



BRASTER®

BRASTER®

USER MANUAL

Braster in-home breast examination system



READ CAREFULLY BEFORE USING THE DEVICE
KEEP FOR FUTURE REFERENCE

TABLE OF CONTENTS

GLOSSARY.....	3
IMPORTANT SAFETY INFORMATION.....	7
INTRODUCTION.....	8
1. DESCRIPTION AND INTENDED USE.....	9
1.1. DESCRIPTION.....	9
1.2. INTENDED USE.....	10
1.2.1. INDICATIONS.....	10
1.2.2. CONTRAINDICATIONS.....	10
2. OPERATING PRINCIPLES OF THE DEVICE.....	11
3. PACKAGE CONTENTS.....	11
4. OVERVIEW OF THE BRASTER DEVICE INTERFACE.....	12
5. MATRIX REPLACEMENT.....	15
6. DEVICE PREPARATION PRIOR TO EXAMINATION.....	17
6.1. PREPARATION OF THE BRASTER DEVICE PRIOR TO THE FIRST EXAMINATION.....	17



6.2.	PREPARATION OF THE BRASTER DEVICE PRIOR TO SUBSEQUENT EXMINATIONS	18
7.	EXMINATION	18
7.1.	IMPORTANT INFORMATION.....	18
7.2.	HOW TO PERFORM AN EXAMINATION.....	19
7.2.1.	PREPARATION	19
7.2.2.	QUESTIONS.....	19
7.2.3.	TURNING THE DEVICE ON/OFF	20
7.2.4.	DEVICE CONNECTION.....	20
7.2.4.1.	CONNECTING TO AN iOS DEVICE	22
7.2.4.2.	CONNECTING TO AN ANDROID DEVICE	22
7.2.5.	ACCLIMATIZATION	22
7.2.6.	MATRIX SELECTION	22
7.2.7.	EXAMINATION.....	23
7.2.8.	SENDING THE RESULTS TO THE TELEMEDICAL CENTER.....	30
8.	TROUBLESHOOTING THE MOBILE APP	31
9.	CHARGING	32
10.	SAFE OPERATION	32
11.	CLEANING AND MAINTENANCE	33
12.	SERVICING AND TECHNICAL SUPPORT.....	34
13.	DECLARATION OF CONFORMITY	34
14.	TECHNICAL AND OPERATIONAL SPECIFICATION OF THE DEVICE	35
15.	ADVERSE EVENT AND MEDICAL INCIDENTS.....	36
16.	FCC REGULATORY STATEMENT	36
17.	CANADIAN REGULATORY STATEMENT	37
18.	DISPOSAL.....	37



GLOSSARY

Analysis of additional test results – analysis of test results provided by the user, such as mammography, breast ultrasound, biopsy or blood tests. This analysis is carried out by a physician with reference to the results of thermographic imaging. The results are presented in the form of a document.

Braster Automatic Interpretation (Braster AI) – software responsible for analyzing the thermal images, along with the medical information provided by the user via the Braster Care mobile application.

Braster Device – a device composed of an image acquisition device and a thermographic matrix.

Braster E-shop – the store on www.braster.eu where examination packages and additional services rendered by BRASTER S.A. can be purchased. Please note that in some markets the Braster system as well as examination packages and other services can be purchased only in the e-store of a local distributor. You should be redirected from www.braster.eu to the e-store operating in your market.

Examination Package – a pre-paid package of automatic thermogram interpretations, encompassing a specific number of interpretations or limited in time.

Image Acquisition Device – the main device used in the examination. On the image acquisition device there is an ON/OFF button, a USB slot and an Examination Button. The device is also fitted with electronics and image acquisition system. The inner part of the device consists of a blackened chamber which ensures the appropriate quality of the thermographic images. The image acquisition device is an electronic device and is controlled by a mobile app.

Liquid Crystal Foil – an element of the liquid crystal matrix. The foil contains liquid crystals, which map thermal variations in the breast, creating color images (thermograms).

Liquid Crystal Thermographic Matrix (or liquid crystal matrix or thermographic matrix) – an element of the Braster device composed of a liquid crystal foil and a plastic clamp. The thermographic image is generated on the inner side of the foil surface, i.e. on the side facing inwards (towards the inside of the device). The matrix is an applied part of the device, which means that it comes into contact with the skin of the breast.

Mammography – a radiological examination of the breast, performed on women, in which a series of pictures of the mammary gland is taken using x-rays. With its ability to visualize a number



of characteristic changes and lesions, mammography is used for detection of breast cancer and other nipple pathologies before they manifest clinically. The efficacy of the examination is strictly connected with the structure of the breast, for that reason it is recommended for women older than 50 years of age.

Mobile App – the Braster Care app, software which is needed to perform the examination. It needs to be downloaded onto the user's mobile device (smartphone or tablet) before the first examination. The app is free of charge and available via Google Play (for Android) or via the App Store (for iOS).

Mobile Device – a smartphone or tablet with an Android (version 4.4.4 or higher) or iOS (version 8 or higher) operating system.

My Account – an account on myaccount.braster.eu, where the user must register. In My Account the user can, for example, check the results of a thermographic examination and other pre-ordered services and schedule a pre-paid interview with a physician.

On-line Consultation – an on-line chat between a user and a physician. During the chat, the doctor has access to the user's examinations previously uploaded into the repository. This service can be ordered after logging into My Account*.

Telemedical Center – the location where users' data is stored and where the software needed for the provision of the services offered by BRASTER S.A. is kept.

Thermogram (or thermographic image) – a graphic representation of the thermal image created on the surface of the liquid crystal foil which maps temperature distribution across the breast.

Ultrasound – a non-invasive method in which ultrasound is used to visualize tissue. Ultrasound imaging is a basic diagnostic tool used in breast cancer prophylaxis.










User – a woman who uses the Braster in-home breast examination system

EXPLANATION OF SYMBOLS USED IN THE USER MANUAL, ON THE LABEL AND ON THE PACKAGING

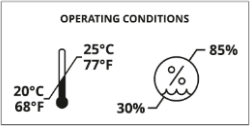
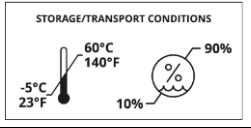





* This may not apply in all markets. Please, check with the local distributor of the Braster system.



BRASTER®

	Caution
	Warning
	Operating instructions (read the user manual)
	Serial number
	The device contains an applied part.
	Date of manufacture
	Manufacturer name and address
	Power supply information
	The device is fitted with protection against solid particles (diameter ≥ 12.5 mm) and vertically falling water drops, with housing inclination to 15° .



	Operating conditions (ambient temperature and humidity)
	Storage and transport conditions (ambient temperature and humidity)
	This symbol means that the medical device satisfies the requirements of the Directive 93/42/EEC.
FCC ID	This symbol means that the device satisfies the requirements of Federal Communications Commission (FCC).
IC	This symbol means that the device satisfies the requirements of Innovation, Science and Economic Development Canada (ISED).
	The device communicates wirelessly via WiFi.
	The device needs to be protected from moisture.
	The device needs protection from light sources.
	This symbol means that you must follow all applicable principles for disposal of this type of waste.



IMPORTANT SAFETY INFORMATION

This section is provided to familiarize the user with critical information needed before the device is used. Some warnings and precautions are given in the other sections of the User Manual.



WARNINGS

Warnings are statements that alert the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the device.

- ! A Braster examination does not replace other diagnostic methods currently used in clinical practice (such as mammography and ultrasound). Be sure to undergo routine mammography or ultrasound screening as recommended by your physician.
- ! Any use, operation and servicing of the device in contravention to this User Manual is prohibited and can cause damage to the device or disrupt its operation. The device must be used and operated as stipulated in the User Manual and serviced in a place indicated by BRASTER S.A. The manufacturer will not be held responsible for any consequences of improper use of the device.
- ! The device must not be charged while an examination is in progress. Using the device when it is being charged from the mains supply may lead to electrocution. Avoid contact with the device when it is being charged.
- ! Do not use the device if the housing of the device is damaged, as that may cause electrocution.
- ! The device should be charged using a mains USB charger (parameters: DC 5V 1A) which complies with IEC 60950-1 or IEC 60601-1. Switch the device off before charging it.



CAUTIONS

Cautions are statements that alert the user to the possibility of a problem with the device associated with its use or misuse, i.e. device failure, device malfunction, damage to the device or data loss.

- ! To ensure the safe and appropriate operation of the device read the information on precautionary measures set out in the chapter of this User Manual titled “Important Safety Information” and other information included herein before using the device. The illustrations and screenshots used in this User Manual may slightly differ from the actual appearance of the device and mobile app.



- ! Thermographic matrices lose their properties after 24 months from their first use. If you use the matrices after the lapse of 24 months from their first use, a reliable interpretation of the examination will not be possible. To ensure proper operation of the device, replace the set of matrices with new ones at least every 24 months.
- ! The device and matrices may be damaged if stored in a hot and/or moist place and/or in direct sunlight. Store them in a dry, cool and shaded place.
- ! You will pay for data transfer in accordance with your operator's tariff.
- ! If you use parts other than those indicated in the User Manual or if you modify the Braster device or connect it to devices that are not mentioned in the User Manual, you may cause problems with its operation and/or cause damage that will be attributable to the user, for which the manufacturer will not be held responsible.
- ! You must only use the parts indicated in the User Manual and connect the Braster device to devices that are mentioned in the User Manual. Do not modify the Braster device.
- ! Charge the device for at least one hour before the first examination.

INTRODUCTION

This User Manual comes as standard with the Braster in-home breast examination system intended for self-examination of breasts. Read the User Manual before using the device for the first time. The User Manual contains the necessary information on all of the functions of the device, its safety and the breast examination process.

It is recommended that you retain this User Manual for future reference.

BRASTER S.A. is the owner of an innovative, proprietary technology for the manufacturing mixtures of liquid crystals and a special-purpose liquid crystal emulsion. This manufacturing process was developed based on Continuous Liquid Crystal Film (CLCF) technology. The technology used by BRASTER S.A. is protected by international patent applications.

- ⚠ Improper operation of the device which is inconsistent with the User Manual may pose risk to the health and life of the user or third persons. You must comply with the User Manual when using the product. Only use the Braster device if you have become familiar with the product and have read the User Manual.
- ⚠ The device must only be used for the purpose intended by the manufacturer. Arbitrary use of the product which is inconsistent with the User Manual may result in the loss of guarantee rights and claims in case of damage.



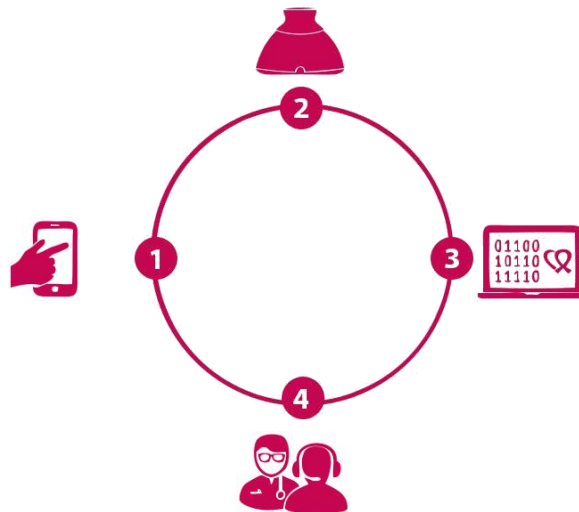
1. DESCRIPTION AND INTENDED USE

1.1. DESCRIPTION

The Braster in-home breast examination system, hereinafter referred to as the Braster system, is an active medical device intended for thermographic breast examination. The system consists of:

- the Braster device, which is composed of:
 - the image acquisition device, and
 - the thermographic matrix;
- the Braster Care mobile app; and
- the Braster AI automatic interpretation software.

Additionally, as well as other services, BRASTER S.A. offers access to a team of qualified medical experts who can be contacted by users via www.braster.eu*



See picture 1: Components of the Braster system

1. The Braster Care app
2. The Braster device

* This may not apply in all the markets. Please, check with the local distributor of the Braster system.



3. The Braster AI software

4. A team of experts

During the examination apply the Braster device to the breast area. The device is fitted with a liquid crystal foil which creates color images when heated. At the end of the examination the acquired thermographic images are stored in the mobile app and sent to the telemedical center, where they are automatically analyzed by Braster AI. Should any potentially dangerous pathological changes be indicated, you will be instructed to consult your doctor.

The Braster medical device does not perform measurements, but instead records temperature distribution across the breast (qualitatively, but not quantitatively), based on which the thermographic images are analyzed.

- ⚠ Braster examination DOES NOT REPLACE OTHER DIAGNOSTIC METHODS CURRENTLY USED IN CLINICAL PRACTICE (SUCH AS MAMMOGRAPHY AND ULTRASOUND), but it is an ideal complement to the recognized examinations such as ultrasound and mammography.

1.2. INTENDED USE

1.2.1. INDICATIONS

The Braster system is intended for domestic breast examination by adult women as an adjunct to recognized examinations such as ultrasound and mammography.

1.2.2. CONTRAINDICATIONS

The Braster system is not intended for women who are undergoing or have undergone breast cancer treatment, i.e. breast-conserving surgery, mastectomy (unilateral or bilateral), systematic treatment (chemotherapy, hormonal therapy, biological therapy) and radiation therapy.

Temporary contraindications against using the Braster device:

- pregnancy or breastfeeding (up to three months after weaning);
- general infection, with a body temperature of or in excess of 38°C;
- breast infection with pain, skin redness and bruises (when the said symptoms are present);
- during the second phase of the menstrual cycle – due to changes in breast physiology in the menstrual cycle it is best to perform thermographic examination between day three and day twelve of the cycle;



- lack of a recommended temperature (too hot or too cold) in the room where the examination is to be performed – the ambient temperature must be between 20 °C and 25°C ;
- surgical procedure in the breast area with benign lesion diagnosis:
 - fine-needle biopsy – up to four weeks after the procedure,
 - thick-needle biopsy or Mammotome’s breast biopsy – up to 12 months after the procedure,
 - breast tumor resection – up to 12 months after the procedure,
- aesthetic implant placement, filler injections (e.g. hyaluronic acid) and lipotransfer – up to 12 months after the procedure.

2. OPERATING PRINCIPLES OF THE DEVICE

The Braster device uses a type of technology known as contact thermography. Contact thermography is a method for functional imaging of organ function. In medicine, thermography is based on a phenomenon known as the ‘dermo-thermal effect’, in which the thermal processes that occur in the organ examined (inside the body) manifest on the surface of the skin as temperature anomalies.

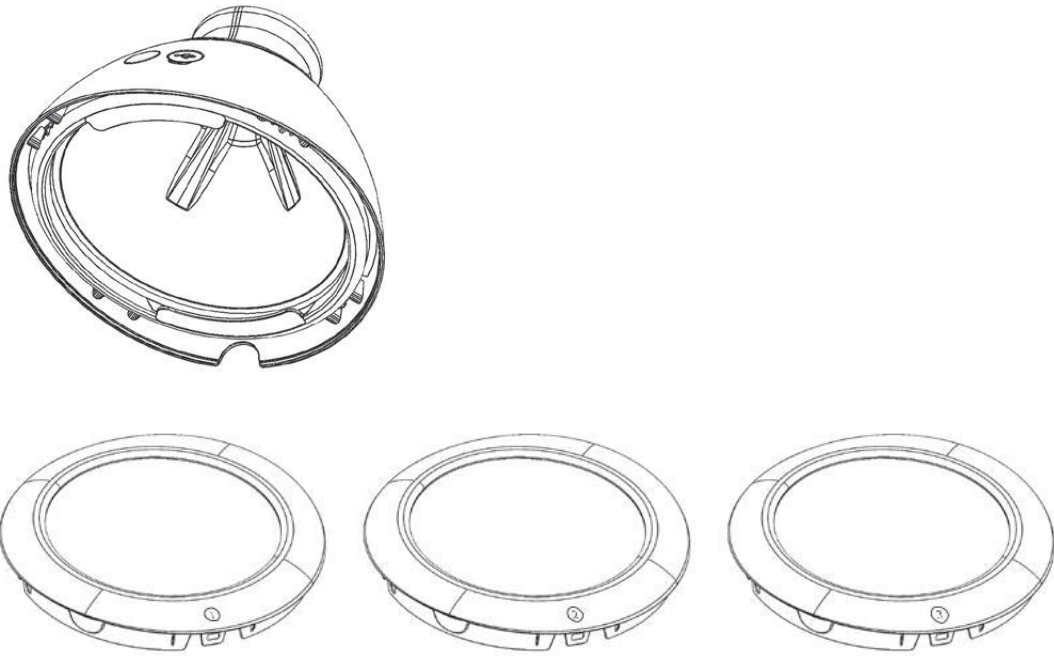
Cancer cells have a higher metabolism than normal cells and build a dense capillary network, thus forming areas of local hyperthermia (increased temperature), which are recorded on the surface of the examined breast as a thermal marker of an anomaly. Pathological lesions with suspected malignancy have a characteristic morphological structure and higher temperature than normal areas of the body. As a result, they are shown in the thermogram as areas of different colors.

Contact thermography is a complementary examination. It complements recognized examinations such as ultrasound and mammography.

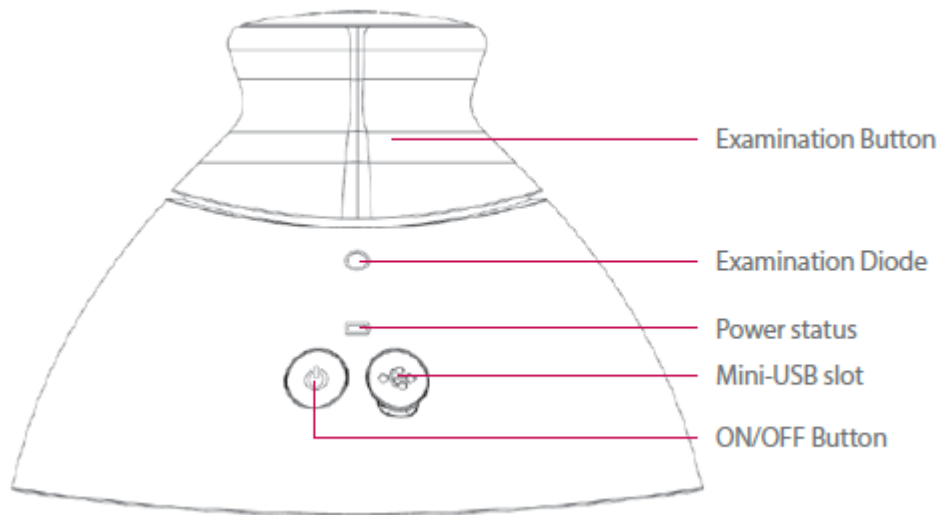
3. PACKAGE CONTENTS

The package contains:

- an image acquisition device, model: BRA-1.0 (see fig. 2A),
- a set of three thermographic matrices numbered 1, 2 and 3, model: TMS-1.0 (see fig. 2B),
- a mini USB cable,
- a storage pouch,
- a cleaning cloth,
- a user manual.



4. OVERVIEW OF THE BRASTER DEVICE INTERFACE



See figure 4: the Braster device interface



1. Examination button
2. Examination diode
3. Power status
4. Mini-USB slot
5. ON/OFF button

ON/OFF Button – turns the device on/off

- Press the button and hold it for 2 seconds to turn the device on (if the device is off).
- Press the button and hold it for 5 seconds to turn the device off in emergency mode (if the device is on). In normal mode, the device will turn off automatically after the examination is finished or after 10 minutes of idleness. Only use this function in emergencies.

Examination Button – activates acquisition of thermographic images

- The button is pressed – acquisition of thermographic images is active (activated Examination Diode).
- The button is not pressed – acquisition of thermographic images is not active.

Activation Diode Status	Power Diode Status	Description
No light	No light	The device is off
No light	Blinking green	The device is on
No light	Steady green	The device is connected with a mobile device
Pulse white	Steady green	Thermogram acquisition in progress
No light	Steady orange	Charging in progress
No light	Blinking orange	The examination cannot be performed. The battery level is too low.

Tab. 1. Diode colors in user interface

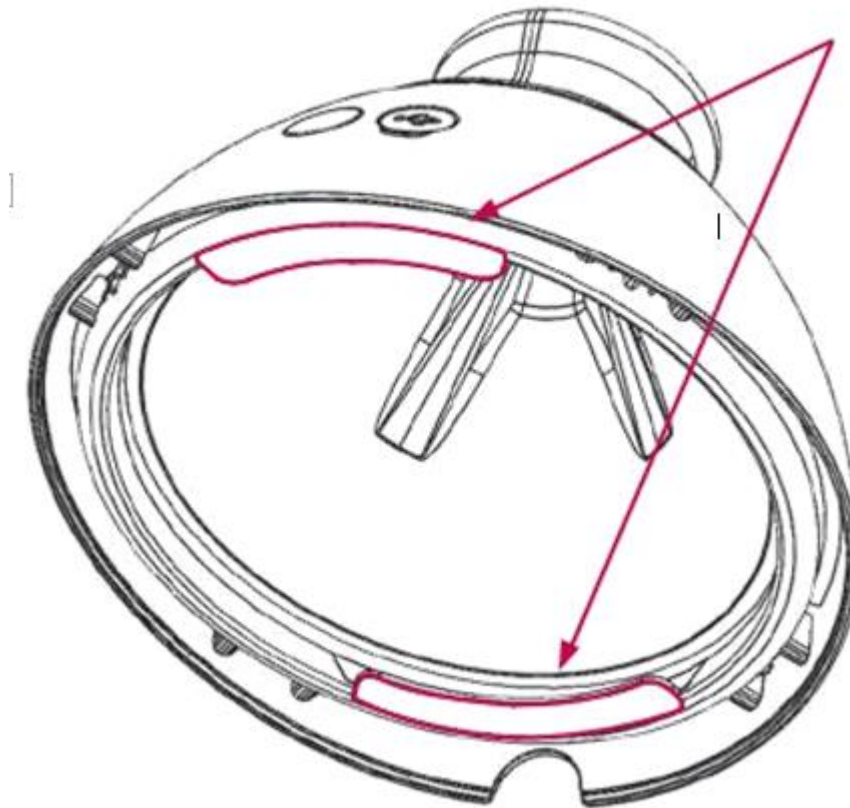


Mini-USB slot – is located under a rubber cap. To access the slot, you need to raise the cap. The mini-USB slot is intended for:

- updating software for the image acquisition device;
- battery charging.

Device label – placed in the shadowed chamber of the device, visible when the matrix is removed. The label contains the serial number of the device, which is also the name of the WiFi signal broadcast by the device, and password (see fig. 4A: Position of the label and 4B: Sample label with name of the WiFi signal and the password: 1. Name of the Wi-Fi signal broadcast by the device, 2: Password to WiFi signal broadcast by the device).

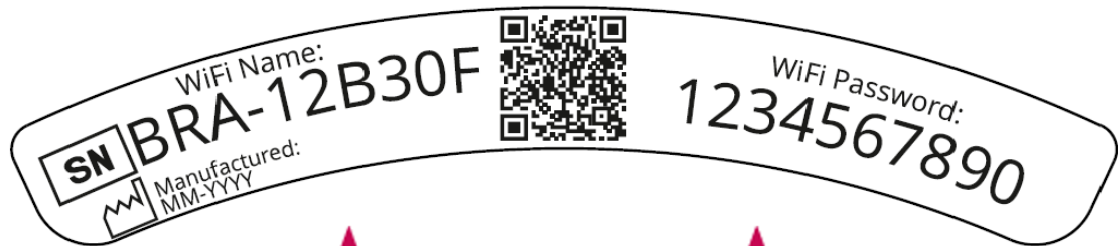
Device label





BRASTER®

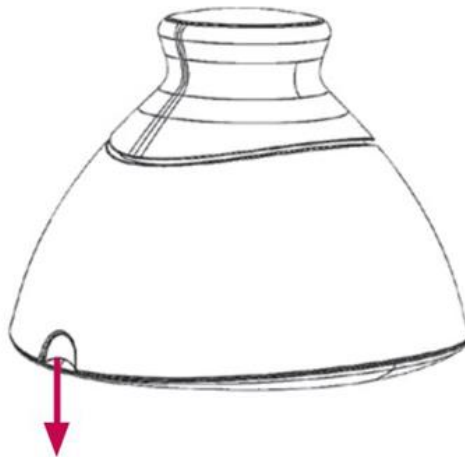
- ⚠ Do not remove the label. Write down the data which is on the label and keep it in a safe place.



Name of the WiFi signal broadcast by the device

Password to the WiFi signal broadcast by the device

5. MATRIX REPLACEMENT

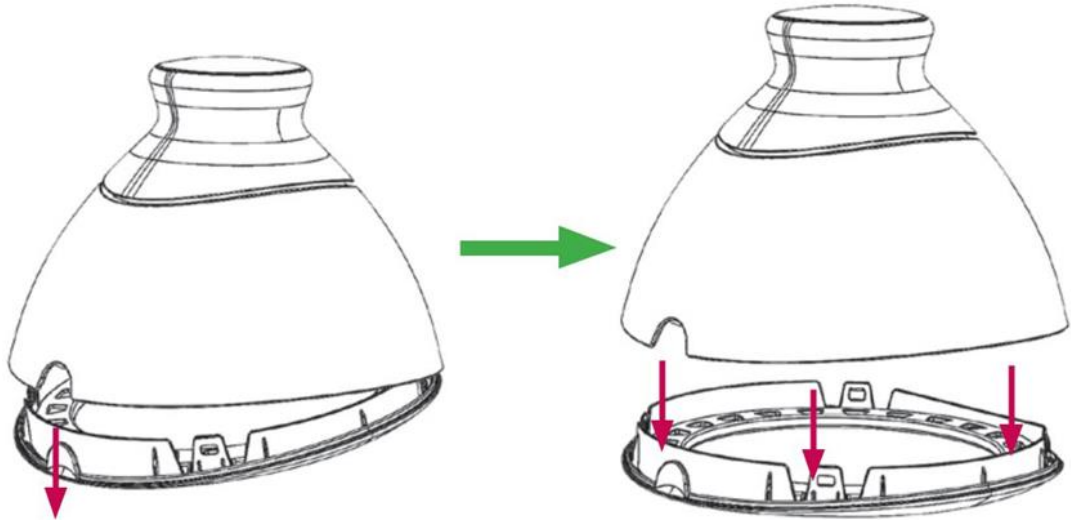


SEE fig. 5

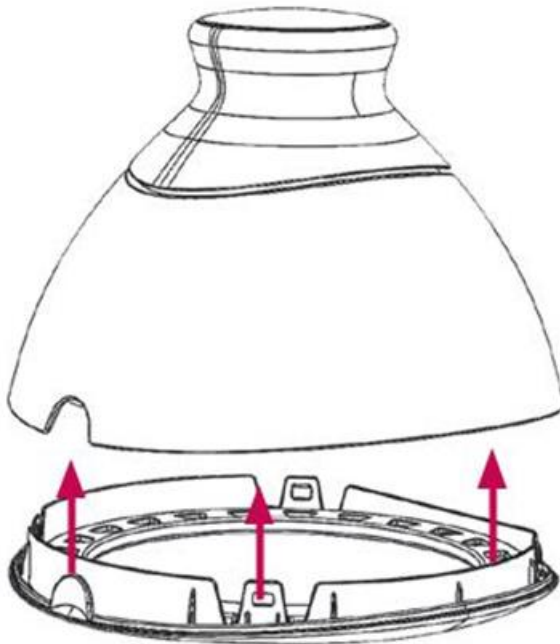


BRASTER®

Step 1 (Fig. 5A) Pull the edge of the matrix in the place where there is a notch in the body of the device . Preferably hold the notch on the matrix with your thumb and support the matrix from below with your other fingers.



Step 2 (Fig. 5B) Pull the matrix off the device





Step 3 (Fig. 5C) Attach the matrix, pushing it parallel to the housing. Preferably hold the notch on the matrix with your thumb and support the matrix from below with your other fingers.

6. DEVICE PREPARATION PRIOR TO EXAMINATION

6.1. PREPARATION OF THE BRASTER DEVICE PRIOR TO THE FIRST EXAMINATION

- a. After unpacking the device, check it for completeness. The box should contain: the image acquisition device, three matrices (numbered 1, 2 and 3), a mini USB cable, a storage pouch, a user manual and a cleaning cloth. If you find that any of those elements are missing, immediately fill in the compliant form available on the Braster website.
- b. The matrix is an applied part of the device, which means that it comes into direct contact with the skin. Therefore, before the first use clean and disinfect the inner and outer surfaces of all matrices (as per the description and by using the measures specified in chapter 11 of the User Manual).
- c. **Charge the device for at least one hour before the first examination.**
- d. **First download the free Braster Care mobile app** onto your smartphone or tablet and create your account on myaccount.braster.eu in order to perform an examination. You can do that while the battery is being charged. To do that:
 1. Download the free Braster Care app from the App Store, if your mobile device has the iOS operating system (i.e. is an iPhone or an iPad), or from Google Play, if your mobile device is an Android device;
 2. Install the Braster Care app on your mobile device;
 3. Start the Braster Care app on your mobile device;
 4. Click the SIGN UP button at the bottom of the screen.
- e) Register at My Account as instructed:
 1. If after clicking the SIGN UP button you are not redirected automatically, go to myaccount.braster.eu;
 2. Fill in the data and click the Sign up button;
 3. Go to your e-mail account and find the e-mail with the activation link. If you cannot find it in the main folder, check the "Spam" folder;
 4. After you have activated the account by clicking the activation link, type your login (the e-mail address which you used for registration) and password (the one which you used for registration) on the login page, and click "Log In";
 5. Fill in the data and click "continue";



6. In “Your medical data” tab select the size of your breast, according to the instructions;
 7. Fill in the remaining medical data;
 8. Log out after completing registration.
- f) When charging is complete, start the app and follow the instructions described in chapter 7.

6.2. PREPARATION OF THE BRASTER DEVICE PRIOR TO SUBSEQUENT EXMINATIONS

- a) When preparing for an examination first clean the surface of the liquid crystal matrices. You must clean all of the matrices, with particular attention to the surface of the foil recorded by the optical system, i.e. the surface on the inner side of each matrix.
- b) When the matrices have been cleaned, start the app and follow the instructions provided in chapter 7.

7. EXMINATION

7.1. IMPORTANT INFORMATION

- ⚠ **Do not use the device when it is being charged from the mains supply.**

Before the first examination:

- download the Braster Care app from Google Play or the App Store onto your mobile device;
- make sure that you have bought the Examination Package – if you have not, buy it in the Braster e-store or the e-store of the local distributor;
- check the size of your breasts according to the Braster scale in “Your medical data” on *myaccount.braster.eu*

REMEMBER

- ⚠ Do not perform an examination in a room where the temperature is lower than 20°C or higher than 25°C.
- ⚠ Due to changes in breast physiology during the menstrual cycle, it is best to perform thermographic examinations between day three and day twelve of the cycle.

1. On the day before the examination:

- avoid procedures which may increase blood circulation in the breast area (physiotherapy, massages, etc.).



2. On the day of the examination:

- make sure that you are between days three and twelve of your menstrual cycle or, if you do not menstruate, that about 30 days have passed from your previous exam;
- do not take a bath or a shower within approximately two hours before the examination;
- do not drink alcohol;
- do not use peelings on your breasts and/or neckline and do not perform armpit depilation, as that may irritate your skin;
- do not stay near to sources of heat or cold, such as heaters or air conditioners, for at least thirty minutes before and during the examination;
- avoid intense physical effort for approximately two hours prior to the examination;
- do not use cosmetics and do not wet the skin on your breasts within two hours prior to the examination – your skin should be clean and dry;
- do not have a sauna or a steam bath.

7.2. HOW TO PERFORM AN EXAMINATION

7.2.1. PREPARATION

- Place the switched-off Braster device in front of you. Take your mobile device with the Braster Care app installed as stated in chapter 6 of the User Manual and place it in front of you. Check that your mobile device is connected to the Internet.
- Start the Braster mobile app on your smartphone or tablet.
- Log into the app by inserting your login and password (which are the same as for My Account).
- Click “Start” to start the examination. You do not need to undress at this stage.

During the examination the mobile device will display a navigation screen with all of the stages. The stage you are currently going through will be highlighted. Click the name of the stage to start it. The navigation screen will be displayed after each stage. Note that you must go through all of the stages of the examination one by one. The app will not let you skip any stage. Once you have finished a step, you will not be able to go back to it.

7.2.2. QUESTIONS

In this part you will answer questions which will check whether you can perform the examination on that particular day. These questions will also be useful for interpretation of the results. Some



of them will be “YES” or “NO” questions. If your answer enables you to perform the examination, you will be redirected to the next screen. However, if due to some excluding conditions you cannot perform the examination, an explanatory note will be displayed. You can always return to the previous question by clicking “BACK”.

In some of the questions you will select your answer from a larger number of options. Always remember to answer truthfully, as your answers affect the reliability of the results.

7.2.3. TURNING THE DEVICE ON/OFF

Turn the device on by pressing the ON/OFF button and holding it for about two seconds. When the device is on the battery icon will flash green. When the device is connected to a mobile device the battery icon will be steady green.

In normal conditions the device turns itself off automatically once the examination has been completed. To turn the device off in emergency mode press the ON/OFF button and hold it for five seconds.

The device turns off automatically after ten minutes of inactivity. Therefore if you find it necessary to interrupt the examination for more than ten minutes, you will need to turn the Braster device on and connect with the mobile device once again to continue.

7.2.4. DEVICE CONNECTION

Connecting the Braster device differs slightly for Android and iOS.

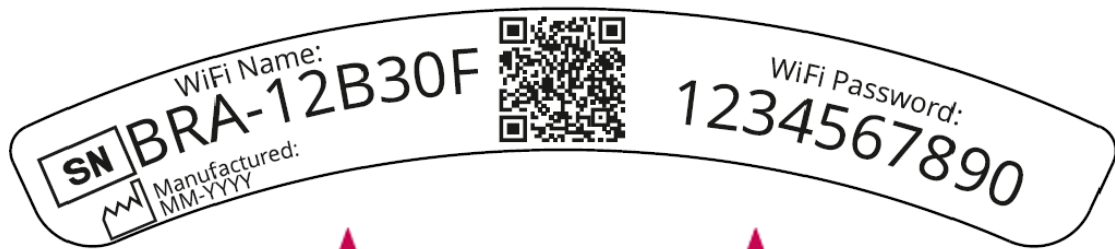
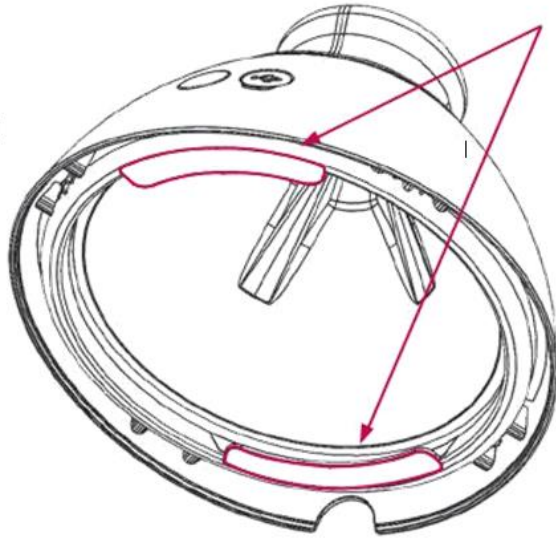
To connect the Braster device follow the instructions displayed on subsequent screens on your mobile device.

Position the device in such a way as to see the label with the name of the Braster signal and the password. Remember that the label is inside the device and is visible only when the matrix has been removed (fig. 4A & 4B).



BRASTER®

Device label



Name of the WiFi signal broadcast
by the device

Password to the WiFi signal
broadcast by the device

7.2.4.1. CONNECTING TO AN iOS DEVICE

Click “Settings” on the connection screen. Go to the WiFi settings. From the list of WiFi signals select the Braster signal specified on the label and insert the password. Return to the app. A message will display information that a connection has been established.

Do not worry if you went back to the desktop of your mobile device and not to the app. Just go to the app again. At this point you should already be connected to the device.

If, for some reason, you are unable to go to WiFi settings on the connection screen in the app by clicking “Settings”, leave the app, go to “Settings” in your mobile device, select the “WiFi” tab and select the signal of your Braster device. Then return to the app.

The app will remember your login and password, so there will be no need for you to re-enter them when carrying out an examination in the future.

7.2.4.2. CONNECTING TO AN ANDROID DEVICE

Select the signal of your Braster device on the connection screen. Enter the password given on the device label. A message will display information that a connection has been established.

The app will remember your login and password, so there will be no need for you to re-enter them when carrying out an examination in the future.

⚠ PLEASE NOTE THAT YOUR MOBILE DEVICE WILL NOT HAVE ACCESS TO THE INTERNET WHEN IT IS CONNECTED TO THE BRASTER DEVICE

7.2.5. ACCLIMATIZATION

The next stage of the examination is a six-minute acclimatization, i.e. regulation and stabilization of breast skin temperature. To do this, you need to undress from the waist up. Acclimatization is key if you want to obtain good quality thermographic images during the examination. Only with a properly conducted acclimatization can you be sure that the results will be reliable.

To complete the acclimatization process, follow the instructions displayed on subsequent app screens.

7.2.6. MATRIX SELECTION

At this stage, you need to select the matrix for the examination. Your Braster device came with a set of three matrices. Each of them works in a different range of temperatures. Remember that



BRASTER®

your bodily temperature depends on, among other factors, the day of your menstrual cycle and your age and metabolism. In order to produce a high-resolution thermographic image that will show best the distribution of temperatures across your breasts, you will have to select a matrix before each examination.

To select the matrix make one application for each breast. At the matrix selection stage the exact application place is not very important. Preferably apply the device to the central area of your breast, making sure that the whole matrix adheres tightly to the body. The app will guide you step by step through this process.

First put matrix No. 2 on the device (the number of the matrix is stated on the plastic frame). Follow the instructions displayed on subsequent screens.



When instructed apply the device centrally to your breast and press the Examination Button (the grey button on the top). The clicking sound means that the button has been pressed correctly. Remember to hold the Examination Button down as long as the screening is in progress. Do not move the device across your breast, but hold it firmly in one place. When instructed, release the button and move the device away from your breast (see fig. 6: device application to the breast).

! REPEAT THESE STEPS FOR YOUR LEFT BREAST.

If matrix No. 2 is suitable for you, you can start the examination. If it does not suit you, you will be asked to remove matrix No. 2 and repeat the applications with matrix No. 1 or 3. Once the appropriate matrix has been selected, you can start the examination.

7.2.7. EXAMINATION

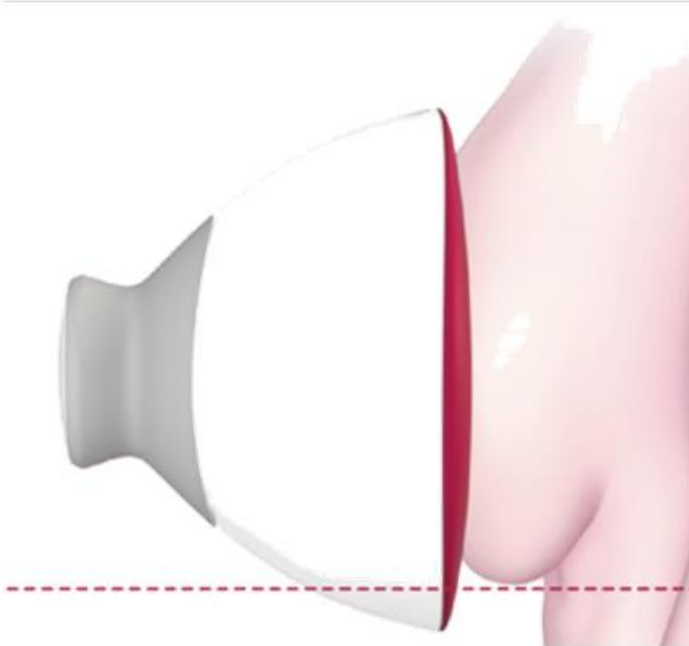
Before you start the examination, read the instructions displayed when you click “Examination” on the navigation screen. From those instructions, you will learn exactly what to do during the examination and how to apply the device to your breasts.

To ensure top quality thermographic images during the examination:

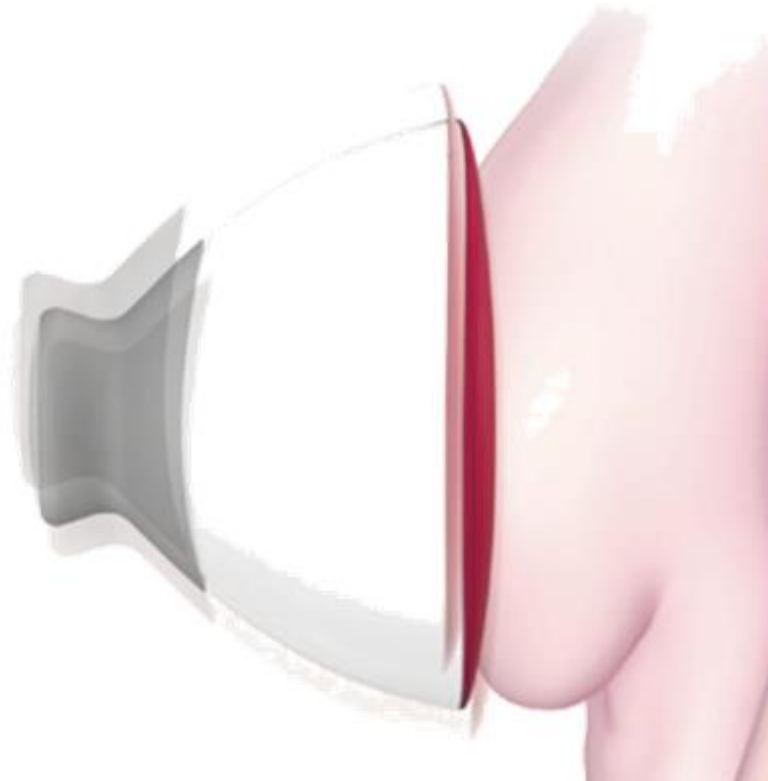


BRASTER®

- apply the device perpendicular to your breast (see fig. 7: correctly applied device);



- do not push your breast up;
- do not move the device across your breast, instead hold it firmly in one place (see fig. 8: improperly applied device);



- do not move the device away until instructed;
- keep the Examination Button pressed as long as the screening is in progress (see fig. 9: pressing the button);



BRASTER®



- do not touch your breast with your hands during the examination.

Go to myaccount.braster.eu to see sample device applications on female models.

Depending on the breast size which you entered in your medical data on your account, you will be required to make one, three or five applications to each breast.

⚠ ALWAYS BEGIN WITH YOUR RIGHT BREAST

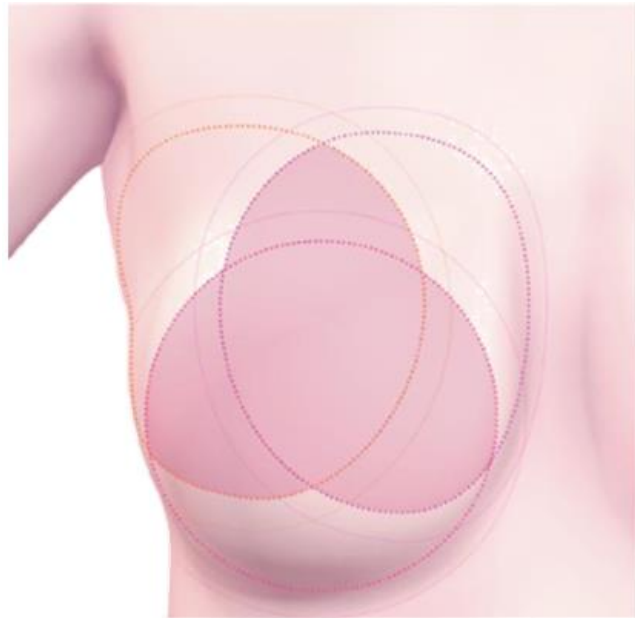
This is very important, as the thermographic images of your breasts produced in individual examinations are compared one to another, so that any alarming changes can be detected as early as possible. Therefore it is important that we always compare the right breast with the right breast and the left breast with the left breast.

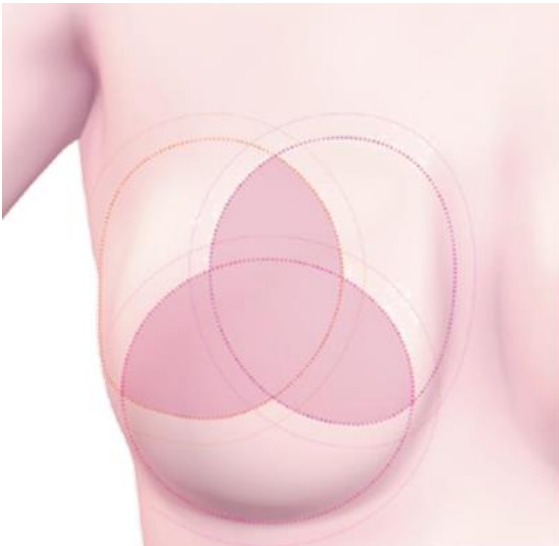
If your breast size is 1, during the examination you will have to make one central application to the breast, making sure that the lower edge of the matrix (i.e. the black part (the thermographic foil)) adheres to your breast (not your abdomen) (see fig. 10). Do not push your breast up. Follow the instructions displayed on the screen of your mobile device. Each application takes 15 seconds. The time intervals between applications last approximately ten seconds (depending on



BRASTER®

breast temperature and ambient temperature). The matrix should not be in contact with your body during the intervals.





If your breast size is 2 or 3, see fig. 12A for size 2 and fig. 12B for size 3. During the examination you will have to make :

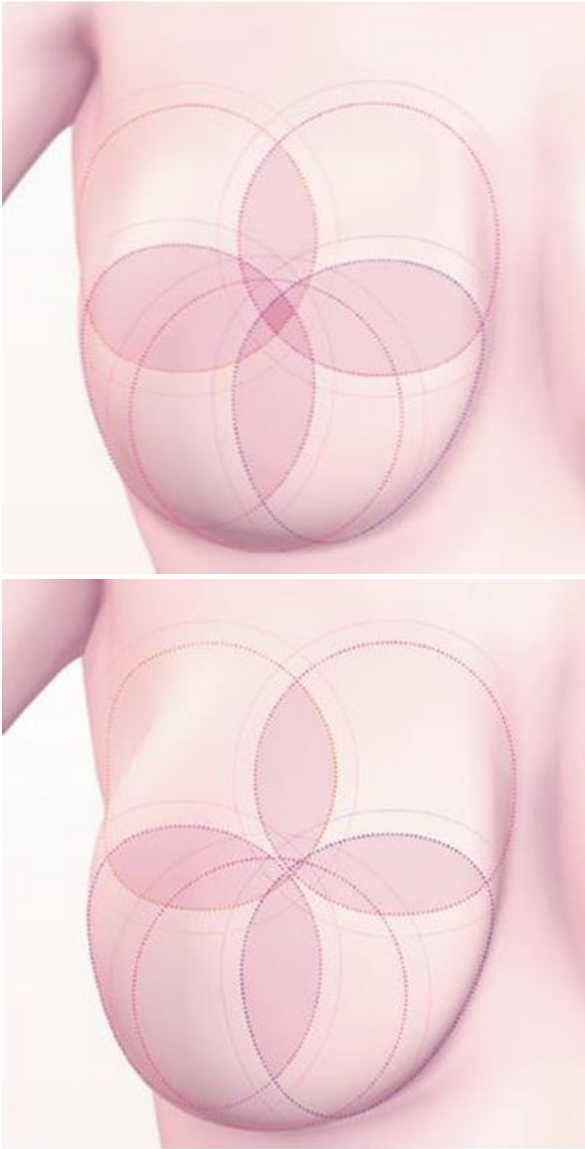
- 1) One central application to the breast, making sure that the lower edge of the matrix (i.e. the black part (the thermographic foil)) adheres to your breast (not your abdomen). Do not push your breast up.
- 2) One upper application to the outer part of your breast, on the border with your armpit, making sure that the edge of the matrix (i.e. the black part (the thermographic foil)) touches upon the lateral edge of your breast and does not extend beyond it.
- 3) One upper application to the inner part of your breast, making sure that the edge of the matrix (i.e. the black part (the thermographic foil)) does not extend to your other breast and your breastbone.

The applications may overlap, but do not worry if in your case they do not overlap as shown in the illustrations. The crucial thing is to make sure that your entire breast is screened.

Follow the instructions displayed on the screen of your mobile device. Each application takes 15 seconds. The time intervals between applications last approximately ten seconds (depending on breast temperature and ambient temperature). The matrix should not be in contact with your body during the intervals.



BRASTER®



If your breast size is 4 or 5 see fig. 13A for size 4 and fig. 13B for size 5, during the examination you will have to make:

- 1) One central application to your breast, making sure that the lower edge of the matrix (i.e. the black part (the thermographic foil)) adheres to your breast (not your abdomen). Do not push your breast up.

Divide the breast into four equal quadrants, as if there was a vertical and a horizontal line crossing the center of your breast. Now make:



- 2) One lower application to the outer part of your breast, making sure that the lower edge of the matrix (i.e. the black part (the thermographic foil)) adheres to your breast (not your abdomen). Do not push your breast up.
- 3) One upper application to the outer part of your breast, on the border with the armpit, making sure that the edge of the matrix (i.e. the black part (the thermographic foil)) touches upon the lateral edge of the breast and does not extend beyond it.
- 4) One upper application to the inner part of your breast, making sure that the edge of the matrix (i.e. the black part (the thermographic foil)) does not extend to your other breast but runs across the centerline of your breastbone.
- 5) One lower application to the inner part of your breast. The lower edge of the matrix (i.e. the black part (the thermographic foil)) should adhere to your breast (not your abdomen). Do not push the breast up.

The applications may overlap, but do not worry if in your case they do not overlap as shown in the illustrations. The crucial thing is to make sure that your entire breast is screened.

Follow the instructions displayed on the screen of your mobile device. Each application takes 15 seconds. The time intervals between applications last approximately ten seconds (depending on breast temperature and ambient temperature). The matrix should not be in contact with your body during the intervals.

7.2.8. SENDING THE RESULTS TO THE TELEMEDICAL CENTER

Once you have made all applications you will be informed that the examination has come to an end and you will be able to send your collected data for analysis. Please note that before you send the data you first need to disconnect your mobile device from the Braster device and connect to a WiFi network. Due to the size of the thermographic images produced during the examination, it is not recommended to send them by mobile data. The examination results will be sent to your account on the My Account platform (*myaccount.braster.eu*) within two business days.

If you click “Finish” after having sent the examination, you will be redirected to the start screen, where you can check the status of the examination (“Sent for analysis”). When the results of the examination have been sent to your account from the telemedical center, the status will change to “Results available”.

You do not need to send the collected data for analysis immediately after completing the examination. You can send them whenever is convenient for you, when you have access to the Internet (preferably via WiFi). All you need to do is to go to the app, click “List of examinations”,



select the appropriate exam and choose whether to send it or delete it. Please note that you must either delete the results or send them for analysis before you carry out a new examination, otherwise the system will not let you perform the next exam.

The app will let you know when the result of your examination is available. To read it, go to My Account on the website *myaccount.braster.eu*. In My Account platform, you can also buy additional services offered by BRASTER S.A. and supplement your medical data.

8. TROUBLESHOOTING THE MOBILE APP

In certain cases an examination will not be possible. To unlock the examination, you will be asked to perform additional actions.

- 8.1. The Braster device uses WiFi technology to transmit data to the mobile device. WiFi technology, by design, relies on sharing radio bandwidth with other users. If the WiFi environment in your location is overcrowded and/or many other WiFi signals are available, performance of the Braster device may be decreased resulting with longer registration time during applications or even, in extreme WiFi conditions, inability to register full set of images.
- 8.2. Power indication may change color during examination from green to orange and back when the battery is not fully charged.
- 8.3. If you have not bought an examination package, the app will display an appropriate message and examination will be impossible. You will have to buy an examination package to continue. To do this, go to the Braster e-store or the e-store of the local distributor of the Braster system. If you do not want to buy an examination package right now, click "Cancel the Examination".
- 8.4. If the battery of your smartphone or tablet is too low, examination will be impossible until the device has been charged to the level indicated in the message. Click "Cancel the Examination to return to the start screen,".
- 8.5. If there is not enough disc space in your mobile device to save a complete examination, examination will be impossible until the appropriate amount of disc space has been freed up. Click "Cancel the Examination" to return to the start screen.
- 8.6. If after entering your login and password to the Braster Care app a "Server is unavailable" message is displayed you should install an additional certificate. Some versions of Android mobile devices will require an additional certificate to be installed. Please write to contact center to find out more: contactcenter@braster.eu.



9. CHARGING

Charge the device with a USB mains charger consistent with IEC 60950-1 or IEC 60601-1, charger parameters: DC 5V 1A, USB slot (specification of the feeding device). Switch the device off before charging. When being charged do not place the device in a position in which disconnection of the USB cable is difficult.

- ⚠ The device must not be charged when an examination is in progress.
- ⚠ Do not turn the device on when it is being charged.

To charge the battery remove the rubber cap from the USB slot on the side of the Braster device, next to the On/Off Button. Connect one end of the USB cable to the Braster device and the other to the charger. Connect the charger to a power source (see fig. 14: location of the USB slot: a) mini-USB slot, b) USB slot).

When the device has been connected to the charger the Power status diode will be lit as steady orange. The diode turns itself off when the battery is fully charged. Full charging takes approximately three hours. The device must be disconnected from the power source via the USB cable, which must be safely disconnected from the mains supply when charging is complete.

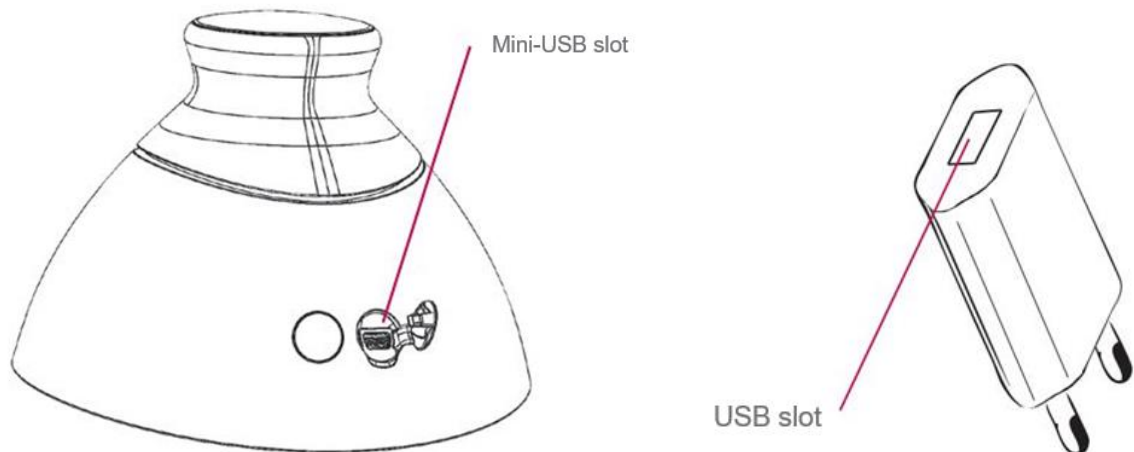


Fig. 18. Location of the USB slot

10. SAFE OPERATION

Follow the recommendations below to ensure the safe operation of the Braster device:

- Before you first use the device charge the battery using the USB cable.



- Only use accessories and materials supplied or recommended by the manufacturer.
- Never let the image acquisition device or the matrices to come into contact with water.
- After the examination store the device with a matrix on. Place the device with the matrix facing downwards, making sure that dust does not get into the matrix. Keep the device in the pouch provided.
- Do not put any items into the image acquisition device, as that may cause damage for which the manufacturer will not be held responsible.
- Do not allow the foil to come into contact with sharp objects.
- During the examination do not place any objects between the image acquisition device and the mobile device. Otherwise connection between the image acquisition device and the mobile device may be lost.
- The device can only be repaired by the manufacturer's servicing team. Any other attempt at repair will result in the voiding of the guarantee.
- Keep the device away from children.

11. CLEANING AND MAINTENANCE


Disinfect the inner and outer surfaces of all of the three matrices and clean them thoroughly.

Disinfection consists of spraying Octenisept, Softasept or salicylic alcohol over all of a matrix, on both sides, and cleaning it thoroughly with a disposable cotton gauze or tissue. By disinfecting you make sure that the surface is free of pathogenic microorganisms and bacteria, viruses and fungi.

Next wipe both surfaces of the matrix with the cloth provided in the set. Before an examination the surface of the matrix should be clean and free from pollutants (e.g. fingerprints, dust).

The inner side of the matrix is technologically matted.

The foil surface on the inner side of the matrix bears directional scratches, which have been made deliberately in a technological procedure performed in order to achieve appropriate light diffusion in the working space of the image acquisition device.

 **The device must not be washed or immersed in water. Do not clean the applied parts of the matrices, which come into contact with your breast skin, with any mechanical agents that may cause damage to such surfaces (e.g. brushes) and do not use agents that contain organic solvents (e.g. gasoline, acetone) as, once damaged, matrices will not be fit for further use.**



BRASTER®



The image acquisition device and the matrices must be kept in the original packaging, at temperatures between -5°C and $+60^{\circ}\text{C}$. Do not expose the device to UV radiation (e.g. from UV lamps used for air disinfection or from the sun).

12.SERVICING AND TECHNICAL SUPPORT

If you need support regarding the selection of appropriate device settings, or use of the device, or its storage and maintenance, or if you want to report a malfunction of the device or any other unexpected circumstances, contact the local distributor of the Braster system or the manufacturer. The contact details are available on www.braster.eu.

USER'S RESPONSIBILITIES

The Braster device must be used in accordance with the recommendations given in this User Manual and on labels. Do not use the device if it has been damaged. Any parts that are missing, incomplete, damaged or worn out must be immediately replaced at an authorized guarantee service point. Any actions connected with repairs or replacements may only be performed by personnel of an authorized guarantee service point. Responsibility for failures caused by improper operation, maintenance or repairs or resulting from damage or modifications made by persons other than personnel of an authorized guarantee service point shall be with the user.

GUARANTEE

The Braster device is covered by the manufacturer's guarantee for 24 months. The guarantee shall only be valid if accessories and spare parts approved by BRASTER S.A. are used.

Any repairs of the Braster device must be made by BRASTER S.A. Any repairs performed by unauthorized persons will result in the voiding of the guarantee. To ensure the full functionality and accuracy of the device, periodic, chargeable post-guarantee servicing is recommended every 12 months after the lapse of the guarantee period.

13.DECLARATION OF CONFORMITY

BRASTER S.A. hereby declares that the Braster system conforms with the essential requirements and other relevant provisions of the Directive 93/42/EEC and the Directive 2011/65/EU.

ELECTROMAGNETIC COMPATIBILITY



The Braster device is intended for use in an electromagnetic environment with controlled RF interference. The customer or the user of the image acquisition device may help prevent electromagnetic interference by maintaining the minimum required distance between the mobile device and cellular radio devices (transmitters).

14. TECHNICAL AND OPERATIONAL SPECIFICATION OF THE DEVICE

Weight of the image acquisition device (excluding matrix)	305 g
Weight of one matrix	87 g
Device size (excluding matrix)	diameter 17.2 cm height 13 cm
Limits of storage conditions	-25°C to +5°C (-13°F to +41°F), and +5°C do +35°C (+41°F to +95°F) in ambient humidity of up to 90%, without condensation, and +35°C do +70°C (+95°F to +158°F) with vapor pressure of up to 50 hPa
Recommended storage conditions	-5°C to +60°C (+23°F to +140°F) humidity between 10% and 90% (without condensation)
Limits of operating conditions	+5°C to +40°C (+41°F to +104°F) humidity between 15% and 90% (without condensation)
Recommended operating conditions	+20°C to +25°C (+68°F to +77°F) humidity between 30% and 85% protected against UV radiation
The limits of the operating conditions guarantee the electrical safety of the device. To protect the thermographic matrices against excess wear and damage, keep within the recommended operating and storage conditions.	



Maximum approved operation altitude	3500 m above sea level
Approved atmospheric pressure (for the device to be used)	700–1060 hPa
The device can be paired with	A smartphone or tablet with a WiFi module and RAM of at least 100 MB. Required operating system: Android 4.4.4 or higher / iOS 8 or higher.
Charger	DC 5V 1A with a USB slot and meeting the IEC 60950-1 or IEC 60601-1 standards

15. ADVERSE EVENT AND MEDICAL INCIDENTS

Any adverse event or serious incident that has occurred in relation to the device should be reported to the manufacturer on the address given in section 19 and to the competent authority of the country in which the user is established.

16. FCC REGULATORY STATEMENT

This device complies with part 15 of the FCC rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

The Braster device has been tested and found to comply with the limits for a Class B digital device. These limits are designed to provide reasonable protection against harmful interference in a residential installation. The Braster device generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the User Manual, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If the device does cause harmful interference to radio or television reception, which can be determined by turning the device off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the device and receiver.



BRASTER®

- Connect the device to an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

△ **Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter. The manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications to this device.**

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment in accordance with FCC rule part 2.1093 and KDB 447498.

17.CANADIAN REGULATORY STATEMENT

The Braster device complies with ISED Canada Licence-exempt RSSs. Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device. This device complies with the safety requirements for RF exposure in accordance with RSS-102 Issue 5 for portable conditions.

The Braster device contains internal, integrated antenna and it cannot operate in conjunction with any other antenna or transmitter.

L'appareil Braster est conforme aux RSS exclus de la licence ISED Canada. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Cet appareil est conforme aux exigences de sécurité pour l'exposition aux radiofréquences conformément au RSS-102 Issue 5 pour les conditions portables.

Le dispositif Braster contient une antenne interne intégrée et il ne peut pas fonctionner avec d'autres antennes ou transmetteurs.



BRASTER®

18.DISPOSAL



This symbol is used by the Company as part of the resource-efficient initiative and health and environment protection, in accordance with governmental instructions. The symbol means that the electronic device (including batteries) must not be thrown away together with conventional household waste. Should you need more information on the dedicated waste collection points, please contact your local authorities.

CONTACT THE MANUFACTURER

BRASTER S.A.

Szeligi, ul. Cichy Ogród 7
05-850 Ożarów Mazowiecki,
Poland
phone no. +48 22 295 03 50

e-mail: contactcenter@braster.eu

OFFICE

PGE Narodowy
al. Ks. J. Poniatowskiego 1
03-901 Warszawa, Poland

Rev. 4, 2017.07.13_ENG



CE
2274

www.braster.eu