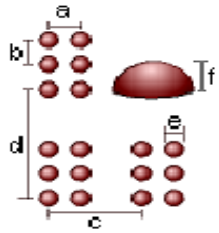
FAG BRAI³ dot Checker – some background information:

by Lukas Pescoller, 13.04.2010

Braille Labeling of Medicines: Meeting Directive 2004/27/EC

A new European Directive places obligations on the marketing holder of medicinal products for human use concerning the provision of Braille labels. The implementation date is 30th October 2005 for medicinal products approved after this date. The directive applies to all medicinal products starting with 30th October 2010. For the user, the key items on the label are product name, dosage and expiry date.

Braille characters consist of one to six embossed dots which can have 64 different configurations. There are various standards for the size, the spacing and the height of the dots. Most Braille producers in the UK use the Standard American dimensions rather than the English Interpoint dimensions. The EC Guidance recommends the use of Marburg Medium Braille cell size.



A significant problem with Braille is the lack of redundancy in the system. This means that a single not recognized dot can completely change the meaning. This has implications for Braille medicine labels since a change in meaning could have serious consequences for the user.

Braille is usually produced by embossing dots on long-fibre paper. To lessen the risk of dots becoming damaged, the traditional approach has been to spray the back of the paper with shellac. An alternative is to emboss the Braille on plastic sheets but most computer-controlled Braille embossers output on paper not plastic.
The embossing technology destroys the structure of the paper and therefore the readability of the Braille text over time is limited. A new ink jet like technology is now available to print directly Braille labels with dynamic content. This is important especially when printing expire dates. Quickly drying Ink with high viscosity is applied on any possible substrate (paper, plastic, thick plastic, wood, etc), forming a Braille dot.

A Study of Legible Braille Patterns on Capsule Paper: Diameters of Braille Dots and Their Interspaces on Original Ink-printed Paper

WATANABE Tetsuya and OOUCHI Susumu have studied the implications of Braille dot characteristics to the readability of the text in terms of speed and errors. The outcome of the study shows a strong implication of dot diameter, inter dot space and dot height to the readability of the text. In addition the dot shape has a considerable impact on the readability of the text: high, un-sharp dots could be less readable than small-sharp dots.

Dot height measurement according to ECMA – European Carton Makers Association

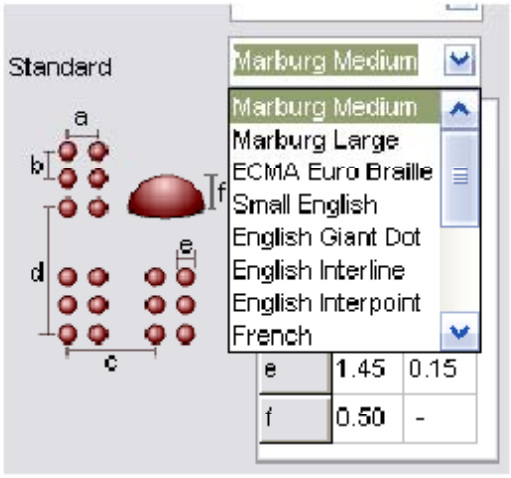
POSITION PAPER Braille on medicinal packaging Submission to interested parties
September 2008

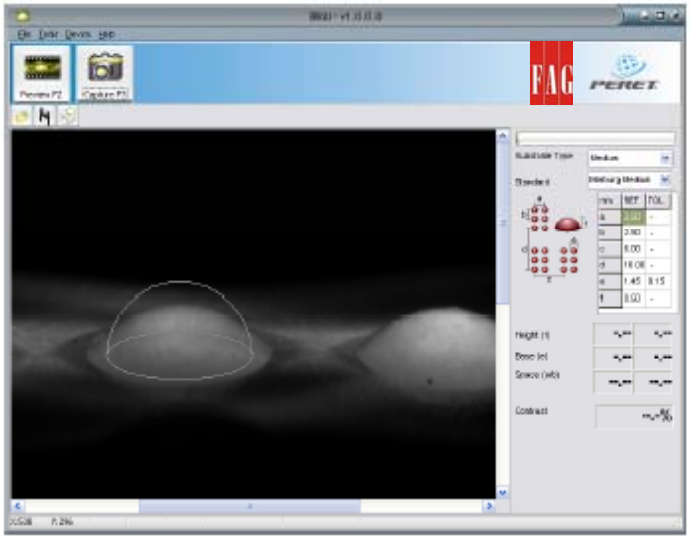
1: Braille cell dot height requirement of the existing draft CEN standard document:
In order to ensure that Braille readers can identify the name of the medicinal product, the Braille cell dot height measured on production samples prior to leaving the packaging (e. g. carton or label) manufacturer shall be:
a) For embossed materials the target Braille cell dot height shall be: 0.2 mm, with a minimum of 0.1 mm. The standard deviation shall be no higher than 0.025 mm.
b) For other Braille production methods, e. g. screen-printed labels, the target Braille cell dot height shall be: 0.2 mm, with a minimum of 0.16 mm. The standard deviation shall be no higher than 0.010 mm.
2: Braille cell dot height measuring requirement of the existing draft CEN standard document:
The number of samples and the method of measurement shall be agreed between the customer and supplier. The Braille cell dot height shall be measured across the Braille text in at least three places from cells containing at least three dots.

BRAI³ - the Braille Dot Shape & distance checker

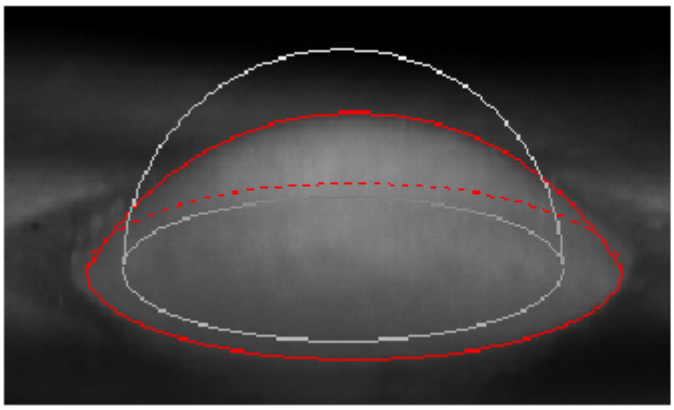
The study of WATANABE Tetsuya & OOUCHI Susumu shows, that a simple to use device is required, that enables Braille Label manufactures to control the dimensions and the shape of the produced dots in a quick and objective manner.
FAG Graphic Systems SA will present the BRAI³ Braille Dot Checker at IPEX. The product is composed of a handheld Sensor connected via USB2.0 to the PC and proper analysis Software. The FAG BRAI³ sensor can easily be positioned over a Braille character line with the help of a highlighted positioning line visible through a positioning Window.

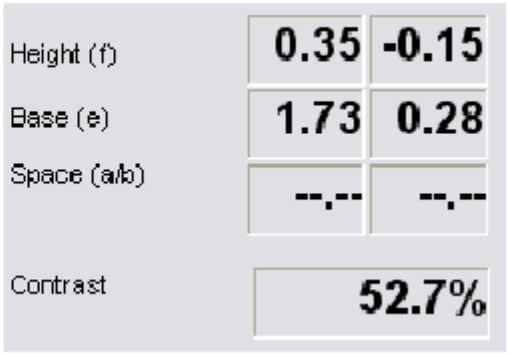
Once the Sensor is in correct position, a picture of the Braille line (3 dots) can be captured. The Braille Standard, that should be used to work with, can be selected from a database. The mouse pointer now automatically will draw a dot of the size according to the selected standard. The dot shape can be moved over the dots captured with the image by moving the mouse.





Move the mouse pointer over the centre of the Braille dot in the middle of the image and click the left mouse button.





The actual measured dot is highlighted with red lines and can be visually compared with the dot, expected by the selected standard. In addition the dot dimensions and differences to standard are calculated and displayed:
- Height and difference in dot height between actual and standard in mm
- Base diameter and difference between actual and standard in mm
- Contrast defined as roundness compared to a round half-ball of the same height. The contrast is the proper value to qualify the dot shape. The higher the contrast is the higher is the readability of the text.

In order to measure the inter dot space move the mouse pointer over the center of the next dot (left or right) and click the left mouse button.
The outline of the previously selected dot turns yellow. The new selected dot is measured and the height, base diameter and contrast are displayed. In addition the absolute inter dot space and its difference to the standard is displayed in mm

The software automatically checks the agreement of actual measurement (red outlined dot) to standard and displays the result as:

FAIL: more than 1 item is out of tolerance

WARNING: at least one item is out of tolerance

OK: all measurements are in tolerance

Statistics

The ECMA guidelines does recommend a measurement of the Braille cell dot height across the Braille text in at least three places from cells containing at least three dots. The standard deviation should be 0.025mm for embossed materials and 0.01 for other materials.
The BRAI³ software does support this with a statistic function. The actual measurement can easily be added to the statistics table and mean, range and standard deviation can be calculated.

Print Reports

The BRAI³ software supports the print of a report to document the quality of a production. The report can be configured. A company logo can be loaded. 2 Head lines and 3 bottom lines can be added to the report.