BREYE FDA 21 CFR Part 11 compliance

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FDA 21 CFR Part 11 Background

By 21 CFR Part 11 the FDA defines requirements for electronic devices creating and managing digital data used in the medical field. The data can be text, images, audio or video.

Whenever data created by the electronic device is delivered to FDA (f.e. 510(k)-Submission) or is presented in an FDA-Audit, the creation and modification of any data has to be documented. Any creation and modification activity need to be traced to a single user.

The BREYE Braille Dot Analyzer is used to create quality reports of Braille dots, printed or embossed on folding carton packaging, Labels, or any other cardboard material. The reports are created as digital PDFs including target references, tolerances, measurement data and images. The reports can be printed and manually signed or digitally signed by the user.

BREYE Software release offers the features to make the BREYE Braille Dot Analyzer FDA 21 CFR Part 11 compliant in terms of a closed system.

> *B §11.10 Controls for closed systems*
> *Persons who use closed systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and, when appropriate, the confidentiality of electronic records, and to ensure that the signer cannot readily repudiate the signed records as not genuine.*

The following chapters will explain, how the system can be used in compliance with FDA 21 CFR Part 11, as far as applicable.

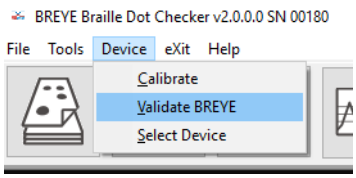
Validation to ensure accuracy, reliability, consistent intended performance

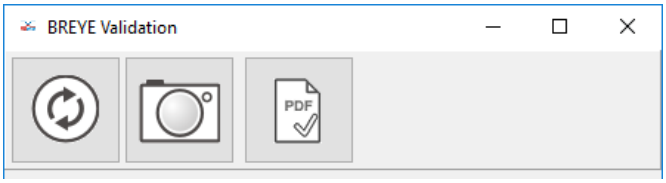
> *B §11.10 (a) Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.*

The BREYE can be validated using the BREYE TARGET reference. The BREYE TARGET reference is mechanically stable and can be used for at least 2 years.

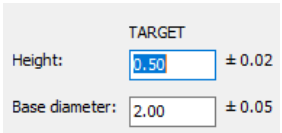


The BREYE Software features a Validation procedure that can be accessed from the main menu

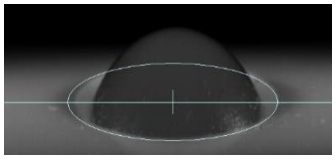




Insert the target height and base diameter as printed on the BREYE TARGET.




Click the Preview button to set the device parameters for validation and run a live image in the main window. Position the BREYE using the blue ellipse as reference



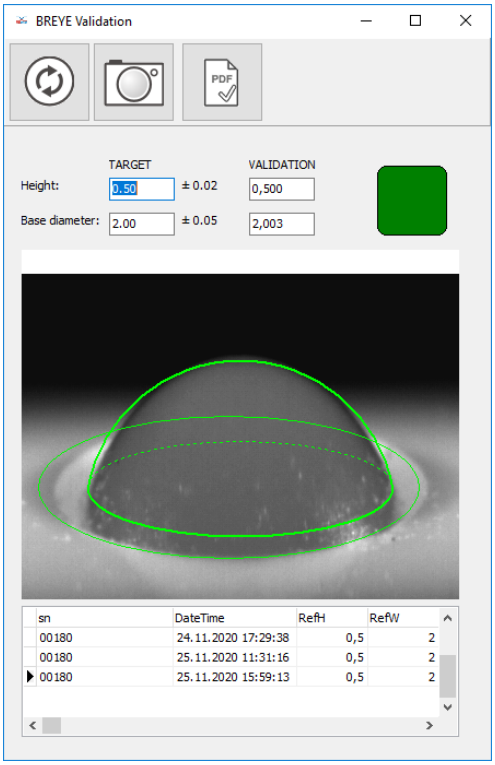

Click the capture button to capture an image and to calculate the dimensions of the BREYE TARGET reference.

The VALIDATION dimensions are calculated automatically. The VALIDATION numbers are compared with the reference target numbers and if in tolerance, there will be displayed a green flag.

If slightly out of tolerance, such as the mis-calibration is very small, the operator gets prompt to recalibrate the device. If the VALIDATION is totally out of tolerance, the calibration at the manufacturing location or service center is recommended.



Click the PDF Icon to create a Validation report. The validation result and date will be added to permanently to the validation database. The regularity of validation can be traced. The PDF report is automatically saved and can be printed.





Create copies in human readable form suitable for inspection

> *B §11.10 (b) The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the agency.*

The BREYE system creates any report in PDF form, which does fulfill this requirement.

Protection of records

> *B §11.10 (c) Protection of records to enable their accurate and ready retrieval throughout the records retention period.*

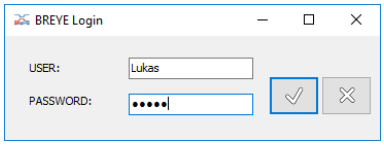
As many companies in this area are using their own backup IT-Systems, the protection of records can be achieved by simply creating backups of the PDF reports created and saved in sub-folders of the installation directory. In order to guarantee the completeness, any creation of a report is documented in the user log database, that's an integral part of the BREYEv2.x system.

Secure and traceable access to the system

B §11.10 (d) Limited system access to authorized individuals.

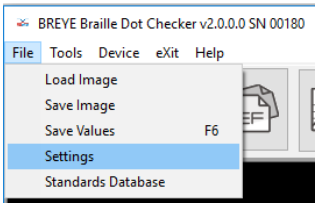
The FDA 21 CFR Part 11 compliance requires that only authorized, trained, approved users can access the system and create measurement data and reports.

The BREYE features a User database, such as whenever the software is started, the user is prompt to login.



Only registered users can login and use the device. After installation the list of registered users is empty and the login is performed automatically with superuser rights. The BREYE now should be set up to work with registered users only.

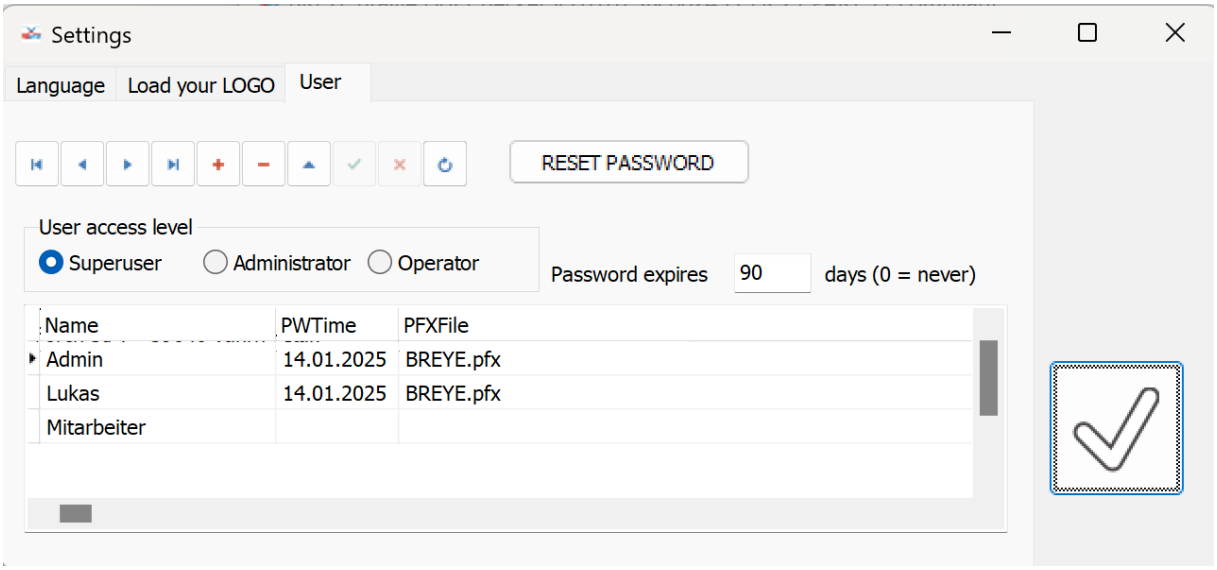
Open the settings window by selecting the settings menu item from the main menu.



Select the USER Page of the settings window and insert the list of registered users into the database.

B §11.10 (g) Use of authority checks to ensure that only authorized individuals can use the system, …, access the operation or computer system input or output device, alter a record, or perform the operation at hand.

Any user has to be qualified as superuser or Administrator or Operator status. The last insertion or modification of the time is stored in the database. In addition a pfx file can be added for digital signature (typically located in a protected space of the company network).



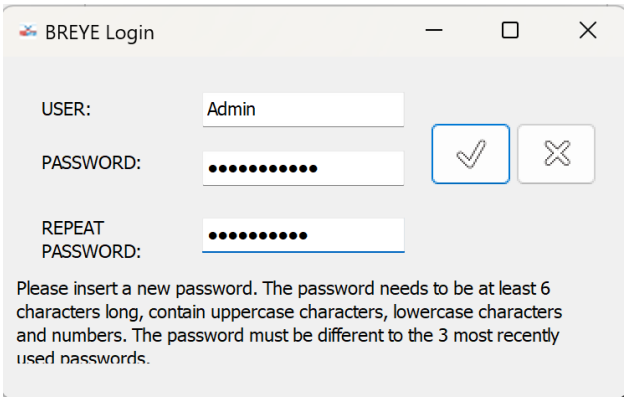
There can be registered as many users as required. Register a separate user for any operator, that should have access to the system.

In order to register a new user, change or delete a password, or to change the user qualification, the current user needs to have superuser qualification TRUE.

The following functions are reserved to the superuser

- Register new users, change or delete passwords, change user rights
- Add, delete or modify references and tolerances
- Perform a system validation

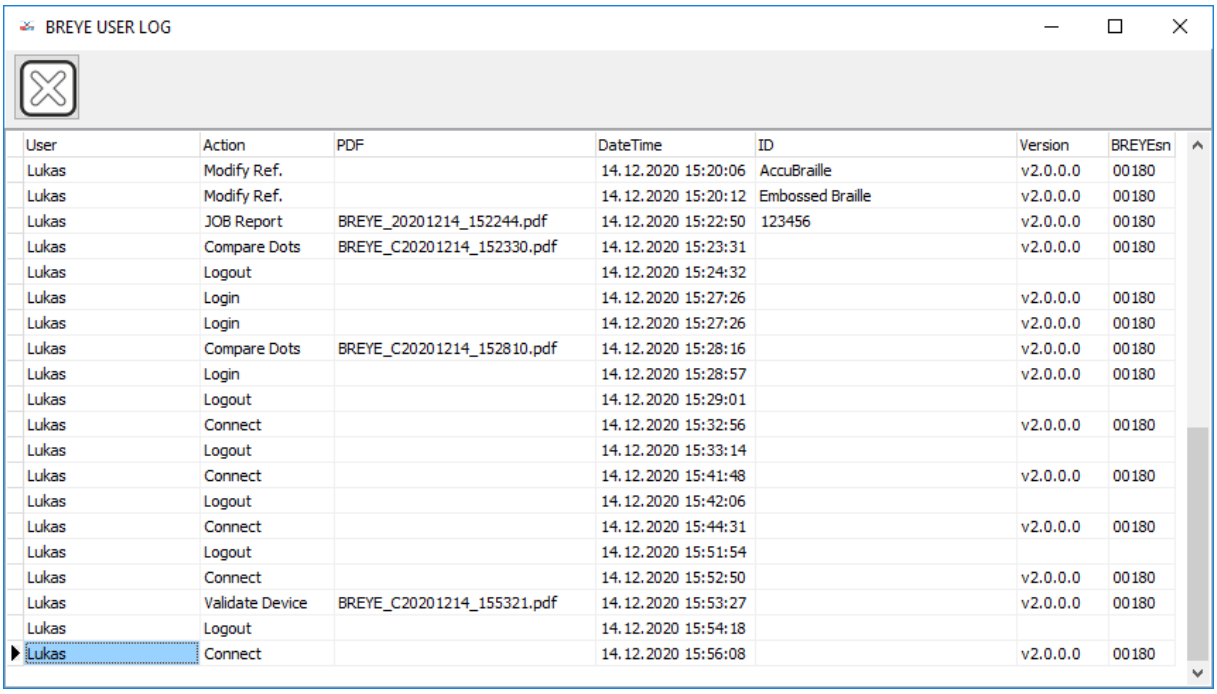
At the very first access or if the password has expired, or deleted the password has to be inserted fulfilling a set of requirements described in the password insertion window



Access and Data collection Log by user

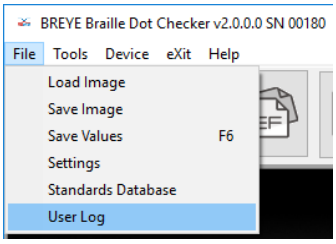
> *B §11.10 (e) Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records.*

Any data collection action performed by a user will be stored in a LOG database.



User	Action	PDF	DateTime	ID	Version	BREYEsn
Lukas	Modify Ref.		14.12.2020 15:20:06	AccuBraille	v2.0.0.0	00180
Lukas	Modify Ref.		14.12.2020 15:20:12	Embossed Braille	v2.0.0.0	00180
Lukas	JOB Report	BREYE_20201214_152244.pdf	14.12.2020 15:22:50	123456	v2.0.0.0	00180
Lukas	Compare Dots	BREYE_C20201214_152330.pdf	14.12.2020 15:23:31		v2.0.0.0	00180
Lukas	Logout		14.12.2020 15:24:32			
Lukas	Login		14.12.2020 15:27:26		v2.0.0.0	00180
Lukas	Login		14.12.2020 15:27:26		v2.0.0.0	00180
Lukas	Compare Dots	BREYE_C20201214_152810.pdf	14.12.2020 15:28:16		v2.0.0.0	00180
Lukas	Login		14.12.2020 15:28:57		v2.0.0.0	00180
Lukas	Logout		14.12.2020 15:29:01			
Lukas	Connect		14.12.2020 15:32:56		v2.0.0.0	00180
Lukas	Logout		14.12.2020 15:33:14			
Lukas	Connect		14.12.2020 15:41:48		v2.0.0.0	00180
Lukas	Logout		14.12.2020 15:42:06			
Lukas	Connect		14.12.2020 15:44:31		v2.0.0.0	00180
Lukas	Logout		14.12.2020 15:51:54			
Lukas	Connect		14.12.2020 15:52:50		v2.0.0.0	00180
Lukas	Validate Device	BREYE_C20201214_155321.pdf	14.12.2020 15:53:27		v2.0.0.0	00180
Lukas	Logout		14.12.2020 15:54:18			
Lukas	Connect		14.12.2020 15:56:08		v2.0.0.0	00180

The LOG is displayed clicking the Menu Item File/User Log



The following actions are added to the Log database:

- Login
- Logout
- Modification of users that are allowed to login
- Modification of References
- Creation of a Job Report (Production Quality Report)
- Creation of a Dot Compare Report
- Connecting another BREYE Braille Dot Analyzer with a different serial number
- Validation of the BREYE Dot Analyzer

Whenever it makes sense there is stored information in addition to the user's name, time stamp, Software version and BREYE serial number:

- PDF File name when a PDF Report is created (Validation, Job Report, Dot Compare report)
- JOB ID number if available
- Reference name in case a reference has been added or changed.

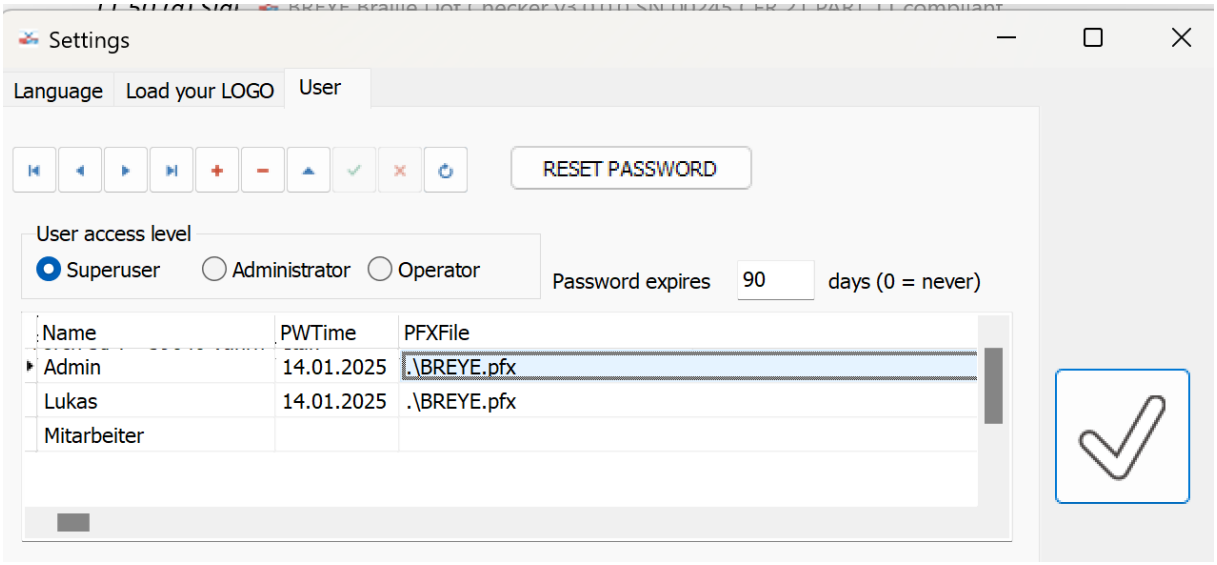
Electronic Signature

B §11.50 Signature manifestations.

11.50 (a) Signed electronic records shall contain information associated with the signing that clearly indicates all of the following:

1. *The printed name of the signer;*
2. *The date and time when the signature was executed; and*
3. *The meaning (such as review, approval, responsibility, or authorship) associated with the signature*

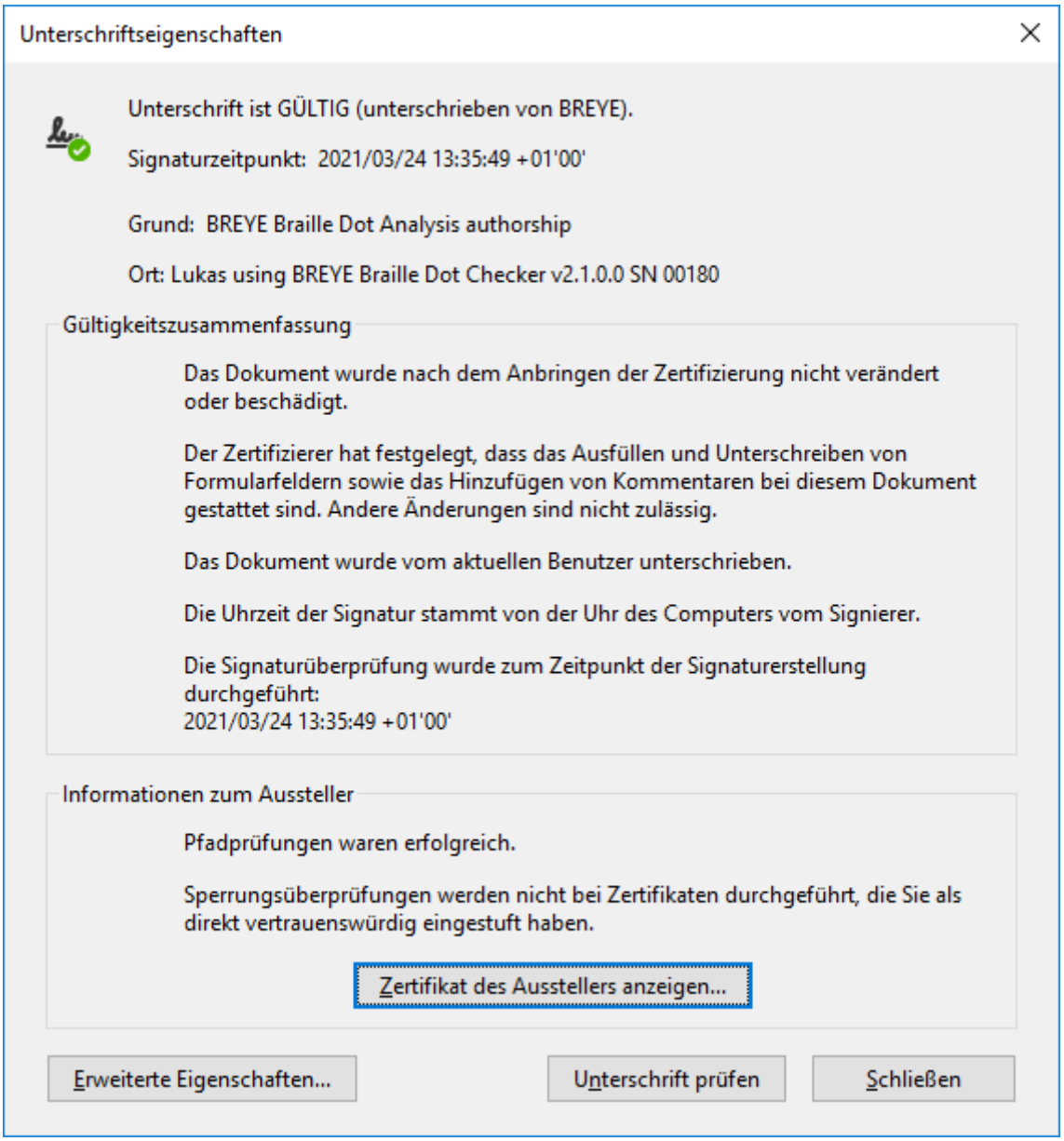
Any authorized operator can be linked to a signature certificate in PFX file format. In case the PFX file is available and valid, there will be added a digital signature to the Job quality report.



The signed PDF file is saved with the suffix <signed>.



Clicking the gray rectangle gives access to details of the signature. Example:



The PFX file has to be provided by the user of the system.

Traceability of critical actions

System validation

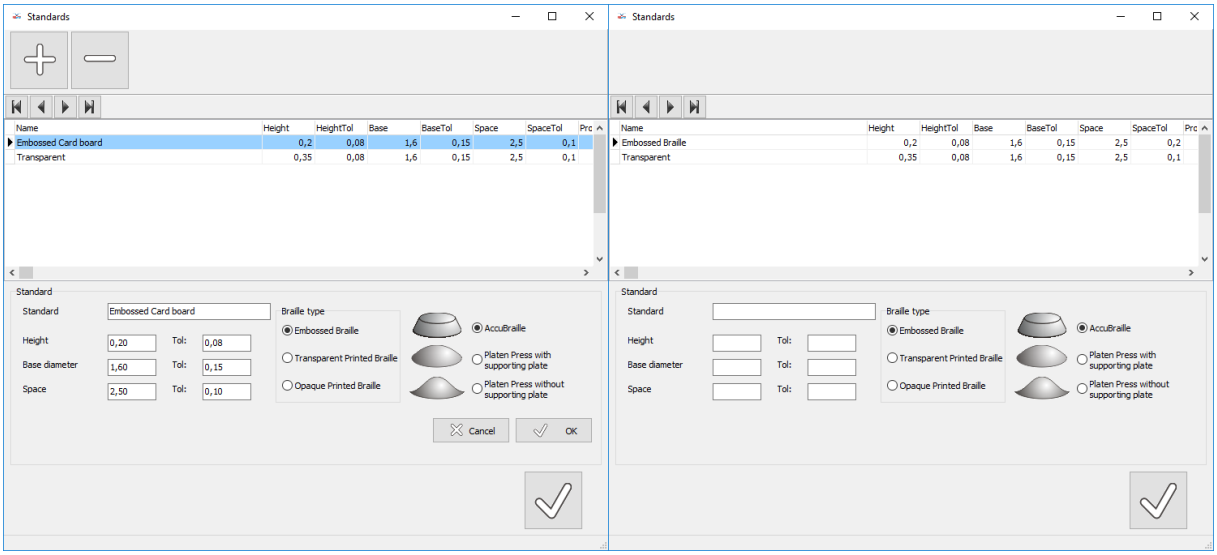
Whenever the system is validated the following data is stored in addition to the validation measurement values and references:

- date and time
- the BREYE user
- the computer Identification
- the Windows Login name
- the BREYE software version

If a calibration has been performed, the validation / calibration process is registered.

Reference database

All references are stored in an encrypted database. The only possibility to add, delete or modify references and tolerances is by means of the BREYE software with superuser login.



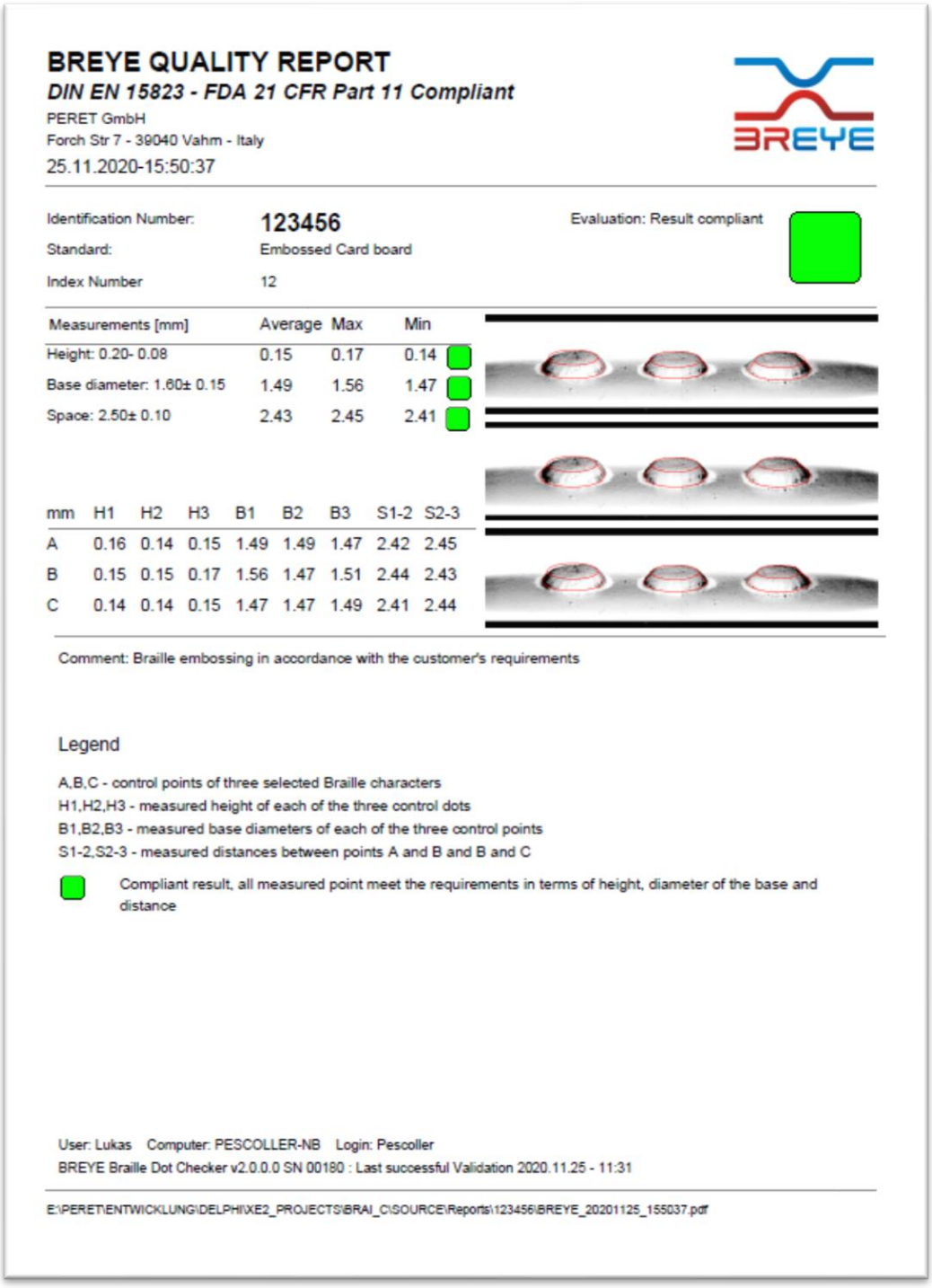
Superuser standard user

Any reference will contain in addition to target and tolerances also the following information:

- date and time of creation or last modification
- the BREYE user
- the computer Identification
- the Windows Login name

Production Quality Reports

Any production quality report will contain detailed information about when and by whom it has been created.



BREYE QUALITY REPORT

DIN EN 15823 - FDA 21 CFR Part 11 Compliant

PERET GmbH
Forch Str 7 - 39040 Vahm - Italy
25.11.2020-15:50:37

Identification Number: **123456**
Standard: Embossed Card board
Index Number 12

Evaluation: Result compliant

Measurements [mm]	Average	Max	Min
Height: 0.20- 0.08	0.15	0.17	0.14
Base diameter: 1.60± 0.15	1.49	1.56	1.47
Space: 2.50± 0.10	2.43	2.45	2.41

mm	H1	H2	H3	B1	B2	B3	S1-2	S2-3
A	0.16	0.14	0.15	1.49	1.49	1.47	2.42	2.45
B	0.15	0.15	0.17	1.56	1.47	1.51	2.44	2.43
C	0.14	0.14	0.15	1.47	1.47	1.49	2.41	2.44

Comment: Braille embossing in accordance with the customer's requirements

Legend

A,B,C - control points of three selected Braille characters
H1,H2,H3 - measured height of each of the three control dots
B1,B2,B3 - measured base diameters of each of the three control points
S1-2,S2-3 - measured distances between points A and B and B and C

Compliant result, all measured point meet the requirements in terms of height, diameter of the base and distance

User: Lukas Computer: PESCOLLER-NB Login: Pescoller
BREYE Braille Dot Checker v2.0.0.0 SN 00180 : Last successful Validation 2020.11.25 - 11:31

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