USER MANUAL

Braster Pro
– breast examination system

BRASTER® PRO

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GLOSSARY

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 or device – a device composed of an image acquisition device and a thermographic matrix manufactured by Braster S.A.

Braster Pro – a system for thermographic breast examination manufactured by Braster S.A. The system includes: the Braster device, Braster Care mobile app and AI algorithms for automatic interpretation of thermograms produced during the examination. The Braster Pro system is available in two versions: Basic and Premium.

Braster scale – a scale of breast sizes developed by BRASTER S.A. It helps to determine how many applications should be made in order to cover the whole breast area within an examination.

Braster e-store – www.braster.eu where the Braster device, examination packages and the set of thermographic matrices can be purchased. Please note that in some markets the Braster device as well as examination packages and other services can be purchased only from a local distributor.

Clinic administrator – a person authorized by the clinic owner to manage users and examination packages in the clinic in HCP Portal.

Examination package – a package containing a certain number of interpretations of thermographic images. Without the purchased examination package it is not possible to perform the examination with Braster Pro.

HCP Portal – hcpportal.braster.eu portal, where the user of Braster Pro version Premium must register in order to conduct examinations. In HCP Portal the user of Braster Pro version Premium can, for example, check the results of patient's thermographic examination.

Image acquisition device – the device used in the examination. On the image acquisition device, there is an ON/OFF button, a USB slot and a grip. 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 the 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.

Mobile app or app – the Braster Care app, software which is needed to perform the breast examination with the Braster device. It needs to be downloaded onto mobile device (smartphone or tablet) before the first examination. The mobile 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 (for system requirements, go to: https://www.braster.eu/system).

My Account – myaccount.braster.eu portal, where the user of Braster Pro version Basic must register in order to conduct examinations. In My Account the user of Braster Pro version Basic can, for example, check the results of a thermographic examination.

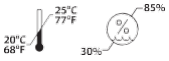
Patient – a woman 18 years of age or older, whose breasts are examined with Braster Pro by healthcare professional.

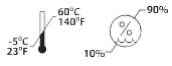
Telemedical center – BRASTER'S S.A. infrastructure used for the provision of the services, in particular the analysis of the examinations' results offered by BRASTER S.A.

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.

User – a healthcare professional who uses Braster Pro for breast examination in a clinical setting.

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

	Caution
	Warning
	Operating instructions (read the user manual)
SN	Serial number
	The device contains an applied part
	Date of manufacture
	Manufacturer’s name and address
5V⎓1A	Power supply information
IP22	The device with a matrix on is fitted with protection against solid particles (diameter ≥ 12.5 mm) and dripping water when tilted up to 15°
	Operating conditions (ambient temperature and humidity)

	Storage and transport conditions (ambient temperature and humidity)
CE 2274	This symbol means that the medical device satisfies the requirements of the Directive 93/42/EEC
Wi-Fi	The device communicates wirelessly via Wi-Fi
	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. Additional warnings and precautions are also 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.

- ! It is important to note that an examination with the use of Braster Pro does not replace existing diagnostic methods currently used in clinical practice (such as mammography, ultrasound, MRI). Any use, operation and servicing of the device breeching this User Manual is prohibited and may 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 contains a Lithium-ion polymer battery. To reduce risk of fire or burns, do not disassemble, crush, puncture, short external contacts or circuits, dispose of in fire or water, or expose a battery pack to temperatures higher than 60°C.
- ! The device must not be charged while an examination is in progress. Use of the device while charging may lead to electrocution. Avoid contact with the device while 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 USB Power Adapter (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 safety 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.
- ! According to Braster's most recent studies thermographic matrices lose their properties after 36 months from their first use. To ensure the proper operation of the device, replace the set of matrices after 36 months since the first use. However, please note that Braster S.A. still conducts studies on the matrices' service life and it may be extended even further in the future.
- ! 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.
- ! 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. 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 encounter problems with its operation and/or cause damage that will be attributed to the user, for which the manufacturer will not be held responsible.

! Charge the device for at least 30 minutes before the first examination.

INTRODUCTION

This User Manual comes with the Braster Pro – breast examination system intended for breast examination in a clinical setting. Read the User Manual before using the device for the first time. The User Manual contains the necessary information on all of the functions and features 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 of liquid crystal mixtures and special purpose liquid crystal emulsions. This manufacturing process was developed based on Continuous Liquid Crystal Film (CLCF) technology. The technology used by BRASTER S.A. is protected by international patents.

⚠ 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 Pro – breast examination system, hereinafter referred to as the "Braster Pro", is a medical device intended for thermographic breast examination. The system is available in two versions: Basic and Premium. The system in both versions consists of:

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

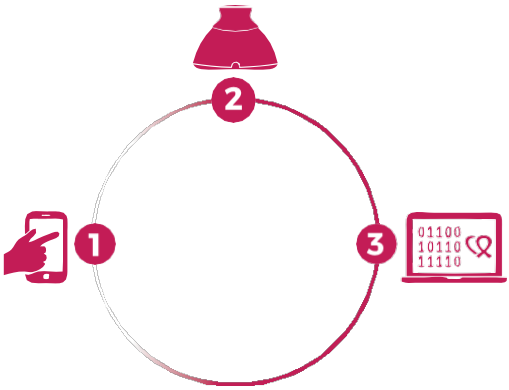


Fig. 1: Components of the Braster Pro:

1. The Braster Care app
2. The Braster device
3. The Braster AI software

During the examination apply the Braster device to the patient's breast area. The device is fitted with a liquid crystal foil which creates color images when it comes in contact with the surface of the Breasts. 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. After analysis the result is available:

- for the user of Braster Pro version Basic in My Account portal,
- for the user of Braster Pro version Premium in HCP Portal.

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

⚠ The Braster examination DOES NOT REPLACE EXISTING DIAGNOSTIC METHODS CURRENTLY USED IN CLINICAL PRACTICE (SUCH AS MAMMOGRAPHY AND ULTRASOUND). It is a useful complementary tool to the aforementioned examinations.

1.2. INTENDED USE

1.2.1. INDICATIONS

Braster Pro is intended for breast examination as an adjunct to ultrasound and mammography examinations. The device detects thermal irregularities that require confirmation by diagnostic methods or healthcare consultation. The device should be used by qualified healthcare professionals trained in its use.

1.2.2. CONTRAINDICATIONS

The Braster Pro 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 Pro:

- 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);
- inadequate 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 (FNB) – up to four weeks after the procedure,
  - core-needle biopsy (CNB) or Mammotome's breast biopsy – up to 6 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 medical imaging technique for detecting changes in tissue metabolism. 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.

The neoplastic process is characterized by a higher metabolic rate among other things through the formation of a dense pathological capillary network. 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 commonly performed 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 cleaning cloth,
- a quick start guide.

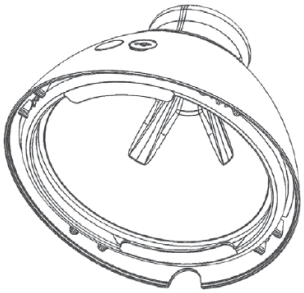


Fig. 2A: Image Acquisition Device

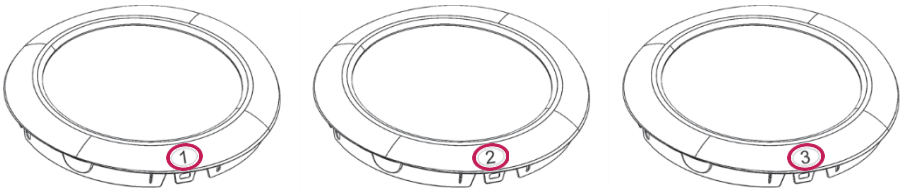


Fig. 2B: Set of three thermographic matrices numbered 1, 2 and 3

4. OVERVIEW OF THE BRASTER DEVICE INTERFACE

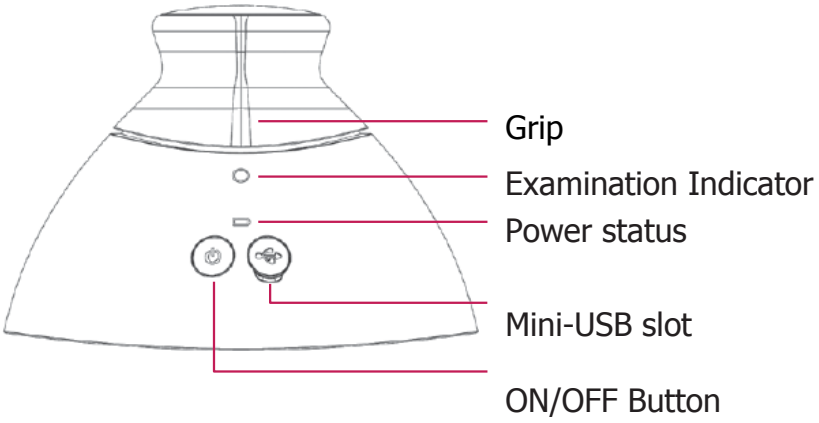


Fig. 3: The Braster device interface

ON/OFF Button – turns the device on/off

- to turn the device on press the button and hold it for 2 seconds.
- the device will turn off automatically after the examination is finished or after 10 minutes if it is not connected to the mobile app. To turn the device off in emergency mode press the button and hold it for 5 seconds.

Grip – activates acquisition of thermographic images during the examination.

- The grip is pressed during the examination – acquisition of thermographic images is in progress (activated Examination indicator).
- The grip is not pressed – acquisition of thermographic images is not in progress.

Examination Indicator Status	Power Indicator 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
Pulsing white	Steady green	Thermogram acquisition in progress
No light	Steady orange	Charging in progress
No light	Blinking orange	The examination cannot be performer. The battery level is too low.
Steady white	No light/orange	Firmware upgrade mode
Blinking white	No light/orange	Firmware upgrade in progress

Tab. 1. Indicator colors in user interface

Mini-USB slot – is located under the 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 inside the device, visible when the matrix is removed. The label contains the serial number of the device, which is also the name of the Wi-Fi signal broadcast by the device, and password (**see Fig. 4A** and **4B**).

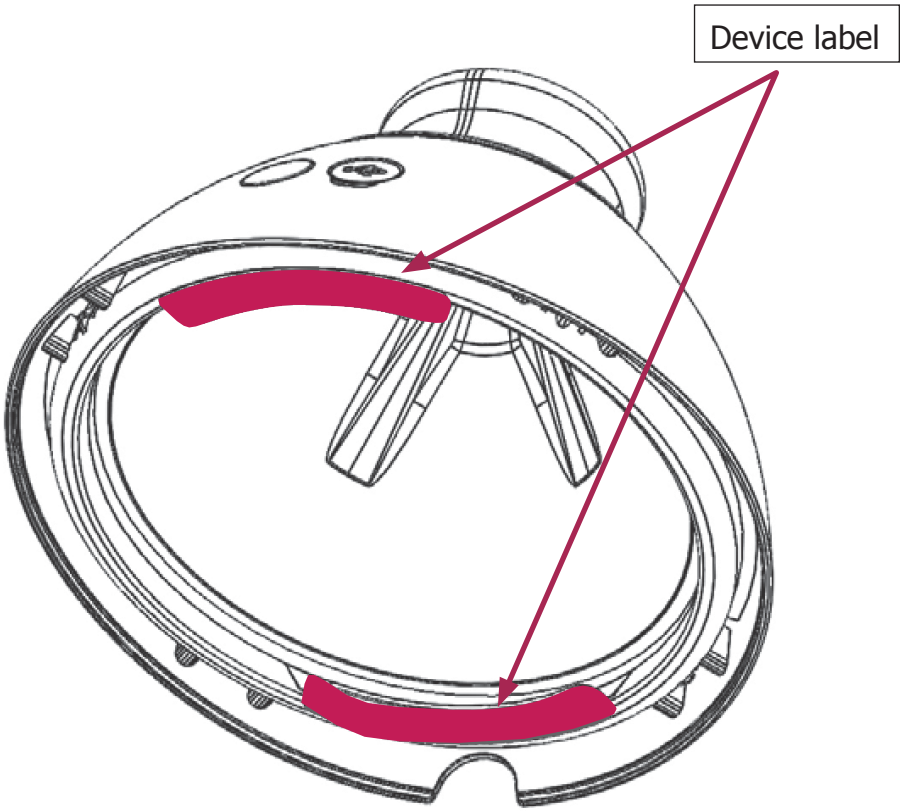


Fig. 4A: Position of the label

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

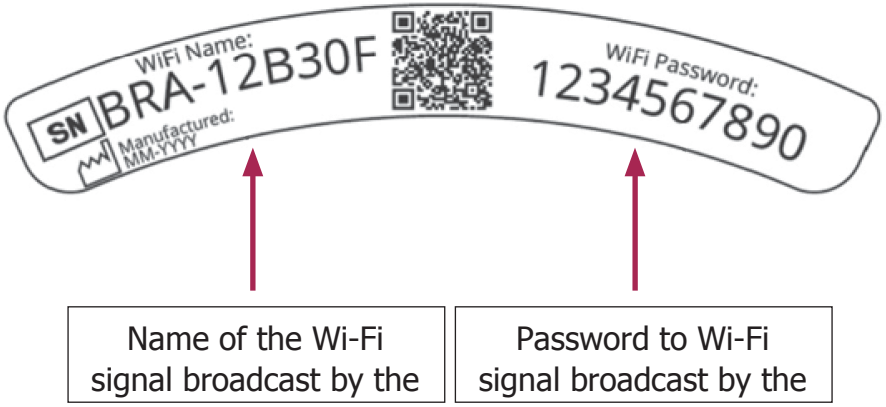


Fig. 4B: Sample label with name of the Wi-Fi signal and the password

5. MATRIX REPLACEMENT

Step 1

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.

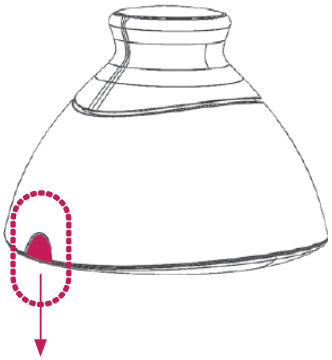


Fig. 5A

Step 2

Pull the matrix off the device.

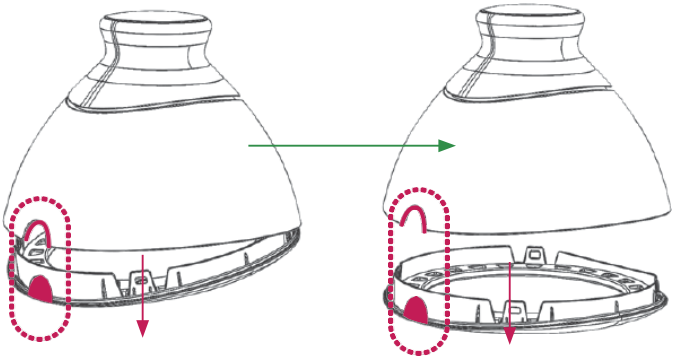


Fig. 5B

Step 3

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.

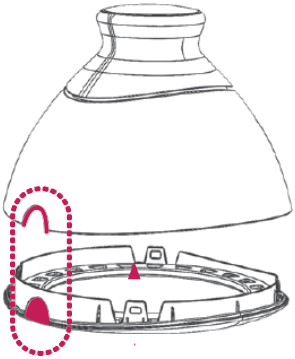


Fig. 5C

6. DEVICE PREPARATION PRIOR TO EXAMINATION

6.1. PREPARATION OF THE BRASTER DEVICE BEFORE 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 quick start guide and a cleaning cloth. If you find that any of those elements are missing, immediately fill in the complaint form available on the Braster website.
b. The matrix is a part of the device, which means that it comes into direct contact with the skin. Therefore, before each use, disinfect and clean the inner and outer surfaces of all matrices (as per the description and by using the measures specified in chapters 11 and 12 of the User Manual).
c. **Charge the device for at least 30 minutes before the first examination.**
d. If you are a user of Braster Pro version Basic, to perform an examination, sign up at myaccount.braster.eu. For this purpose:
    1. Go to www.braster.eu and press "My Account".
    2. Complete the data and in the account type field select "Braster Pro - for professional use". Indicate the country in which you provide services and enter your activation code. Please note that the activation code can be used only in the given country.
    3. Press the "Sign Up" button.
    4. Go to your email account and find an email from BRASTER S.A. with activation link. If you can't find it, check the "Spam" folder.
    5. Activate the account by clicking on the activation link.
e. If you are a user of Braster Pro version Premium, to perform an examination, register at HCP Portal. For this purpose:

1. Ask the Administrator of the clinic to create an account for you at HCP Portal.
2. Go to your email account and find an email from BRASTER S.A. confirming registration with a link to change the password. If you can't find it, check the "Spam" folder.
3. After changing the password, log in as a user at hcpportal@braster.eu and accept terms and conditions.

f. Download the 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 has the Android operating system.
g. Install the Braster Care app on your mobile device.
h. Make sure that charging of the device is complete, start the Braster Care app and follow the instructions described in chapter 7.

6.2. PREPARATION OF THE BRASTER DEVICE BEFORE SUBSEQUENT EXAMINATIONS

a. When preparing for an examination, first disinfect and clean the surface of the liquid crystal matrices. You should pay particular attention to the surface on the inner side of each matrix. It is important to use the recommended cleaning and disinfection agents and thoroughly clean the surface of the foil so as to not leave any fingerprints, smudges, dust etc. as it can alter the interpretation of the thermographic examination (for more information see chapter 11 titled "Disinfection" and chapter 12 titled "Cleaning and Maintenance").
b. When the matrices have been cleaned, start the mobile app and follow the instructions provided in chapter 7.

7. EXAMINATION

7.1. IMPORTANT INFORMATION

⚠ **Do not use the device while it is being charged.**

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, if you wish to compare the subsequent results of the same patient, select the examinations performed on a similar day of the menstrual cycle.

Prior to the examination, please make sure that the patient:

1. On the day before the examination:
   - avoided procedures which may have increased blood circulation in the breast area (physiotherapy, massages, etc.).
2. On the day of the examination:
   - is 18 years of age or older;
   - avoided procedures which may have increased blood circulation in the breast area (physiotherapy, massages, etc.);
   - did not take a bath or a shower within approximately two hours before the examination;
   - did not use peelings on her breasts and/or neckline and did not perform armpit depilation, as this may have irritated her skin;
   - refrained from sources of heat or cold, such as heaters or air conditioners, for at least thirty minutes before and during the examination;
   - avoided intense physical effort for approximately two hours prior to the examination;
   - did not use cosmetics and did not wet the skin on her breasts within two hours prior to the examination – her skin should

be clean and dry;
- did not have a sauna or a steam bath.

7.2. HOW TO PERFORM AN EXAMINATION

7.2.1. PREPARATION

- Place the Braster device in front of you. Make sure it is switched off. Have at hand your mobile device with the Braster Care app installed (as stated in chapter 6 of the User Manual). Check that your mobile device is connected to the Internet.
- Start the Braster Care mobile app on your smartphone or tablet.
- Log into the mobile app by entering your login and password. Login and password are the same as for your individual account on myaccount.breaster.eu, if you are a user of Braster Pro version Basic, or on hcpportal.braster.eu, if you are a user of Braster Pro version Premium.
- Register the device with which you will use for examination by clicking on the icon on the start screen and then press the "Register" button. The mobile app will ask you to enter the network name and password that you will find inside the device. After successful registration, return to the start screen.
- Click on the icon to begin the examination. The patient does not need to undress at this stage yet.

The mobile app will guide you through all the stages of the examination and will not let you skip any of them. Once you have finished certain stage, you will not be able to return to it.

7.2.2. PATIENT SEARCH (ONLY FOR BRASTER PRO VERSION PREMIUM)

If you are a user of Braster Pro version Premium, you must:

- select a patient before starting an examination if the patient has already undergone such an examination in this clinic or network of clinics,

- add the patient if she is examined in this clinic or network of clinics for the first time.

Always try to find a patient according to her data and only if she is not on the list, add her. To add a patient, click on  the icon and save the patient's ID and date of birth.

7.2.3. TURNING THE DEVICE ON/OFF

Turn the device on by pressing the ON/OFF button for two seconds. When the device is on, the battery icon will flash green. When the device is connected to your mobile device, the battery icon will be steady green.

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

The device turns off automatically after ten minutes if it is not connected to the mobile app.

7.2.4. DEVICE CONNECTION

To connect the Braster device follow the instructions displayed in the mobile app.

⚠ DURING THE CONNECTION WITH THE BRASTER DEVICE, THERE WILL BE NO INTERNET ACCESS ON THE MOBILE DEVICE

7.2.5. CONTRAINDICATIONS

In this part of the examination you need to check if you can examine patient’s breasts with the Baster device that day. Only after confirming with the patient that there are no contraindications, it is possible to proceed to the next stage of the examination.

7.2.6. ACCLIMATIZATION

The next stage of the examination is a six-minute acclimatization, i.e. regulation and stabilization of breast skin temperature. To do this, ask the patient 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 mobile app screens.

For Braster Pro version Basic you must enter the examination ID (it can be, e.g. a unique number assigned to the patient) and the patient's date of birth.

During the acclimatization the patient must answer several questions. Remember to make sure that the patient answers truthfully because her answers affect the reliability of the result.

7.2.7. MATRIX SELECTION

At this stage, you need to select the matrix for the examination. Your Braster device was provided with a set of three matrices. Each of them works in a different range of temperatures. In order to produce a high resolution thermographic image that will show the distribution of temperatures across the patient’s breasts, you will need to select a matrix before each examination.

To select a matrix, make one application of the Braster device to the central area of each breast. The mobile app will guide you step by step through this process.

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

⚠ START THE MATRIX SELECTION WITH THE RIGHT BREAST.

When instructed apply the device centrally to the breast and press the grip (**see Fig. 3**: to see the location of the grip). The clicking sound means that the grip has been pressed correctly. Remember

to hold the grip down as long as the examination is in progress. Make sure, that the whole matrix adheres tightly to the body Do not move the device across the breast, hold it firmly in one place. When instructed, release the grip and move the device away from the breast (**see Fig. 6**).

Fig. 6: Device application to the breast

⚠ REPEAT THESE STEPS FOR THE LEFT BREAST.

If matrix no. 2 is suitable for the patient, you can start the examination. If it does not suit the patient, you will be asked to remove matrix no. 2 and repeat the applications with matrix no. 1 or 3. You may be asked to return to matrix no. 2 if it is more suitable for the patient's body temperature. Once the appropriate matrix has been selected, you can start the examination.

7.2.8. EXAMINATION

To ensure top quality thermographic images during the

examination:

- apply the device perpendicular to the patient's breast (**see Fig. 7**);
- do not lift the patient's breast;
- do not move the device across the patient's breast, instead hold it firmly in one place (**see Fig. 8**);
- do not move the device away until instructed to do so;
- keep the grip pressed as long as the examination is in progress;
- do not touch the breasts during the examination and make sure that the patient also does not touch them.

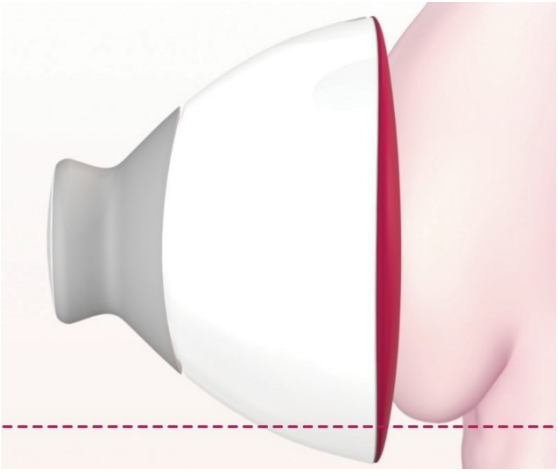


Fig. 7: Correctly applied device

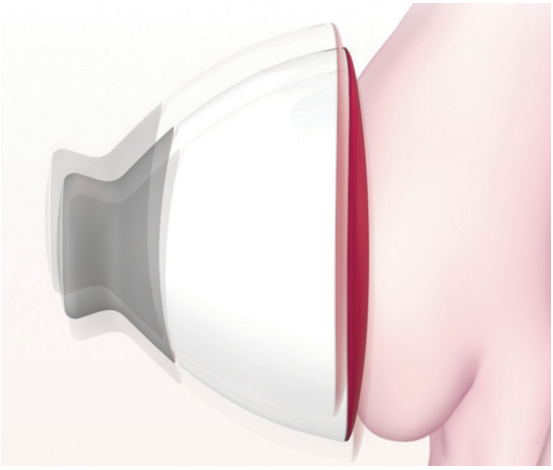


Fig. 8: Improperly applied device

Depending on the breast size which you indicated at the beginning of the examination, you will be required to make three or five applications to each breast.

⚠ ALWAYS BEGIN WITH THE RIGHT BREAST

Breast size 1, 2 or 3

If patient's breast size is 1, 2 or 3 (**see Fig. 9A** for size 1 or 2 and **Fig. 9B** for size 3), during the examination you will need to perform:

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 the breast (not to the abdomen). Do not push the breast up.
2. One upper application to the outer part of the breast, on the border with the axilla, making sure that the edge of the matrix touches upon the lateral edge of the breast and does not extend beyond it.
3. One upper application to the inner part of the breast, making sure that the edge of the matrix does not extend to the other

breast and the sternum.

The applications may overlap, but do not worry if in some of your patients' cases they do not overlap as shown in the illustrations. The crucial thing is to make sure that the entire breast is covered.

Follow the instructions displayed on the screen of your mobile device. Each application takes about 15 seconds (depending on the Wi-Fi conditions, e.g. other transmitters or radio noise). The time interval between applications lasts approximately 10–15 seconds (depending on the breast temperature and the ambient temperature). The matrix should not be in contact with the body during this time.

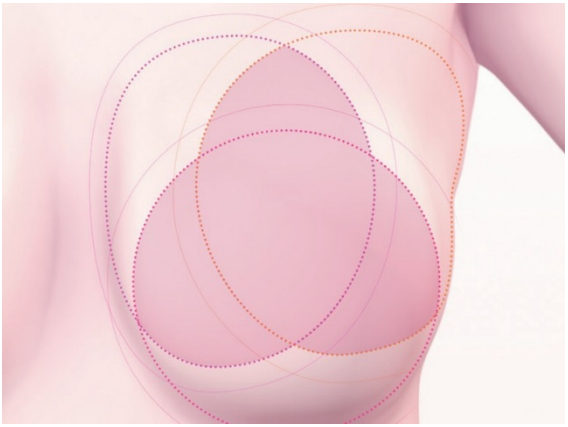


Fig. 9A Breast size 1 and 2

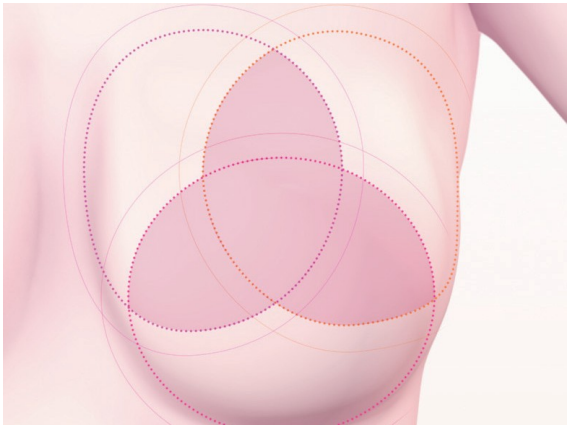


Fig. 9B Breast size 3

Breast size 4 or 5

If patient's breast size is 4 or 5 (**see Fig. 10A** for size 4 and **Fig. 10B** for size 5), during the examination you will need to perform:

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 the breast (not to the abdomen). Do not push the

breast up.

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

2. One application to the lower-outer quadrant of the breast, making sure that the lower edge of the matrix adheres to the breast (not the abdomen). Do not push the breast up.
3. One application to the upper-outer quadrant of the breast, on the border with the axilla, making sure that the edge of the matrix) touches upon the lateral edge of the breast and does not extend beyond it.
4. One application to the upper-inner quadrant of the breast, making sure that the edge of the matrix does not extend to the other breast but runs along the centerline of the sternum.
5. One application to the lower-inner quadrant of the breast. The lower edge of the matrix should adhere to the breast (not the abdomen). Do not push the breast up.

The applications may overlap, but do not worry if in some of your patients' cases they do not overlap as shown in the illustrations. The crucial thing is to make sure that the entire breast is covered.

Follow the instructions displayed on the screen of your mobile device. Each application takes about 15 seconds (depending on the Wi-Fi conditions e.g. other transmitters or radio noise). The time interval between applications lasts approximately 10–15 seconds (depending on the breast temperature and the ambient temperature). The matrix should not be in contact with the body during this time.

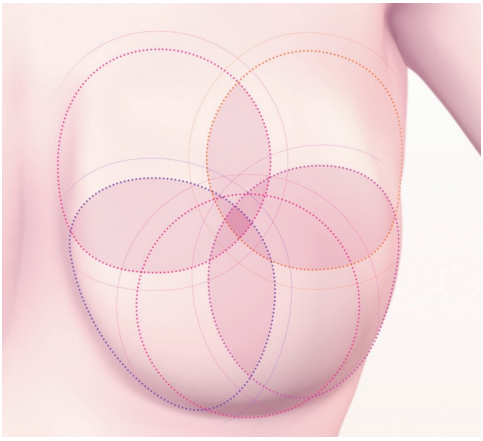


Fig. 10A Breast size 4

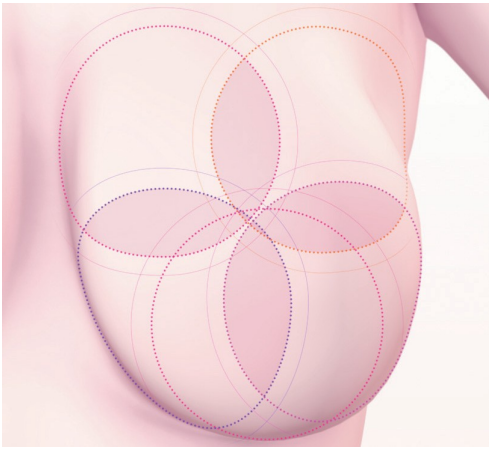


Fig. 10B Breast size 5

7.2.9. SENDING THE RESULTS TO THE TELEMEDICAL CENTER

Once you have made all the applications, you will be informed that the examination has come to an end and that you are able to send your collected data to the Braster telemedical center for analysis. Before you send the data, please make sure that your mobile device reconnects to your local Wi-Fi network. Due to the size of the

thermographic images produced during the examination, it is not recommended to send them via mobile data but by a Wi-Fi network.

For Braster Pro version Basic, if no manual interpretation is needed, the examination result will be sent to your account on myaccount.braster.eu within a few minutes.

For Braster Pro version Premium the patient's details must be confirmed when sending the thermographic images. If no manual interpretation is needed, the examination result will appear within a few minutes in the patient's data on hcpportal.braster.eu.

However, if manual interpretation is required, you may be asked to provide supplementary patient's data and the final result will be available within 2 working days from the moment of submitting the required data.

Select "Finish" after having sent the examination. After clicking on the icon  you can check the status of the examination ("Sent for analysis"). When the results of the examination have been sent from the telemedical center, the status will change to "Result available".

Please note that after each examination you should send the thermographic images produced during the examination to the telemedical center, otherwise the system might not let you perform next examination.

8. TROUBLESHOOTING THE MOBILE APP

In certain circumstances, carrying out an examination will not be possible. Below you may find tips on how to troubleshoot certain problems.

1. The Braster device uses Wi-Fi technology to transmit data to the mobile device. Wi-Fi technology, by design, relies on sharing radio bandwidth with other users. If the Wi-Fi environment in your location is overcrowded and/or many other Wi-Fi signals

are available, performance of the Braster device may be decreased resulting in a longer registration time during applications or even, in extreme Wi-Fi conditions, inability to register a full set of images. In this situation, please go to a place where the Wi-Fi environment is not overcrowded or return to the examination later that day.

2. If you do not have an active examination package or have used up all purchased examinations, the mobile app will display an appropriate message and sending of the examination will be impossible. You will need to buy an examination package to continue. If you do not want to purchase an examination package right now, select "Cancel the Examination".
3. If the battery level of your smartphone or tablet is too low, i.e. is charged in less than 30%, the examination will be impossible to perform until the device has been charged to a level indicated in the message. Select "Cancel the Examination" to return to the start screen.
4. If there is not enough disc space in your mobile device to save a complete examination, the examination will be impossible to perform until the appropriate amount of disc space is made available. Select "Cancel the Examination" to return to the start screen.

9. CHARGING

Charge the Braster device with a USB-A 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. For safety purposes, while charging, place the device in a position where you may easily remove the USB cable from the device.

⚠ The device must not be charging while an examination is in progress.

⚠ Do not turn the device on while it is being charged.

To charge the battery, pull the rubber cap with the USB sign situated on the side of the Braster device next to the ON/OFF buton. Connect one end of the USB cable to the Braster device and the other end to the charger (the plug is not included in the set). Connect the charger to a power source (**see Fig. 11**).

When the device is connected to the charger, the device power status indicator will be lit as steady orange. The indicator switches 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 the charging is complete.

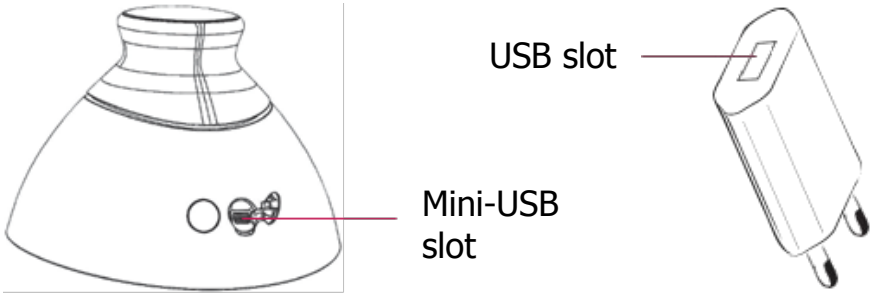


Fig. 11: Location of the USB slot

10. SAFE OPERATION

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

- Before you use the device for the first time, charge the battery using the USB cable provided.
- Only use accessories and materials supplied or recommended by the manufacturer.
- Never let the Braster device or the matrices 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 device. Keep the device in the original box.
- Do not place any items into the image acquisition device, this may cause damage to the internal framework of the device. For any damage caused by the user, the manufacturer will not be held responsible.
- Do not allow the foil on the matrix to come into contact with any sharp objects.
- During the examination, do not place any objects between the image acquisition device and the mobile device. If objects are placed between, the 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 to repair the device will void the warranty.
- Keep the device away from children.

11. DISINFECTION

Before each examination disinfect the inner and outer surfaces of all of the three matrices. Disinfection consists of spraying Softasept or disinfectants based on isopropyl alcohol over entire 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 such as bacteria, viruses and fungi.

⚠ The device must not be washed or immersed in water. Do not clean the applied parts of the matrices, which come into contact with the 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.

12. CLEANING AND MAINTENACE

Wipe thoroughly both surfaces of all of the three matrices with the provided cloth. It is important that the surface of the matrix is clean, i.e. free of any visible contamination (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 image acquisition device and the matrices must be kept in the original packaging, at temperatures between −5°C and +60°C. Do not expose the device to UV radiation (e.g. from UV lamps used for air disinfection or from the sun).

Keep the device and matrices in an original packaging to protect them from dust which may impact the quality of thermographic images.

13. SERVICING AND TECHNICAL SUPPORT

If you require technical support or if you want to report a malfunction of the device or any other unexpected circumstances, contact your local distributor of the Braster Pro or the manufacturer. Contact details of the manufacturer are available on www.braster.eu.

USER RESPONSIBILITIES

The Braster device must be used in accordance with the recommendations given in this User Manual and 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 service point (details are available on

www.braster.eu). Any actions connected with repairs or replacements may only be performed by the personnel of an authorized service point. The manufacturer is not liable for any damages caused by non-compliance with the User Manual.

Warranty

The Braster device is covered by the manufacturer's warranty for 24 months. The warranty shall only be valid if accessories and spare parts approved by BRASTER S.A. are used and the device is used as described in the User Manual and according to the intended use.

Any repairs of the Braster device must be made by the manufacturer's servicing team. Any repairs performed by unauthorized persons will result in voiding of the warranty.

14. DECLARATION OF CONFORMITY

BRASTER S.A. hereby declares that the Braster Pro conforms with the essential requirements and other relevant provisions of the Directive 93/42/EEC and the Directive 2011/65/EU. If you would like to receive the declaration of conformity, contact the manufacturer (contact details are given on the last page of this User Manual).

ELECTROMAGNETIC COMPATIBILITY

The Braster device is intended for use in an electromagnetic environment with controlled radio frequency 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). This equipment is not subject to the protection from harmful interference and may not cause interference with duly authorized systems.

15. 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 to +35°C (+41°F to +95°F) in ambient humidity of up to 90%, without condensation, and +35°C to +60°C (+95°F to +140°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 them in 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 Wi-Fi module and a RAM of at least 100 MB. For system requirements, go to: https://www.braster.eu/system
Charger	DC 5V 1A with a USB slot and meeting the IEC 60950-1 or IEC 60601-1 standards

16. ADVERSE EVENT AND MEDICAL INCIDENTS

Any adverse event or serious incidents that occur in relation to the Braster device should be reported to the manufacturer on the address given in Section "Contact to the Manufacturer" and to the competent authority of the country in which the user is established.

17. FCC REGULATORY STATEMENT

This Braster 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 may 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.
- 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 approved by the party responsible for compliance will 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.

18. CANADIAN REGULATORY STATEMENT

The Braster device complies with ISED Canada License-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 an internal, integrated antenna and it cannot operate in conjunction with any other antenna or transmitter.

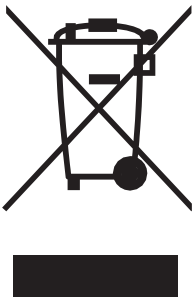
L'appareil Braster est conforme aux RSS exclus de la licence ISED Canada. L'exploitation est autorisée aux deux conditions suivantes: (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur

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.

19. DISPOSAL



This symbol is used by the company Braster S.A. 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 TO 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

www.braster.eu

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