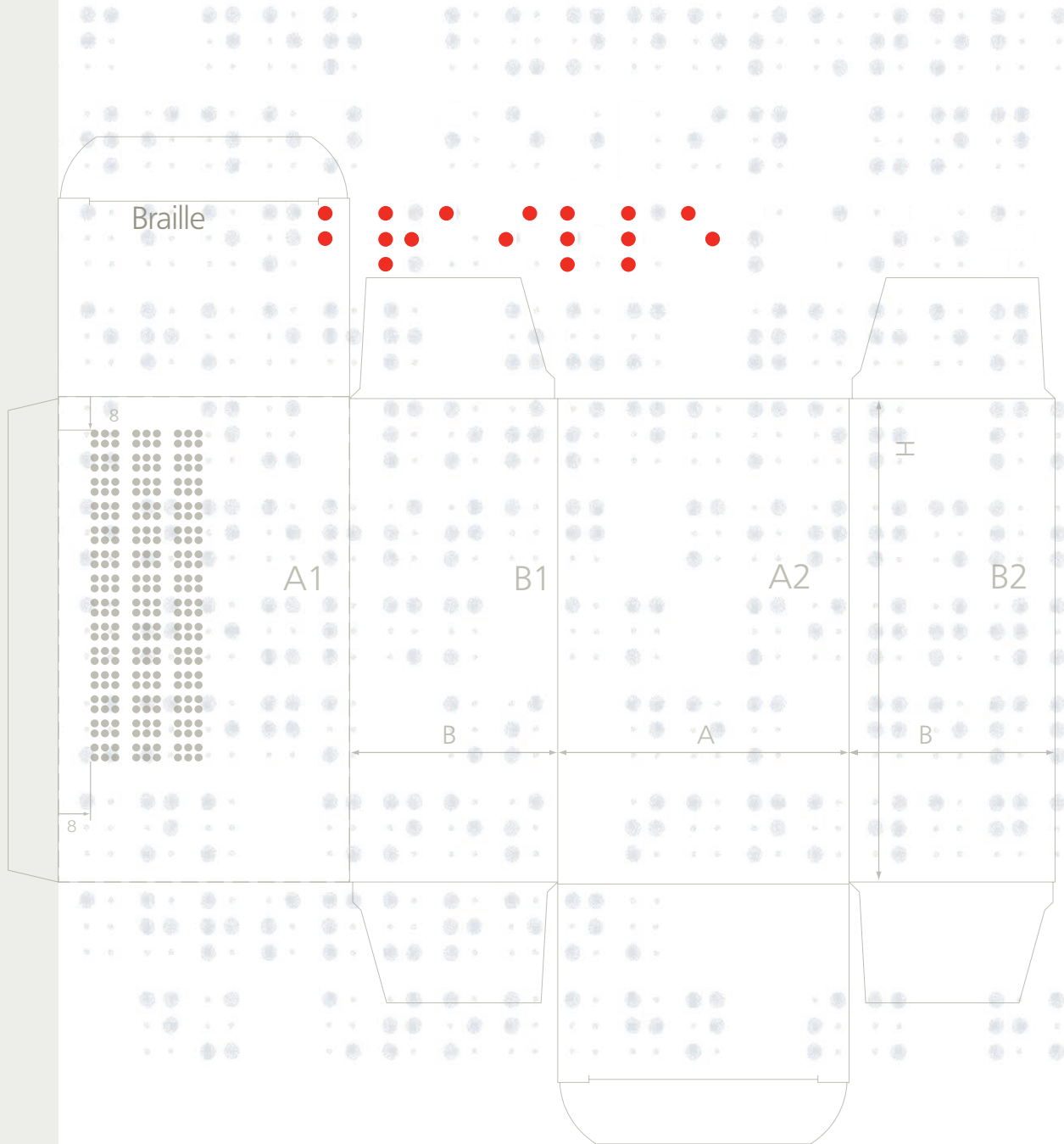


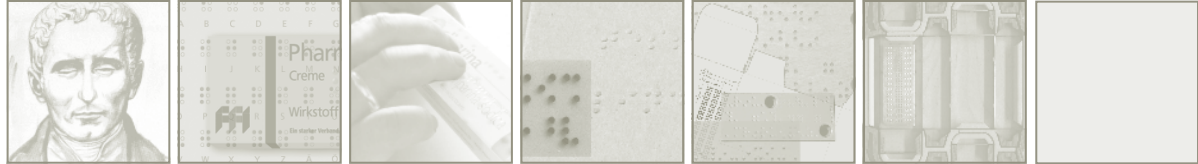
Technical guidelines

Braille

in the folding carton production

Focussed on the dot...





Preface

1

History, braille in the folding carton production

Basic grid and standard alphabet

2

Letters, punctuation marks, numbers

Standardisation of the braille

3

Font, dot diameters, dot distances, character and line spacing, height of the embossing

Technical requirements

4

Functional and optical characteristics, material selection

Fabrication

5.0

Basic pattern, implementation in the production, amount of text

5.1

5.2

Target course, quality assurance

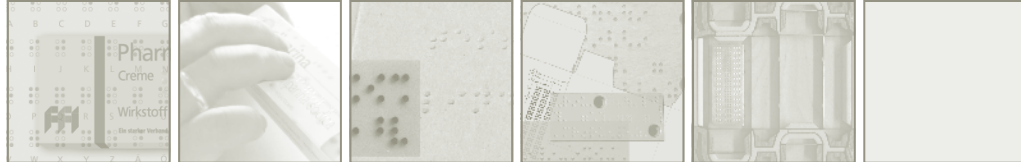
6.0

6.1

Conclusion

7





The legal necessity to emboss the denomination of the drug in braille on folding cartons is determined by the European drug legislation (guideline 2001/83/EC-human codex).

This provision has to be transferred into national law by all member countries of the European Union. In Germany, this has already been accomplished by the German drug law (§10 paragraph 1b AMG).

In the year 1825 **Louis Braille (1809-1852)** from France had invented a braille-system, with which the alphabet as well as punctuation marks and numbers of seeing people could be presented in a palpable form. This braille-system has established itself internationally and formed the basic braille for all languages.

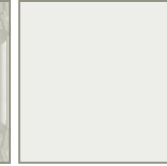
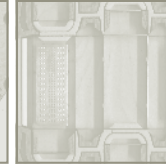
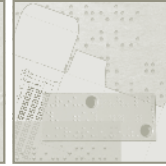
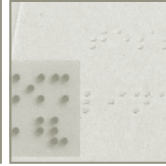
For the German-speaking areas the "Braille commission of the German speaking countries" has defined the rules for Braille. The system which has been agreed upon in 1998 is available in written form¹⁾. Mathematic and other braille rules have been published in further systematics. World-wide there are different braille fonts. They are different basically because of the usage of special characters.

This guideline is a code of practice for the standardised fabrication of braille on folding cartons. It was published by the "German trade organisation of folding carton industry" (Fachverband Faltschachtel-Industrie/FFI) in co-operation with the "German federal association of Pharmacy" (Bundesverband der Pharmazeutischen Industrie/BPI), the "German federal association of drug producers" (Bundesverband der Arzneimittelhersteller/BAH), the "German Generics association" (Deutscher Generikaverband), the "Association of researching drug producers" (Verband der forschenden Arzneimittelhersteller/VFA). In doing so, rules have been developed which can be understood as a standard for the technical implementation of the braille as well as a recommendation for a secure and unobstructed sequence of steps from the creation of the artwork files up to the delivery of the folding cartons.

Especially because of technical or organisational reasons, agreements between customers and producers of folding cartons which deviate from this guideline may be valid. These agreements should only be agreed upon in order to process exceptions to the rule or due to of extraordinary circumstances, because usually they may be associated with higher efforts and/or costs.

¹⁾ "The System of the German braille" (Das System der Deutschen Blindenschrift), 3rd edition, published by the "German Study Institute for the Blind" (Deutsche Blindenstudienanstalt e. V.), Marburg, 2001, ISBN: 3-89642-011-9





The basic grid of the braille sign consists of 6 dots, which are positioned like the “six” of a dice – in two upright lines of 3 dots each, side by side. They are numbered as follows:

Top left dot 1,		1 ● ● 4
underneath dots 2 and 3,		2 ● ● 5
top right dot 4,		3 ● ● 6
underneath dots 5 and 6	Basic form	

From the 6 dots of the basic form 63 different signs can be created. The standard-alphabet of the “German Study institute for the blind” (Deutsche Blindenstudienanstalt) is agreed upon as allegation. Rules for hyphenation are applied as in regular type, i. e. with hyphenation lines. The reading direction of the braille is the same as the regular type.

Letters

A	B	C	D	E	F	G	H	I	J	K	L	M
N	O	P	Q	R	S	T	U	V	W	X	Y	Z

Numbers

Number sign	1	2	3	4	5	6	7	8	9	0

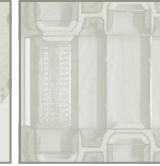
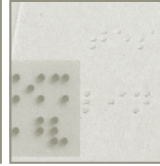
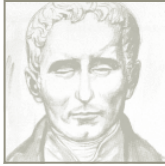
Internationally standardised special characters

,	;	:	!

The most important German punctuation marks and special characters

Ä	Ö	Ü	ß	ST	CH	SCH	IE	AU	EU	EI	ÄU	.
?	“	”	-	'	*	/	()	%				





Examples of nationally different special characters in Europe

Spain				
Italy				
Germany				
Great Britain				

Hint:

When indicating numbers, the “number sign” has to be set additionally in front of the numbers. After the numbers a blank has to be set.

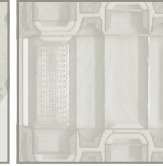
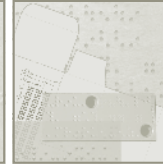
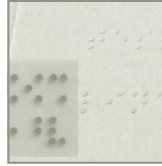
Example:

	1	2	5		M	G
Number sign				space		

Dot by dot...



¹⁾ Usually this indication of the braille is not used on folding boxes in Germany.



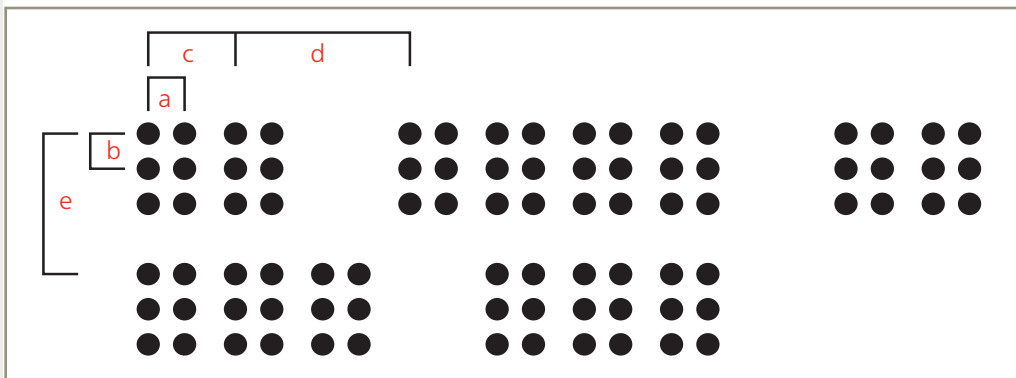
Important dots...

Standardisation of the braille:

The recommendation of the "German Study institute for the blind" (Deutsche Blindenstudienanstalt) Marburg is agreed upon as guideline for a standardised fabrication of braille on folding cartons:

- As a wish of the associations of blind and visually handicapped people the so-called "full type" is used for braille.
- The dot and character dimension "Marburg Medium" today is the most common used, published presentation for blind people. As a consequence of this we use "Marburg Medium" as standard measure.
- The dot diameter is 1.6 mm (basic diameter) = diameter on the female part/matrix and on the printing film/printing file.
- The dot diameter is exactly 2.5 mm (from dot centre to dot centre).
- The character spacing amounts to 6.0 mm (from dot centre to dot centre).
- The line spacing is 10.0 mm with a tolerance of +0.0 mm/-0.1 mm.
- Allusion to the height of the embossing on the surface of the folding carton:
Since measuring the height of the embossing is very difficult because of the back-formation of the embossing, we recommend to verify the height of the embossing visually. The upper level of tolerance is reached when the surface of the folding carton starts to break.

Dot diameters (Marburg Medium)

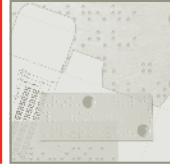


Dimensions: a = 2.5 mm c = 6.0 mm between 2 letters of one word
 b = 2.5 mm d = 12.0 mm hyphenation
 e = 10.0 mm +0.0 mm/-0.1 mm line spacing

Labelling (plain text line) for the pattern for embossing

The braille text has also to be set in plain text outside the die-line. Reading direction and hyphenation of braille text and plain text have to match each other.





Technical requirements

The dots of the braille have to be palpable. One has to remember that in this connection there are different criteria between seeing and blind people. For blind people it is optimal to have a very strong embossing. For seeing people the legibility and the optical characteristic are disturbed, when the carton surface is broken.

Dot diagram...



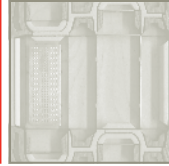
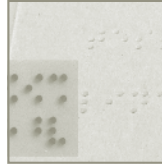
The target is to reach a compromise between functionality and optical characteristics. After the embossing, the idealistically formed dot is exposed to mechanical and climatic influences in the subsequent processes. One has always to calculate a slightly back-formation – depending on the factors of influence.

Material selection

Generally primary and secondary fibre cartons can be used.

One has also to remember that it is not possible to prevent different heights of embossing in the same folding carton or the same lot of production.

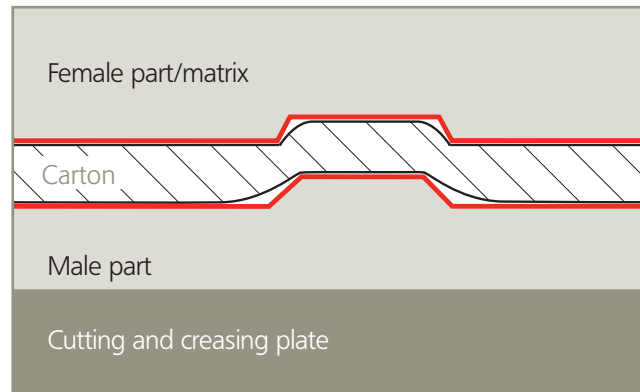




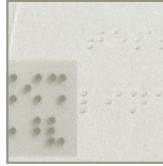
Fabrication

The contents of this guideline is the fabrication of the braille following the latest technical standard, i. e. cutting, creasing and embossing in one step of production in the flat bed cutting and creasing machine. Generally braille can be placed on every main side of the folding carton (A1, B1, A2, B2). For technical reasons braille can only be put on one main side of the carton in a reasonable way.

Embossing the braille



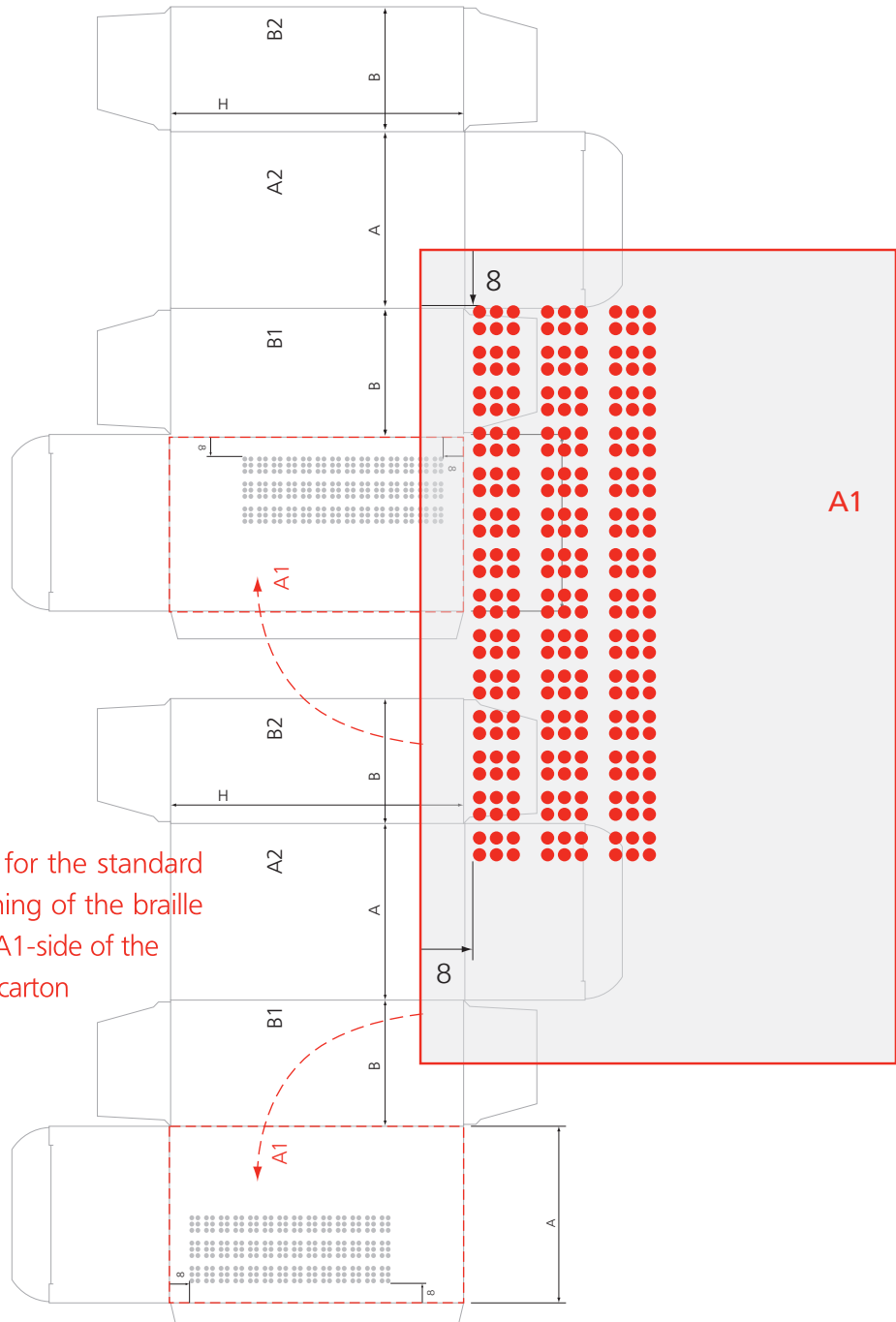
The goal is to create a product-neutral cutting and creasing tool, i. e. only one cutting and creasing tool should be used for all folding cartons of one dimension or blank respectively. In order to reach this target, the braille should be placed on only one (the biggest) main side of the folding carton in accordance with the subsequent maximum possible matrix. In doing so it is possible to reach the least adjustments - also under cost aspects - to the individual product and the set-up process. The braille text will be embossed by the product-individual male part.



Basic scheme

The distance between the place for embossing and the middle of cutting and creasing lines has to be 8 mm (from the end of the dot). The positioning and the universal matrix on the pre-defined side of the folding carton, e. g. A1, has to be laid down once by the customer. There will be no braille on places that contain Barcodes (EAN/PZN) as well as on places where labels/Bollini and perforations are applied on the folding carton.

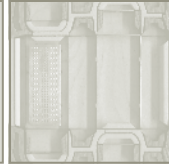
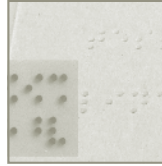
Fixed points...



Pattern for the standard positioning of the braille on the A1-side of the folding carton



If this standardisation is fulfilled, only the lowest costs for tools and set-up times emerge. If an individual cutting and creasing tool is desired, substantial additional costs emerge.



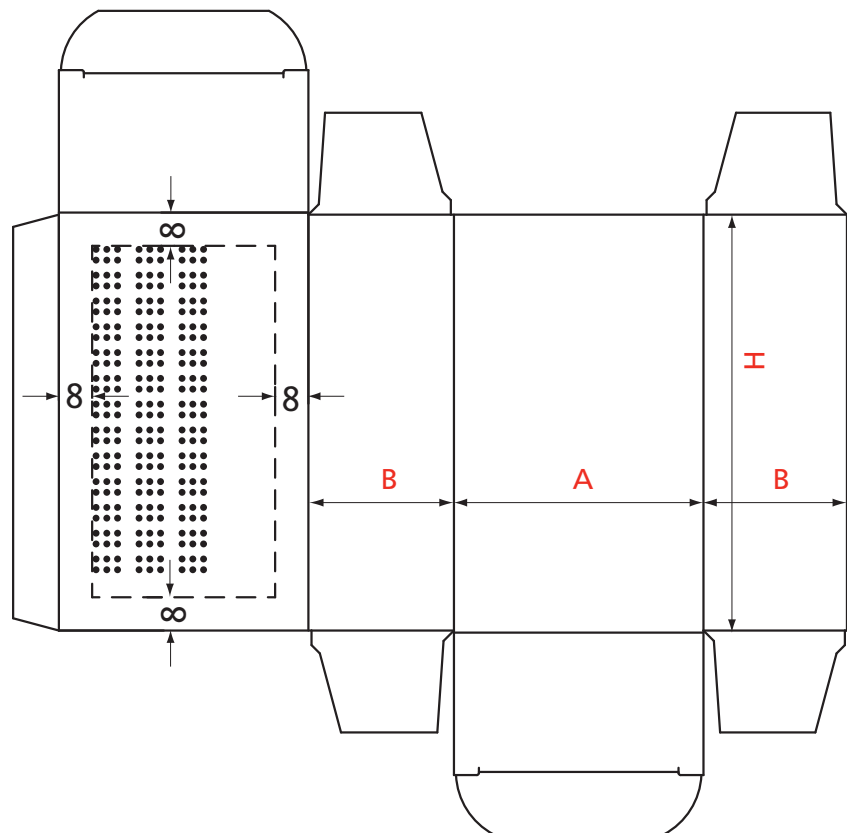
Amount of text

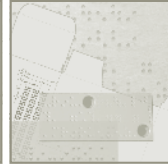
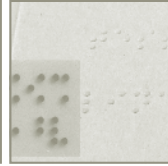
The number of available characters and lines for the braille to be embossed is defined by the dimensions of the folding carton.

Number of braille lines on a main side of the folding carton			
1	2	3	4
22,6	32,6	42,6	52,6
Dimension A/B (minimum) of the folding carton in mm			

Number of braille characters per braille line														
6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
50,1	56,1	62,1	68,1	74,1	80,1	86,1	92,1	98,1	104,1	110,1	116,1	122,1	128,1	134,1
Dimension H (minimum) of the folding carton in mm														

Fixed points...





Implementation of the braille in artwork files and print approvals

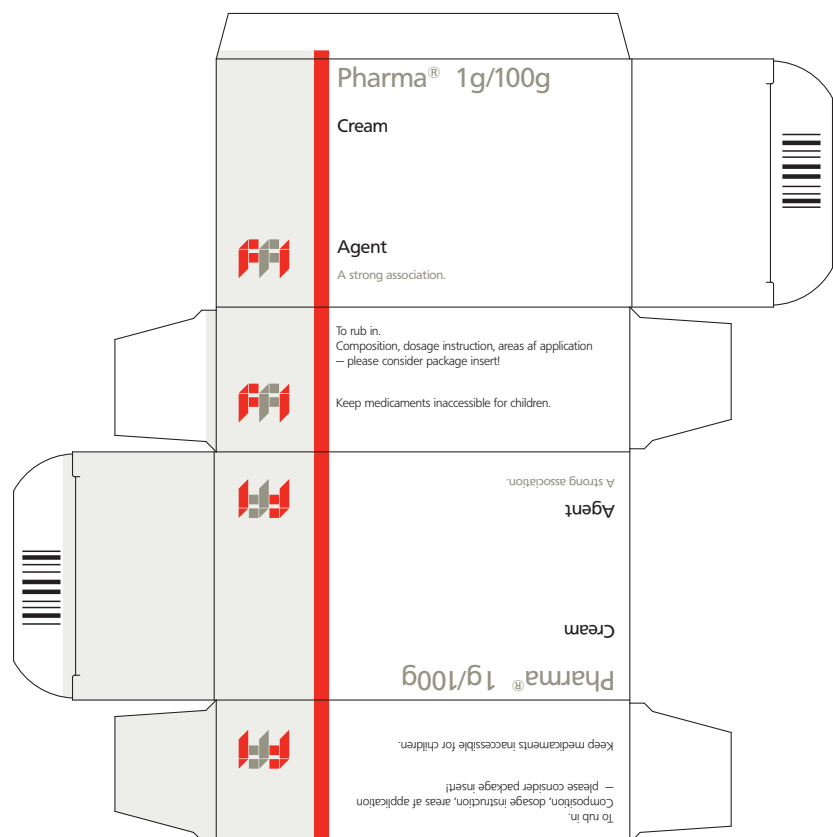
The braille has to be laid down in an extra layer in the artwork file. The colour of the braille must not be used in any other place in the document. The braille in the artwork file, in the print approval, in the cutting and creasing tool and in the produced folding carton must match exactly. The braille text is also set as plain text outside the die-line.

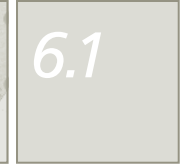
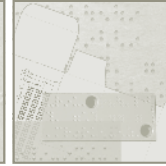
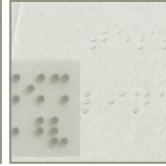
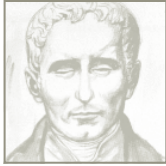
In case of artwork files that have been supplied the braille dots are binding. The braille text and the braille dots must be clearly legible in the documents from the customer. The digital die-line with embedded universal matrix and the subsequent exchange of the printing files has to be clarified between the customer/artwork agency and the folding carton producer. If necessary, the universal matrix for the artwork creation has to be called off from the folding carton producer.

In order to assure an optimal proofing of the braille over all steps of production, valid print approvals for folding cartons with braille must be set up as follows.

The first page contains all colours except for the braille. This page is used for approving the print.

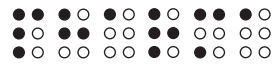
Print approval page 1





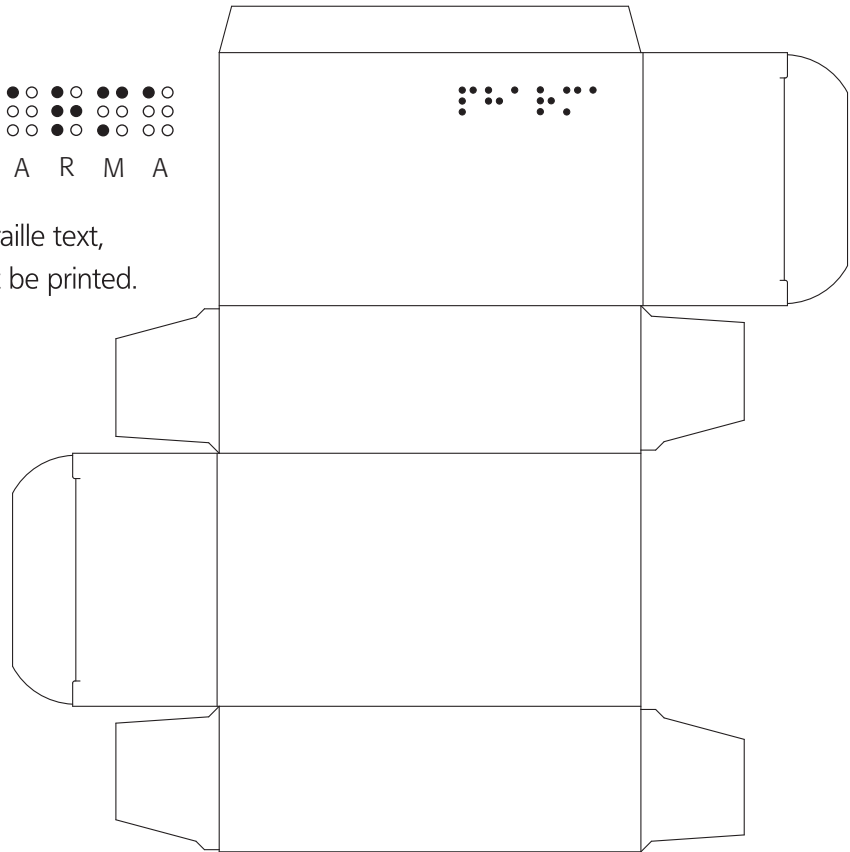
The second page contains the braille print with the die-line and the braille text as plain text.

Braille approval page 2



P H A R M A

Only braille text,
will not be printed.



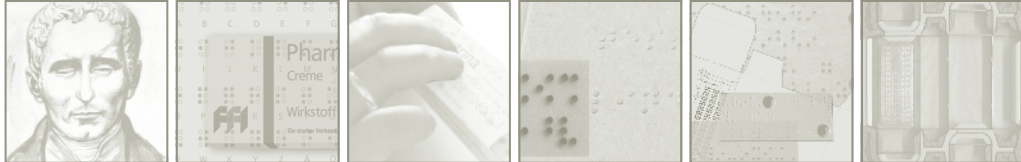
The key point...

Proofing of embossing – Quality assurance agreement with definition of the responsibilities

- In the documents presented by the customer the braille has to be clearly legible.
- The artwork files as approved by the customer are the base for the proofing process.
- All embossed printing must be verified continuously by using proofing plans.

It is reasonable to make or to amend a quality assurance agreement between customer and folding carton producer.





Conclusion: Standardisation reduces costs and brings security

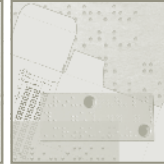
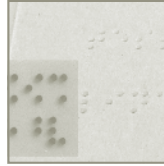
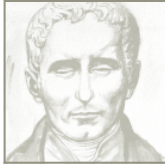
The intended process optimisation requires clear criteria and guidelines for:

- standardisation of the fonts
- standardisation of the positioning
- standardisation of the folding carton formats
- proper forming of the braille dots
- integrated testing and controlling

Under consideration of date and cost aspects it is realised, secure and efficient production processes are more than ever important.

The implementation of the defaults of the drug law can only be achieved economically by exchanging information and with competence and knowledge. The co-operation of all enterprises is crucial for the success.

This recommendation has been created by the companies, Edelman, Faller, Kroha and Theis as well as the branch organisations BPI, Deutscher Generikaverband and VFA in the working circle braille on behalf of the FFI.



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