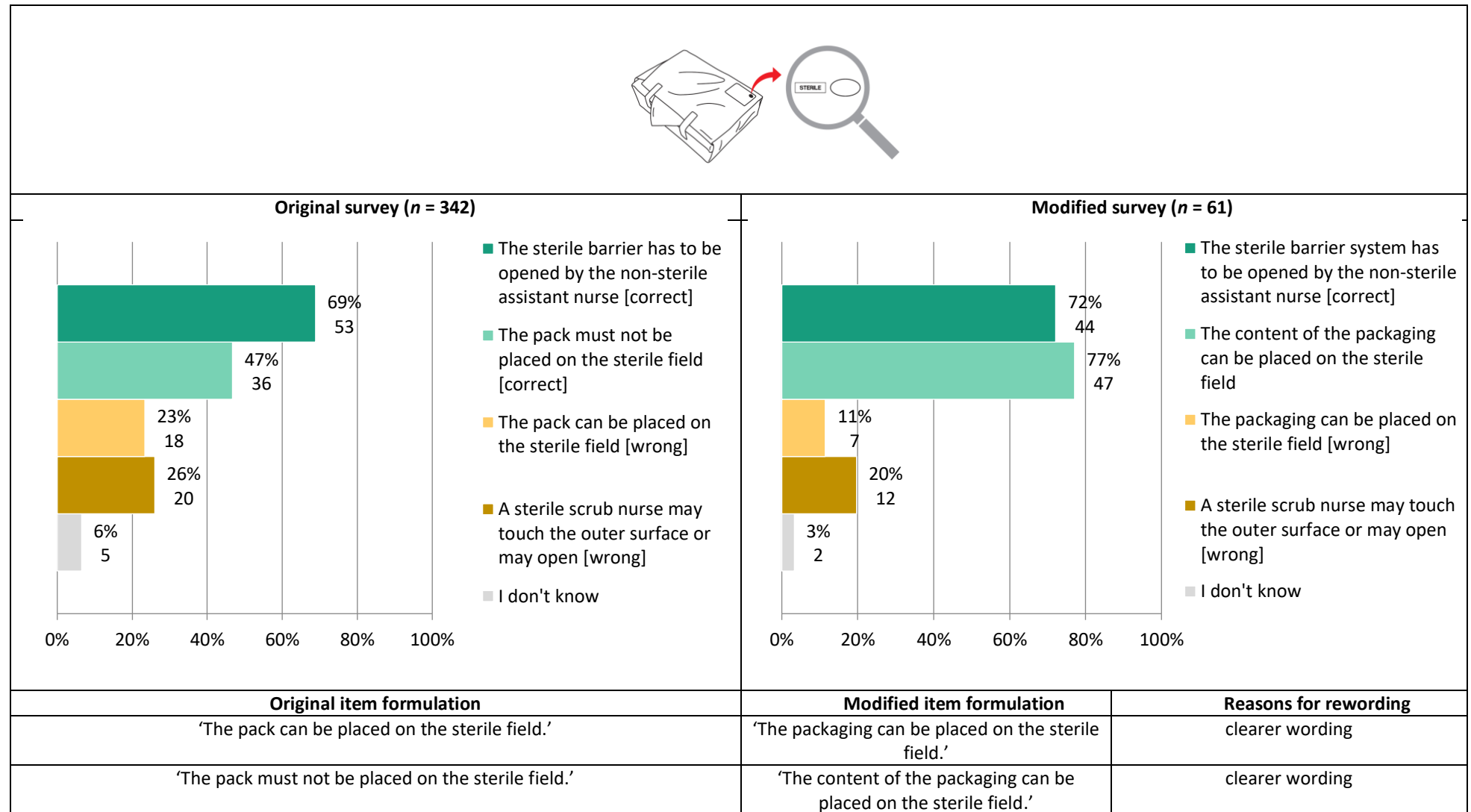
Description of Acceptance Criteria	Color code and percentage of correct answers
validated as easily understandable	66 % to 100 % correct answers
validated as somewhat understandable	50 % to 65 % correct answers
poor understanding Requires re-evaluation of design for better understanding by the user group, or indicates a necessity to learn a symbol's meaning.	Below 50 % correct answers

Note. Pass/fail criteria defined by ISO 27185:2012(E), clause C.4.


**Table 1d.** Comparison of the results of the original and modified versions of the survey for symbol 1. Comprehension testing.

		
Original survey (n = 342)	Modified survey (n = 61)	
<ul style="list-style-type: none"> <li><span style="color: #e69d00;">■</span> It is a double layer packaging configuration. [wrong]</li> <li><span style="color: #1f9e8d;">■</span> It is a single layer packaging configuration. [correct]</li> <li><span style="color: #a6a6a6;">■</span> I don't know.</li> <li><span style="color: #e69d00;">■</span> The packaging is a protective packaging layer. [wrong]</li> </ul>	<ul style="list-style-type: none"> <li><span style="color: #e69d00;">■</span> The packaging is a protective packaging layer without microbial barrier. [wrong]</li> <li><span style="color: #e69d00;">■</span> The packaging is not a validated sterile barrier system. [wrong]</li> <li><span style="color: #a6a6a6;">■</span> I don't know.</li> <li><span style="color: #1f9e8d;">■</span> The packaging is a validated sterile barrier system. [correct]</li> </ul>	
Original item formulation	Modified item formulation	Reasons for rewording
‘It is a double layer packaging configuration.’	‘The packaging is a protective packaging layer without microbial barrier.’	Symbol ‘sterile’ as well as symbol 1 shows a layer - misinterpretation as a double layer might be possible.
‘The packaging is not a protective packaging layer.’	‘The packaging is not a validated sterile barrier system.’	Conscious processing of what had previously been learned.
‘It is a single layer packaging configuration.’	‘The packaging is a validated sterile barrier system.’	The same text that participants have learned before was used.

**Table 1e.** Comparison of the results of the original and modified versions of the survey for symbol 1. Usability testing.



**Table 1f.** Comparison of the results of the original and modified versions of the survey for symbol 3. Comprehension testing.

		
Original survey (n = 342)	Modified survey (n = 61)	
<ul style="list-style-type: none"> <li><span style="color: green;">■</span> The inner protective packaging layer is sterile. [correct]</li> <li><span style="color: gold;">■</span> The inner packaging layer is a validated sterile barrier system. [wrong]</li> <li><span style="color: grey;">■</span> I don't know.</li> <li><span style="color: orange;">■</span> It is a single layer packaging configuration. [wrong]</li> </ul>	<ul style="list-style-type: none"> <li><span style="color: green;">■</span> The inner layer is a protective packaging layer. [correct]</li> <li><span style="color: gold;">■</span> The inner layer is a validated sterile barrier system. [wrong]</li> <li><span style="color: grey;">■</span> I don't know.</li> <li><span style="color: orange;">■</span> The outer layer is a protective packaging layer. [wrong]</li> </ul>	
Original item formulation	Modified item formulation	Reasons for rewording
‘The inner protective packaging layer is sterile.’	‘The inner layer is a protective packaging layer without microbial barrier.’	The same text that participants have learned before was used.
‘The inner packaging layer is a validated sterile barrier system.’	The inner layer is a validated sterile barrier system.’	clearer wording
‘It is a single layer packaging configuration.’	‘The outer layer is a protective layer without microbial barrier.’	clearer wording

**Table 1g.** Comparison of the results of the original and modified versions of the survey for symbol 3. Usability testing.

