BLEPHASTEAM®

EYELIDS WARMING DEVICE, MOIST HEAT TECHNOLOGY

EN

INSTRUCTIONS FOR USE

Version: 2.6 - Release date: 02/23/2021

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BLEPHASTEAM® is a patented medical device based on the results of scientific research by Dr JR FULLER. This innovative device relieves symptoms of Meibomian Glands Dysfunction and associated diseases. It reproduces an environment that naturally enhances tear film quality and stability by reinforcing the thickness of the tear film lipid layer.

This layer prevents tear film evaporation; it is produced by Meibomian glands which are found in the eyelids. These glands can easily be blocked, causing conditions such as **dry eye syndrome, chalazion, blepharitis or ocular rosacea.**

BLEPHASTEAM® spreads latent heat therapy which allows the melting of secretions and unblocks the Meibomian glands, improving tear film stability.

BLEPHASTEAM® has been tested and validated to ensure safe use.

While using **BLEPHASTEAM®**, Meibomian glands are unblocked, tear quality is improved enhancing ocular surface health and comfort, leading to clear vision.

| INTENTED USE

BLEPHASTEAM® is designed for relieving the symptoms caused by abnormal functioning of Meibomian glands and associated diseases such as dry eye syndrome, chalazion, blepharitis or ocular rosacea.

Eyelid hygiene with warming followed by moderate to firm massage is recommended according to the report from the International Workshop on MGD in case of Meibomian Gland Dysfunction.

The heat and moisture provided by the device melt the secretions that block these glands, making it easier to remove the secretions using massage and pressure of the eyelids.

BLEPHASTEAM® improves tear film stability by reinforcing the lipid layer thickness and helps to decrease symptoms such as grittiness/dryness, foreign body sensation or ocular discomfort.

The product is designed for indoor use only. This includes homecare use and/or use in healthcare practices (e.g. ophthalmologists, optometrists…)

For any questions about this device or for medical advice, please contact your eye specialist or Laboratoires THEA (see contact details at the end of this leaflet).

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1. GENERAL INFORMATION

Laboratoires THÉA
12, rue Louis Blériot
63017 Clermont-Ferrand
CEDEX 2 - FRANCE

DISTRIBUTOR:
See list at the end of leaflet

Always keep this user manual and accompanied documents in a safe place close to the device. The user manual should be accessible to the user at all times and the user should read all instructions carefully before using the device.

If you have technical problems with our product, please contact the **BLEPHASTEAM®** service Line. We require the following information in order to provide you with the necessary assistance:

- **Serial number of your BLEPHASTEAM® unit**

France **Laboratoires THEA**
Clermont-Ferrand
www.laboratoires-thea.com
+33 473 98 14 36

2. CLINICAL INFORMATION

2.1. INDICATIONS

BLEPHASTEAM® is designed for relieving the symptoms caused by abnormal functioning of Meibomian glands and associated diseases such as dry eye syndrome, chalazion, blepharitis or ocular rosacea.

Eyelid hygiene with warming followed by moderate to firm massage is recommended by International Guidelines in case of Meibomian Gland Dysfunction (MGD).

The heat and moisture provided by the device melt the secretions that block these glands, making it easier to remove the secretions using massage and pressure of the eyelids.

It has been reported that meibum melts at temperatures between 32°C (in normal subjects) and 45°C. Secretions from more severely obstructed glands have been found to have considerably higher melting points than the secretions from apparently normal, unobstructed glands, and thus to require higher temperatures maintained for longer periods of time for effective therapy. A constant warming of the meibomian glands to ≥38°C is vital in MGD patients to liquefy the meibum oil before eyelid massage, whilst higher temperatures, preferably ≥40°C, are recommended for more severely obstructed glands.

Because the meibomian glands are located on the inner eyelid, it is important to ensure that the inner eyelid achieves a therapeutic temperature and maintains that temperature long enough to melt the meibum. **BLEPHASTEAM®** provides safely a controlled moist heat (thus also generating high levels of humidity that prevents or reduces evaporation from the aqueous layer of the tear film), delivering a temperature of 42.5°C at the ocular surface. The heat released by **BLEPHASTEAM®** melts the meibum that blocks these gland and thus facilitates its clearance though the application of pressure on the eyelids or massage. As shown in a number of clinical studies assessing this device (in patients with MGD and/or dry eye related to MGD), this results in improving gland function, tear film thickness and stability and, ultimately, ocular comfort (i.e., relief of ocular symptoms experienced by patients suffering from MGD).

BLEPHASTEAM® improves tear film stability by reinforcing the lipid layer thickness and helps to decrease symptoms such as grittiness/dryness, foreign body sensation or ocular discomfort.

For any questions about this device or for medical advice, please contact your eye specialist or Laboratoires THEA (see contact details at the beginning of this leaflet).

2.2. CONTRAINDICATIONS

Unless otherwise specified by your doctor, **BLEPHASTEAM®** must not be used in the following cases:

- Acute diseases of the eyes and/or eyelids
- Recent injury and corneal lesions or damage to the eye
- Meibomian seborrhoea (excessive secretion of sebum produced by the Meibomian glands)
- After surgery to or around the eye
- If you are allergic to any component (plastic compounds)

2.3. POTENTIAL SIDE EFFECTS

The possible following side effects have been reported:

- Irritation and redness around the eyes
- Eye pain

  If you note any side effects or unusual sensation after using this device, please contact a health care professional or report the information to the local distributor, to the manufacturer or to your local health authority (see contact at the end of this instructions for use)

2.4. RECOMMENDATIONS FOR USE

It is recommended that you use **BLEPHASTEAM®** twice a day, unless your eye specialist tells you otherwise. Allow at least four hours before each treatment session.

It is important that the instructions for use and the recommendations given by your eye specialist are followed.

Your **BLEPHASTEAM®** device is designed to be used by **one person only** for homecare use or by multiple users in healthcare practices and must be cleaned after each use (See section 7.3 cleaning your **BLEPHASTEAM®**).

2.5. BIBLIOGRAPHY

1. Driver PJ, Lemp MA. Meibomian gland dysfunction. Surv Ophthalmol 1996; 40 (5): 343-67.
2. Foulks GN, Bron AJ. Meibomian gland dysfunction: a clinical scheme for description, diagnosis, classification, and grading. Ocul Surf 2003; 1 (3): 107-26.
3. Ong BL. Relation between contact lens wear and Meibomian gland dysfunction. Optom Vis Sci 1996; 73 (3): 208-10.
4. Arita R, Itoh K, Inoue K, Kuchiba A, Yamaguchi T, Amano S. Contact Lens Wear Is Associated with Decrease of Meibomian glands. Ophthalmology 2009; 116 (3): 379-84. Epub 2009 Jan 22.
5. Martin NF, Rubinfeld RS, Malley JD, Manzitti V. Giant papillary conjunctivitis and meibomian gland dysfunction blepharitis. CLAO J 1992; 18:165-9.
6. McCulley JP, Sciallis GF. Meibomian keratoconjunctivitis. Am J Ophthalmol 1997;84:788-93.
7. Guillon M, Styles E, Guillon JP, Maïssa C. Preocular tear film characteristics of nonwearers and soft contact lens wearers. Optom Vis Sci 1997; 74 (5): 273-9.

2.6 WARNINGS AND PRECAUTIONS

USAGE NOTES
The device must only be used for the intended use described in this manual.
Please read the entire instructions before using **BLEPHASTEAM®.**

WARNINGS

Use on clean eyes without any make-up or dermatologic ointment. Contact lenses and prescription glasses must be removed before the treatment session.

BLEPHASTEAM® should not be used lying down.

It is best to be seated and not to move when using the device.

Blink normally while using the device.

This device should not be used by any patient (including children >3 years old) who has low physical, sensory or mental abilities unless supervised and on the advice of an eye care specialist.

This is a medical device that should only be used by a capable adult or, when used by children or certain adults, under the supervision of a capable adult.

Keep the device out of the reach of children.

When used by children, **BLEPHASTEAM®** must be used in the presence of an adult.

CAUTIONS

Wash your hands before and after use.

BLEPHASTEAM® should be used by children only when supervised by an adult and after talking to an eye care specialist.

For users of contact lenses or glasses, always remove them before using **BLEPHASTEAM®**.

If you have a reaction to **BLEPHASTEAM®**, such as excessive sensitivity to heat or an allergic reaction to one of the components of the device, stop the treatment immediately and talk to your doctor.

Eye drops should not be used for at least 15 minutes before using **BLEPHASTEAM®**.

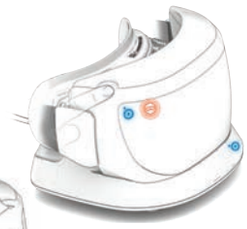
3. OPERATING INSTRUCTIONS

3.1 HOW TO USE YOUR BLEPHASTEAM®

Note that all these stages are perfectly described and illustrated in the quick start manual.

STEP #1

Press the button to start the device.
It will pre-heat during 2-3 mins until the **BLEPHASTEAM®** light will pulse **orange** and give a short intermittent beep.



STEP #2

Remove the water tray and faceseal/ water carrier from base station.

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STEP #3

Fill the water tray with bottled drinking water to the indicated water level.

STEP #4

Thoroughly wet the water carrier by holding the thumb tabs and vigorously rocking the water carrier to and from in the tray for 5-10 seconds.

STEP #5

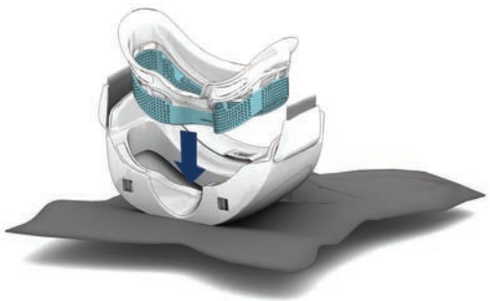
BLEPHASTEAM® is ready to use when 3 beeps and with **green** light pulsing.

If the BLEPHASTEAM® is left waiting for more than 10 minutes, the device will switch off and all the steps of the process will need to be restarted.

STEP #6

Once preheating is complete, remove the device from its base station and insert the water carrier.

It can be done by placing the mask face down and sliding the water carrier into the mask, holding the water carrier by the two tabs on the sides.

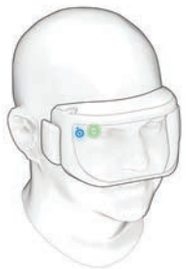


STEP #7

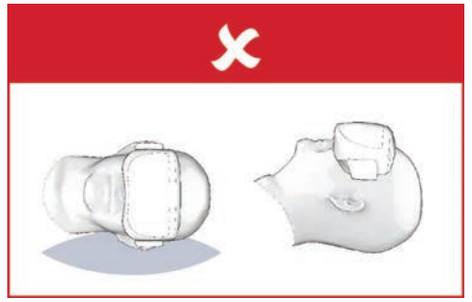
In healthcare practices, patients should wear hair hygiene protection cap before using the mask.

Wear the mask and fit over your eyes.

The strap tension is adjustable.
Treatment is now in progress and will last 10 minutes.
Two beeps will sound to indicate that the treatment is finished, and the light will turn **orange**.



CAUTIONS Do not use lying down

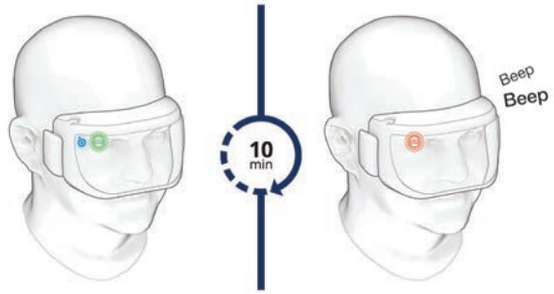


WARNINGS

Do not touch the mask with your hands during the treatment.
BLEPHASTEAM® is vulnerable to damage caused by ESD (Electro Static Discharge), so avoid contact between the device and your clothing.

Treatment takes 10 minutes. At the end of treatment 2 beeps will sound (repeating) and the **orange** status light will be on.

STEP #8



Massage your eyelids, and then **clean them** with a compress such as **BLEPHACLEAN®**.

BLEPHACLEAN® wipes can be ordered from Laboratoires THÉA or from **www.blephasteam.com**

STEP #9

Put the mask on its base after use. The **green** batteries light will flash while charging.

CAUTIONS

Always charge the device after use.

STEP #10

When the batteries are charged, the **green** light will turn OFF. The **blue** icon lights on the base and on the device remains on.

The device is now ready to start any time it may be needed.

It will take approximatively 10 minutes for the device to cool down.

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3.2 AFTER USING YOUR BLEPHASTEAM®

At home:

After use, faceseal and water tray should be cleaned, dried. All components should be stored at room temperature, in the original packaging in order to protect from light and any source of heat.
Water carrier or Faceseal (PN: T2422FSA for adult and T2422FSC for children) is reusable during maximum 3 months. It is important to clean it regularly after use.

The recommended cleaning is with water and let it dry.
Wipe the mask (PN: T2422M) with provided cleaning cloth.
Put the mask on its base station (PN: T2422BS) to reload.
Base should be plugged in.

For healthcare practices use only
Water carrier is dedicated to one patient only.
It should be discarded after patient treatment and replaced between each patient.
Water carrier is not to be reused to avoid any cross contamination between patients.
Not possible to be put in an autoclave.
For Mask (PN: T2422M) cleaning please refer to paragraph 7.3 "cleaning"
Then put the mask on its base (PN: T2422BS) to reload.
Base should be plugged.

Always charge the device after use.
Dry the water tray (PN: T2422WT) completely before storage.

3.3 LONG TERM STORAGE OF YOUR BLEPHASTEAM® (longer than 2 months)

CAUTIONS

Always charge the device before storage (till the indicator green light stops flashing).

Remove batteries when the batteries have run out, or when the instrument will not be used for extended periods (two months or longer). Leaving the batteries inside the instrument for extended periods may cause leakage or batteries fluid. In addition, when batteries have run out, remove all the batteries inside, and replace with new ones.
Failure to do so may result in dead batteries.

4. DEVICE DESCRIPTION AND EXAM ENVIRONMENT

4.1 DEVICE DESCRIPTION

The device is mainly composed of the following elements with Part Numbers (PN) mentioned (illustrated on Figure 1):

- **BLEPHASTEAM®** (PN: T2422M)
- **BLEPHASTEAM®** base station (PN: T2422BS)
- Water carrier or Faceseal (PN: T2422FSA for adult and T2422FSC for children)
- Water tray (PN: T2422WT)
- Power supply (PN: T2422PS)
- Screwdriver (PN: T2422SD)
- Set of rechargeable batteries (PN: T2422BAT)
- Cleaning cloth (PN: T2422CC)

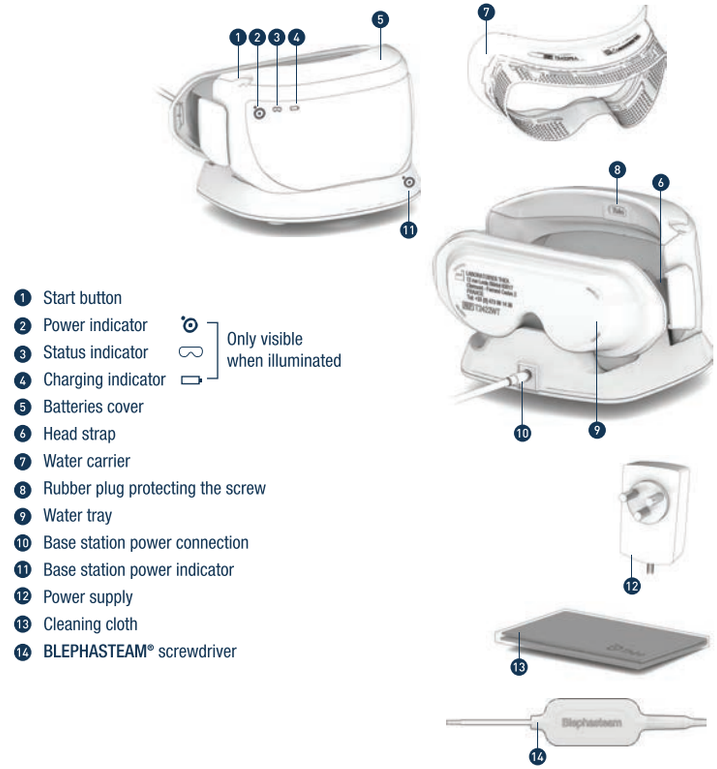


Figure 1: **BLEPHASTEAM®** front side and rear side

4.2 WEIGHT AND SIZE OF THE MAIN ELEMENTS

Element	Weight	Size
Head unit	0.193 kg	167 x 87 mm
Faceseal or Water carrier	0.025 kg	130 x 69 mm
Water Tray	0.033 kg	189 x 29 mm
Base station	0.291 kg	147 x 54 mm
Total weight and size of the **BLEPHASTEAM®**	0.542 kg	189 x 102 x 141 mm

Table 1: Weight and size of the main elements

4.3 USERS

The device is intended for Homecare use (one person only) or for use in healthcare practices (multiple users).
Intended users are adults, children from 3 years old (parents or carers should be present during the treatment), pregnant or breastfeeding women based on the current knowledge.

5. SAFETY

5.1 SYMBOLS

5.1.1 Symbols used in this manual

Symbol	Meaning	Note
	**Warning**	Improper operation may result in serious injury*1 or death to the user, patient
	Caution	Improper operation may result in bodily injury*2 or property damage*3
	**Caution**	Disconnect the device from power supply before servicing/cleaning
	**Note**	Important information for operation
	**Orange light**	Pre-heat step of the **BLEPHASTEAM®** (2-3 mins) light will pulse **orange** and give a short intermittent beep
	**Green Light flashing and 3 beeps sound**	**BLEPHASTEAM®** is ready for use

Table 2: symbols used in IFU

*1 Serious injury means vision loss, high or low temperature burn, electrical shock, fracture, or poisoning that causes a subsequent complication or requires hospitalization or long-term outpatient treatment.
*2 Bodily injury means an injury, burn, electrical shock and so forth that will not necessitate hospitalization or long-term outpatient treatment.
*3 Damage to property means extensive damage to a house and/or household goods as well as a domestic animal and pet.

5.1.2 Symbols on this device

Symbol	Standards	Description
	IEC 60417-5840	Applied part Type BF
	ISO 7010-M002	Please refer to instruction manual
	ISO 15223-1	Manufacturer
	ISO 15223-1	Manufacturing date
	ISO 15223-1	Expiry date

Symbol	Standards	Description
	Symbol 5.3.4 (ISO 7000-0626) of ISO 15223-1:2012	Moisture sensitive device
	The device must be disposed separately from domestic waste in accordance with WEEE provisions for EU member countries, and with local recycling provisions and laws for all the other countries.	
	ISO 15223-1	Serial number
	ISO 15223-1	Product reference
		Patient information web site
		Medical Device
	IEC 60417-5172	Class II device (in compliance with EN 60601-1 standards)
	IEC 60417-5957	For indoor use only
IP 21	IEC 60529	Protection indice: Protects persons against access to hazardous parts with fingers and against the harmful effects due to water vertically dripping against the enclosure
IP 22	IEC 60529	Protection indice: Protects persons against access to hazardous parts with fingers and against the harmful effects due to water dripped (15° titled) against the enclosure
	ISO 7010-W017	Warning; Hot surface

Symbol	Standards	Description
	IEC 60417-5134	Electrostatic sensitive device
	Symbol 5.3.7 (ISO 7000-0632) of ISO 15223-1:2012	Temperature limits within which the device can be safely exposed
	Symbol 5.3.8 (ISO 7000-2620) of ISO 15223-1:2012	Humidity limits within which the device can be safely exposed
	Symbol 5.3.9 (ISO 7000-2621) of ISO 15223-1:2012	Pressure limits within with the device can be safely exposed
CE 0459	"CE marking"	Product compliant with EC Directive 93/42/EEC and subsequent amendments

Table 3: Symbols on this device

5.1.3 Disclaimer

The warranty is valid eighteen months from the manufacturing date. The warranty covers any fault, material damage or manufacturing defect in products used in accordance with the instructions in this leaflet.

This warranty does not preclude the application of current legal guarantees under national legislation governing the sale of consumer goods.

Laboratoires THEA is not responsible for:

- Any damage resulting from disregarding what is described in this manual
- Any damage resulting from malfunctioning caused by a combination of connected devices
- Any damage resulting from transport, improper use or negligence, incorrect handling, modification of the system, poor maintenance, use of wrong voltage, lightning, infiltration of sand or water, use of parts or accessories not provided or recommended in this manual by Laboratoires THEA

5.2 WARNINGS & CAUTIONS

USAGE NOTES

BLEPHASTEAM® must only be used for the intended use described in this manual.
The device must be used in the specified ambient conditions.

WARNINGS

- Do not immerse the whole device in water or clean it in running water
- Do not use the **BLEPHASTEAM®** near a mobile phone or radio emitter
- Do not touch the batteries location with a wet hand. Otherwise, it may cause electrical shock
- Do not short-circuit the batteries location. Otherwise it may cause fire or electrical shock
- Do not disassemble, modify or repair the instrument by yourself. Otherwise, it may cause fire, electrical shock, bodily injury, or instrument malfunction. Refer all servicing to Laboratoires THEA or your authorized THEA dealer. The instrument disassembled, modified or repaired by anyone other than a Laboratoires THEA designated repair facility will void the warranty
- Only use the **specific rechargeable batteries** provided by Laboratoires THEA. Use of batteries not specified by Laboratoires THEA may cause fire or instrument malfunction
- If there is any abnormal odour, sound, heat, or smoke when power "ON" the device, turn the **BLEPHASTEAM®** switch "OFF" immediately. Continued use may cause fire or instrument malfunction. Contact Laboratoires THEA or your authorized Laboratoires THEA dealer for inspection
- **BLEPHASTEAM®** is vulnerable to damage caused by ESD (Electro Static Discharge), so avoid contact between the device and your clothing
- Do not bend, crush or excessively strain the cable
- Do not attach or tighten cable to or around the head or neck. Cable can cause strangulation
- Do not expose the device to moisture. **BLEPHASTEAM®** is not water-proof and does not protect against the ingress of water or moisture

- Do not place **BLEPHASTEAM®** in a microwave
- Do not autoclave **BLEPHASTEAM®** or its components
- Do not connect the device up to another appliance or to another source of power not provided by Laboratoires THEA. Otherwise, it may lead to malfunctioning of the electromedical device or expose the user to higher electrical risks
- Do not operate the device in a hazardous environment that has a risk of explosion or contains volatile solvents (alcohol, etc.) or flammable materials (anaesthetics, etc.) in the vicinity of the device
- Do not expose the device to very high temperatures or flames
- Do not use the device with a damage battery or charger (broken case, poor contact, broken feed cable). If the batteries are damaged (cracked case, leakage of electrolyte, off-shape etc.) they should be replaced by the authorized personnel. Usage of modified batteries may cause an explosion and/or damage the device
- Never attempt to access the internal hardware for any purpose including maintenance while the device is in operation. When a function check is not successful, the user is prompted to contact technical service or the manufacturer
- **Small Children:** Do not leave your **BLEPHASTEAM®** and its accessories within the reach of small children or allow them to play with it. They could hurt themselves or others or could accidentally damage the **BLEPHASTEAM®**. Your **BLEPHASTEAM®** contains small parts with sharp edges that may cause an injury or may become detached and create a choking hazard
- **Animals or insects:** Do not leave your **BLEPHASTEAM®** and its accessories within the reach of animals or insects. After treatment, your device must be put back in its original packaging
- **The use of accessories other than those specified for the device is not recommended. They may result in increased emissions or decreased immunity of the device**

CAUTIONS

- This user manual must always be accessible and close to the device. The instructions manual should be accessible to the user at all times and the user should consider all instructions carefully before using the device
- Do not use *other* batteries than the ones supplied. Damage from the use of these batteries may cause to fi re, injury or instrument malfunction. For more information, see "Precautions for batteries" described in §6
- Do not wipe the exterior of the mask with chemical products or solvent (e.g. acetone or ethanol). It may lead to discolouration or deterioration
- Do not allow terminal to come into contact with water as this may cause failure of the device. If **BLEPHASTEAM®** is dirty, wipe it with a soft cloth containing no water
- Do not install the instrument on unstable location such as on a shaky base or a tilting surface. Otherwise, the instrument may drop or fall over, causing a bodily injury
- If the device experienced an external mechanical impact (knocking, bumping, dropping, etc.), this type of shock may cause malfunctioning of the device. In case of malfunctioning, please contact Laboratoires THEA or your authorized Laboratoires THEA dealer for technical support
- Remove and store the batteries if the main unit will not be used for extended periods. Failure to do so may result in dead batteries
- Insert the batteries in the batteries in the battery compartment or the device may not work properly
- When using or carrying the instrument, hold it or attach it firmly. Dropping the instrument may lead to injury
- Periodic maintenance of **BLEPHASTEAM®** is not required by the user, only daily inspection is recommended. Maintenance of the **BLEPHASTEAM®** is required when the device does not pass its function check. When the function check is not successful, the user is prompted to contact technical support or the manufacturer (see last page)

5.3 ELECTRICAL SAFETY

BLEPHASTEAM® is supplied with a power plug cable. Do not use any other cable. Use the cable supplied with the device to connect the device to the main power socket.

The apparatus should be positioned in such a way that the power cable can under no circumstances be inaccessible.

5.4 COMPLIANCE WITH STANDARDS / REGULATION AND CLASSIFICATIONS

Compliant standards	Description	Classification
IEC 60601-1	• According to the type of protection against electric shock • According to the degree of protection against electrical shock • According to the mode of operation	Class II (double isolation) Type BF Continuous operation
IEC 60601-1-2	• Electromagnetic compatibility	* Refer EMC section 10
IEC 60529	• According to the type of protection against ingress of water as detailed in the current edition of IEC	IP 22 for the mask & IP 21 for the base station
93/42EEC -2007	• According to the EU Medical Device Regulation	Class II a

Table 4: Mains standards & Classification

5.5 BLEPHASTEAM® DESCRIPTION

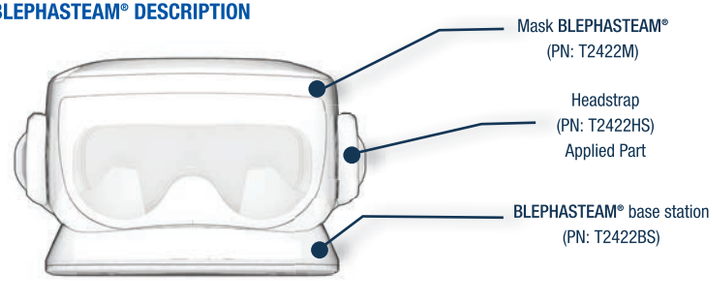


Figure 2: Front view

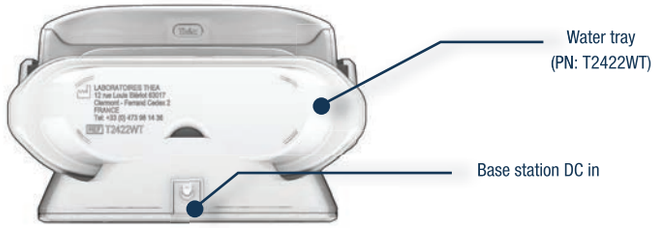


Figure 3: Rear view

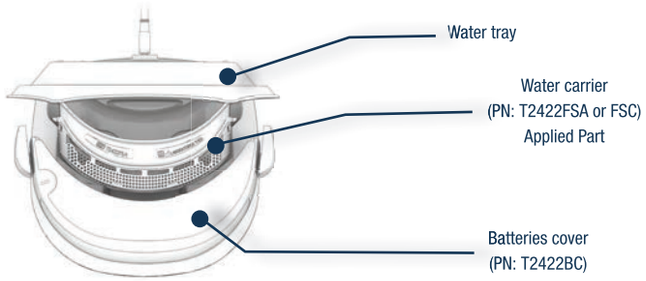


Figure 4: Top view

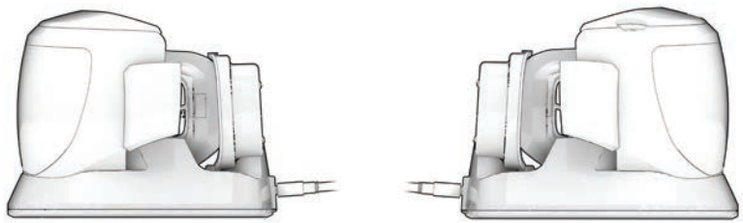


Figure 5: Right & Left sides

5.6 LABELING & POSITION

5.6.1 Base station

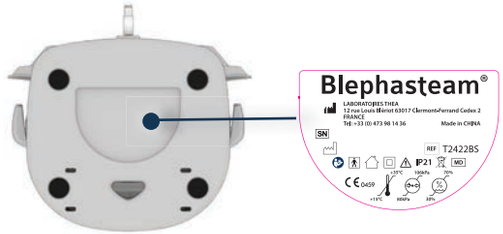


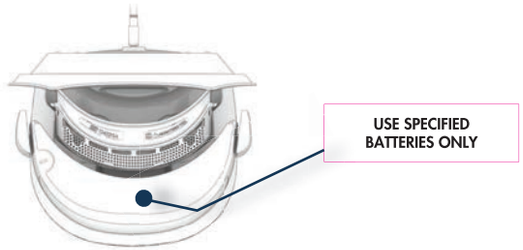
Figure 6: Bottom view

5.6.2 Interior side of BLEPHASTEAM®

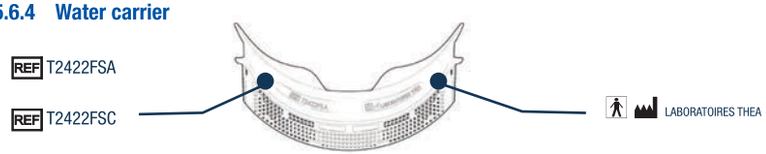
WARNINGS

This symbol indicates that the surface temperature is high. **DO NOT TOUCH.**

5.6.3 Batteries location (under cover)



5.6.4 Water carrier



5.6.5 Water tray

5.6.6 Screw driver

5.6.7 Power supply

5.7 AMBIENT CONDITIONS

Transport	Temperature -10°C to +40°C **(14°F to 104°F)** Atmospheric pressure 500 hPa to 1060 hPa Relative humidity 10% to 90%
Storage	Temperature -10°C to +40°C **(14°F to 104°F)** Atmospheric pressure 700 hPa to 1060 hPa Relative humidity 10% to 90%

When your BLEPHASTEAM device has been stored@ -10°C:
- **unpack and do not use for 1 hour until your device reaches ambient room temperature (around 20°C).**

When your BLEPHASTEAM device has been stored@ 40°C:
- **unpack and do not use for 40 minutes until your device reaches ambient room temperature (around 20°C).**

Operating	Temperature +15°C to +35°C **(59°F to 95°F)** Atmospheric pressure 700 hPa to 1060 hPa Relative humidity 30% to 70%

5.8 TRANSPORT AND PACKAGING

- The device must be transported and stored in original packaging. Storage and transport need to meet conditions described in previous section 5.7
- Keep original packaging in case of return or transport of device
- Check if there is any damage to the packaging box. If damage is found, there is a possibility of damage to the device as well. Please notify the carrier if any damage is found and report to the manufacturer
- Leave the device in a room for 1 hour before unpacking to ensure there is no condensation
- **BLEPHASTEAM®** is packed for shipping/transportation in a double cardboard box: the internal cardboard box with specially shaped forms and cardboard parts support the main console without disassembling the device; the outer cardboard box with vibration insulating layers on the top and bottom isolate the inner box from vibrations and minor mechanical impacts during transport

Keep all original packaging for future use. The system must always be transported in its original packaging method specifically designed to protect it against damage.

5.9 DISPOSAL AT THE END OF LIFE

According to Directives **2012/19/EU WEEE** and **2011/65/EU** RoHS II on the restriction of hazardous substances in electrical and electronic equipment on their disposal.

Public authorities adopt adequate measures to make sure that users, distributors and manufacturers contribute to the collection of electrical and electronic equipment, setting legal requirements for reusing, recovering or recycling said equipment.

The user must take into account the potentially harmful effects to the environment or human health due the improper disposal of the equipment or of parts of it.

This graphic symbol shown in the figure is applied on the equipment's label.
It reminds that all electrical and electronic equipment must be collected and disposed of separately at their end-of life.

5.10 PACKAGE CONTENTS

- Main unit: **BLEPHASTEAM®** (PN: T2422M)
- **BLEPHASTEAM®** base station (PN: T2422BS)
- Faceseal or water carrier (PN: T2422FSA or FSC)
- Water tray (PN: T2422WT)
- AC adapter / Power supply (PN: T2422PS)
- Batteries (pack of 2 batteries Li-ion) (PN: T2422BAT)
- User manual (PN: T2422UM)

- Screwdriver (PN: T2422SD)
- Protective housing/Softcase (PN: T2422SC)
- Cleaning cloth (PN: T2422CC)

6. EQUIPMENT ASSEMBLY / INSTALLATION

6.1 INSTALLATION

BLEPHASTEAM® is packed for shipping/transportation in a double cardboard box: The internal cardboard housing with specially shaped forms and cardboards parts support the mask and accessories. The outer cardboard box with vibration insulating layers on the top and bottom isolate the inner box from vibrations and minor mechanical impact during transport.

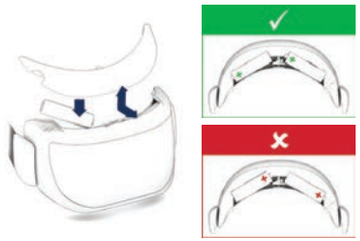
Keep all original packaging for future use. The system must always be transported in its original packaging method specifically designed to protect it against damage.

6.2 INSERTING BATTERIES IN THE MAIN UNIT

Please note that for the first use, you need to install the specific rechargeable batteries provided only by THEA.

❶ Remove the cover with the a screw driver provided.

❷ Firmly insert batteries in correct polarity positions written on the cover. The method of inserting batteries is to insert from the + terminal and push on the - terminal.



❸ Replace the batteries cover and screw it closed.
❹ Then plug the base station with the correct power supply plug provided.
❺ Put **BLEPHASTEAM®** on charge on the base station.

The **BLEPHASTEAM®** must be fully charged before the first use. Charging is complete when the green lights stop blinking.
The battery power allows the user to operate the **BLEPHASTEAM®** *for a minimum of 10 minutes (corresponding to the treatment time).*
The **green** Low Battery LED (See figure in 5.1) on the **BLEPHASTEAM®** mask will illuminate **continuously** prior to the external batteries running out of power.
The **BLEPHASTEAM®** batteries pack is recharged by connecting it to an AC adaptor. Fully recharging the batteries takes approximately 1.5 hours. While charging, the LED indicator will be **blue**. When the batteries are fully charged, the LED will be **green**. If a fault is encountered in the battery pack the **orange** LED device status indicator light flashes/stay on.

Then the base can stay plugged in permanently except if it is not used for a long time.

WARNINGS Precautions for batteries

Do not use any other batteries than the specific ones supplied. Damage from the use of these batteries may lead to fire, injury or instrument malfunction.
- Use the following batteries is strictly recommended

Specific *rechargeable Li-FePO4 Battery 3,2V-600mAh and provided by THEA*
- When using rechargeable batteries, always use the charge recommended by LABORATOIRES THEA

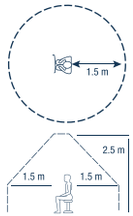
Always take the following precautions to avoid a serious injury, burn or fire caused by heat build-up, ignition, explosion and fluid leakage
- If heat build-up occurs, immediately move away from the instrument. Leakage fluid or the instrument may catch fire and explode

- If battery fluid gets into the eye, rinse it off with clean water and see doctor at once
- If your body or clothes are contaminated with battery fluid, wash it out

USAGE NOTES
Remove batteries when the batteries have run out, or when the instrument will not be used for extended periods (two months or longer). Leaving the batteries inside the instrument for extended periods may cause leakage or batteries fluid. In addition, when batteries have run out, remove all the batteries inside, and replace with new ones.

6.3 PATIENT'S ENVIRONMENT

When the patient may touch the devices (including the connecting devices) or when the patients may touch the person that comes into contact with the devices (including the connecting devices), the patient's environment is shown below.



Rules applicable for the patient environment

In the patient's environment, use the device conforming to IEC 60601-1. If you are compelled to use any device not conforming to IEC 60601-1, use an insulation transformer or the common protective earth system.

7. MAINTENANCE AND INSPECTION

Periodic maintenance of the instrument is not required by the user. Maintenance of the machine is required when the machine does not pass its start-up process check (see section "Troubleshooting"). Then, the user is prompted to contact technical support.
Please read this section carefully in order to use **BLEPHASTEAM®** correctly and safely.

CAUTIONS
Remove and store the batteries if the main unit will not be used for extended periods. Failure to do so may result in dead batteries.
Never attempt to access the internal hardware for any purpose including maintenance while the device is in operation. When a function check is not successful, the user is prompted to contact technical service or the manufacturer.

7.1 DAILY INSPECTION

- Inspect this instrument in accordance with table below:

BLEPHASTEAM® daily inspection table		
Inspection item	**Procedure**	**Acceptability criteria**
Main unit **BLEPHASTEAM®** (PN: T2422M)	Visually verify that there is no problem	There is no deformation When switch "ON", pulse **orange** light is visible, and a short intermittent beep is audible
Batteries location cover (PN: T2422BC)	Visually verify that there is no problem	There is no deformation There is no batteries leakage fluid
Faceseal or water carrier (PN: T2422FSA or FSC)	Visually check if the part is not soiled or damaged	There are no contaminants and the part should be clean There is no deformation
Water tray (PN: T2422WT)	Visually check if the part is not soiled	There are no contaminants and the part should be clean
Head strap (PN: T2422HS)	Visually verify that there is no problem (deformation, etc…)	The head strap should be adjustable
Base station (PN: T2422BS)	Visually verify that there is no problem	There is no deformation When the base is connected, base power **blue** THEA logo indicator is lighted

Table 5: Daily inspection

7.2 REPLACING BATTERIES

When the **orange** and **green** device status light flash alternatively and the **green** batteries charging light is "ON" (continuously), power supply voltage is falling.
Please replace with new batteries.

1. Remove the battery cover from **BLEPHASTEAM®** (specific screw driver is provided).
2. Remove batteries by pressing the (+) part.
3. Insert new batteries (see "inserting batteries in the main unit" for how to insert batteries).
4. When **specific rechargeable batteries run out**, place **BLEPHASTEAM®** on the base station and connect with the charger recommended by Laboratoires THEA. Batteries are 100% charged after 2 hours.

Dispose of batteries in accordance with the designated disposal method.

IMPORTANT
Homecare use:
- Keep in mind that the continuous lighting time will vary depending on a temperature or frequency of charging. In general, the greater frequency of use shortens the continuous lighting time
- If the batteries should be left unused, the performance will gradually decrease even if it will not be used at all. If you have extra batteries, please alternate them regularly to maintain efficient performance

7.3 CLEANING BLEPHASTEAM®

7.3.1 Cleaning the base station (PN: T2422BS)

WARNINGS
Switch off and disconnect the power supply before cleaning.
Do not share **BLEPHASTEAM®** with other people to prevent infection.
When the exterior of **BLEPHASTEAM®** is dirty, follow the steps below to clean it:

1. Turn "OFF" **BLEPHASTEAM®**.
2. Wipe the surface with a firmly squeezed, dampened soft cloth.
3. Wipe off the obstinate dirt with soft cloth, after dampening it in water.

CAUTIONS

- Do not wipe the exterior with chemical products or solvent (e.g. acetone or ethanol). It may lead to discolouration or deterioration
- Do not allow **BLEPHASTEAM®** to come into contact with water as this may cause failure of the device. If **BLEPHASTEAM®** (interior) is dirty, wipe a soft cloth containing no water
- Please remember that **BLEPHASTEAM®**, batteries and charger are not waterproof. Do not use these devices in the bathroom or areas with high temperature, humidity, dust or rain
- Mask could be cleaned up to 500 times

7.3.2 Cleaning the mask (PN: T2422M)

IMPORTANT
Homecare use:
- Wiping the mask of **BLEPHASTEAM®** without removing dust or debris beforehand may scratch the surface
- Wiping the **BLEPHASTEAM®** mask with alcohol/solvent may lead to deterioration of the mask surface

WARNINGS
After cleaning the mask, make sure its integrity is correct (no spots or marks on the screen).

For healthcare practices use
Between two patients, used water carrier should be discarded, **the mask should be cleaned with TRISTEL DUO® OPH only**.
Please follow the cleaning protocol as follow:

STEP #1 Dispense three pumps of TRISTEL DUO® OPH onto a dry wipe (TRISTEL DUO® Wipe is recommended). Use the wipe to spread the foam over the surface of the mask and ensure all areas are covered except the metal parts (below the mask) and the headstrap.

STEP #2 Leave the surface to dry and ensure a minimum contact time of 30seconds.

STEP #3 Rinse the mask with TRISTEL DUO® Rinsing wipes.

- **Further details available and TRISTEL DUO® OPH Products could be ordered on www.tristel.com**

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7.3.3 Cleaning the water carrier (PN: T2422FSA or FSC)

WARNINGS

Homecare use:

- Water carrier or Faceseal **must be cleaned** after each use with water
- Dry the water carrier completely before storage and reuse

IMPORTANT

- Water carriers have an estimated limited lifetime: 3 months

For healthcare practices use only:

Water carriers cannot be used on different patients. After every single use, discard the water carrier. It should not be cleaned or autoclaved.

Water Carrier (PN: T2422FSA for adult or PN: T2422FSC for children) could be ordered from Laboratoires THÉA or from **www.blephasteam.com**.

7.3.4 Cleaning the water tray (PN: T2422WT)

- Water tray must be completely dried after use by draining it upside down

7.3.5 Maintain water dust and light resistance

The device is rated IP 22 using the Ingress Protection rating system.

Your device has been tested in a controlled environment and shown to be water and dust resistant in certain circumstances (meets requirements of classification IP 22 as described by the international standard IEC 60529 - Degrees of Protection provided by Enclosures [IP Code]). Despite this classification, your device is not impervious to water damage in any situation. It is important that all compartments are closed tightly.

Note: If any liquid is found to have entered your device components or an internally sealed system, this condition will void your device warranty. Follow these tips carefully to prevent damage to the device.

- Any device which uses accessible compartments or ports that can be opened, should have these sealed or closed tightly to prevent liquid from entering the system
- Whenever your device gets wet, dry it thoroughly with a clean, soft cloth. If your device has gotten wet, you should dry the inside of the charging port before inserting a power connector to charge your device. If the charging port is not fully dry, your device may operate abnormally. For example, it may charge more slowly or overheat
- If the device is exposed to any liquid, dry it thoroughly with a clean, soft cloth. Failure to dry it as instructed may cause the device to suffer from operability or cosmetic issues
- Do not expose the device to sunlight. If the device is dropped or receives an impact, the water and dust resistant features of the device may be damaged

TROUBLESHOOTING

When a problem occurs, check the items shown below first. Look for the problem from those shown in the following list and apply the applicable remedy. If the described applicable remedy does not eliminate the problem or you encounter a problem that is not listed, contact Laboratoires THEA or your authorized Laboratoires THEA dealer.

This section describes troubleshooting procedures to solve problem you may encounter.

Indication	Cause	Action allow by patients
Blue THEA logo on the base is not lighted	There is no power to the device	Check if the main power outlet is not faulty and is switched ON Check if the power supply on the back of the **BLEPHASTEAM®** is fully in
Blue THEA logo on the headset is not lighted	The headset is not correctly seated on the base station	Lift up the headset and replace carefully back on the base station
4 audible alert beeps, followed by the **green** batteries light flashing. (Should this occur, it will normally be during treatment)	Batteries are becoming tired	Order new batteries (PN: T2422BAT) from stockiest. Replace batteries when convenient. (The device can still be used)
The device status light is flashing **orange** and **green** and the **green** batteries charging light is on (Continuously)	The batteries are exhausted	Replace batteries with new batteries (PN: T2422BAT) (The device cannot be used)
The device status light is flashing **orange** and **green**	The device has detected a temperature anomaly	Remove water carrier, unscrew batteries cover and remove batteries Wait for 15 minutes with device away from any heat source or draft. Replace batteries, cover and screw Return device to the base station and restart normally If the problem persists, contact your **BLEPHASTEAM®** Stockist/reseller
The **orange** and **green** device status lights flash alternatively and the THEA **blue** light flashes	The device has an internal fault	Contact your **BLEPHASTEAM®** Stockist/reseller

Table 6: Trouble shooting

8. TECHNICAL SPECIFICATIONS & PERFORMANCE

8.1 ELECTRICAL RATINGS

Power supply	External module with automatic voltage adaptation: no selection is needed
Input voltage range	100-240 V
Ingress Protection	IP 21
Frequency range	50-60 Hz
Inputs current	0.8 A @ 100 V
BLEPHASTEAM® consumption	12V 1.5A
Class	II (double isolation)
Reference	BI22-120150-AdV
Trade Mark	Biron
BLEPHASTEAM® Life Time	4 Years
Plug adapter is the isolation element of the network	
Batteries	Li-FePO4 rechargeable 3,2V14500-600mAh*
Rated voltage/Rated capacity	DC 3.2V / 600mAh
Trade Mark	**Batteries (by THEA/Ronda)**
Operating Time with full Charge batteries	**10 minutes +/- 1 minute**
Batteries Life Time	**1 year life When used 2 times a day**

The spare batteries (PN: T2422BAT) and Faceseals (PN: T2422FSA or FSC) must be ordered from Laboratoires THÉA or from www.blephasteam.com.

*** Batteries life and values mentioned above might vary depending on usage mode, connectivity and settings.**

8.2 MATERIALS

Water carrier	TPE (Soft plastic) / Polycarbonate (Hard plastic)

EN

9. ELECTROMAGNETIC COMPATIBILITY

9.1 GENERAL PRECAUTIONS AND WARNINGS

- Electrical medical devices and systems are subject to special measures concerning electromagnetic compatibility (EMC) and must be installed in accordance with the EMC instructions contained in this enclosed document
- Portable and mobile radiofrequency communication systems may interfere with electrical medical devices
- Use of accessories and cables other than those supplied with the instruments, except the cable sold by the equipment manufacturer as spare parts, may lead to an increase in emissions and reduce the device's or system's immunity
- The device must not be used in contact with other devices
- This instrument is not designated to be used to an external instrument or placed on top of another. Nevertheless, if such use is inevitable, it is necessary to monitor constantly to ensure the instrument is functioning normally after such use has been adopted

CAUTIONS

- If the device experienced an external mechanical impact on the mask (knocking, bumping, dropping, etc.), this type of shock may cause malfunctioning of the device. In case of malfunctioning, please contact Laboratoires THEA or your authorized Laboratoires THEA dealer for technical support

Essential Performance of the system. (Significant operating characteristics)

BLEPHASTEAM® monitors heat therapy (42.5±3°C) during a period of time (10±1 min) in an enclosed environment.

9.2 ELECTROMAGNETIC EMISSIONS

The device is intended for use in the following electromagnetic environment. The user must ensure compliance with this guideline.

Guidance and manufacturer's declaration - electromagnetic emissions		
The BLEPHASTEAM® is intended for use in the electromagnetic environment specified below. The operator of the BLEPHASTEAM® has to make sure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - Guidance**
Radiated RF emission acc. to CISPR 11	Group 1 Class B	The **BLEPHASTEAM®** uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to impair nearby electronic equipment
Conducted RF emissions acc. to CISPR 11	Group 1 Class A	The **BLEPHASTEAM®** is suitable in all establishments other than those in living areas and those directly connected to the public low voltage power supply network that also supplies buildings used for living
Harmonic emissions acc. to IEC 61000-3-2	Compliant	
Voltage fluctuations/ Flicker emissions acc. to IEC 61000-3-3	Compliant	

Table 7: Electromagnetic emissions

9.3 INTERFERENCE IMMUNITY

The device is intended for use in the following electromagnetic environment. The user must ensure compliance with this guideline.

Guidance and manufacturer declaration - electromagnetic immunity			
The BLEPHASTEAM® is intended for use in the electromagnetic environment specified below. The operator of the BLEPHASTEAM® has to ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - Guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the **BLEPHASTEAM®**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter **Recommended separation distance.**
Conducted RF disturbances according to IEC 61000-4-6	3 Veff 150 kHz to 80 MHz	Not applicable	Recommended separation distance This test is not applicable since the equipment has not power or input/output line
Radiated RF disturbances according to IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	$d=1.2\sqrt{P}$ for 80 MHz to 800 MHz
			$d=2.3\sqrt{P}$ for 800 MHz to 2.5 GHz
			Where P is the maximum emission output power of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m) Field strength from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b] Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1: At 80 MHz and 800 MHz the separation distance for the higher frequency range applies. **NOTE 2: This guidance may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.**			
[a] Field strength from fixed transmitters, such as base stations for radio (Cellular / cordless) and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device BLEPHASTEAM® is used exceeds the applicable RF compliance level above, additional measures may be necessary, such as reorientation or relocating the BLEPHASTEAM®. In case unusual performance is witnessed, additional measures may be required such as change of orientation or location of the BLEPHASTEAM®. **[b] Field strength should be less than 10 V/m in the range between 150 kHz and 80 MHz**			

Table 8: Electromagnetic immunity

The **BLEPHASTEAM®** is intended for use in an electromagnetic environment where radiated RF disturbances are under control. The customer or the user of the device can help prevent electromagnetic interference by maintain a minimum distance between mobile and portable RF communication devices (transmitters) and the **BLEPHASTEAM®** device as recommended below, according to the maximum output power of the radio communications devices.

Recommended separation distances between portable and mobile RF communications equipment and the BLEPHASTEAM®			
The BLEPHASTEAM® is intended for use in an electromagnetic environment in which the radiated RF disturbances are controlled. The BLEPHASTEAM® user can help prevent electromagnetic interference by maintaining a minimal distance between portable and mobile RF communications equipment (transmitters) and the BLEPHASTEAM® as recommended below, according to the maximum output power of the communications equipment.			
Maximum transmitter power output (W)	**Separation distance according to the transmitter's frequency (m)**		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	**80 MHz to 800 MHz** $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum emission output power of the transmitter in watts (W) according to the transmitter manufacturer. **NOTE 1: Between 80 MHz and 800 MHz, separation distance for the highest frequency range applies** **NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.**			

Table 9: Recommended separation distance between portable & RF

Note: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which this product is used exceeds the applicable RF compliance level above, this product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating this product.

9.4 IMMUNITY

The device is intended for use in the following electromagnetic environment. The user must ensure compliance with this guideline.

Guidance and manufacturer declaration – electromagnetic immunity			
The BLEPHASTEAM® is intended for use in the electromagnetic environment specified below. The operator of the BLEPHASTEAM® has to ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - Guidance**
Electrostatic discharge (ESD) acc. to IEC 61000-4-2	- ±8 kV contact discharge - ± 15 kV air discharge	Limited to ±8 kV contact discharge test Limited to ±8 kV air discharge test	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic materials, the relative humidity should be at least 30%
Electrical fast transients/ burst acc. to IEC 61000-4-4	- ±2 kV/100 Hz for power supply lines	±2 kV/100 Hz for power supply lines	The quality of the supply voltage should correspond with one characteristic for a typical commercial or hospital environment
Surge acc. to IEC 61000-4-5	- ±0.5, ±1 kV differential mode	±0.5, ±1 kV differential mode	The quality of the supply voltage should correspond with one characteristic for a typical commercial or hospital environment

Guidance and manufacturer declaration – electromagnetic immunity			
The BLEPHASTEAM® is intended for use in the electromagnetic environment specified below. The operator of the BLEPHASTEAM® has to ensure that it is used in such an environment.			
Voltage dips, short-term interruptions and voltage variations on power supply input lines acc. to 61000-4-11	<5% *Ur* during 0.5 period 40% *Ur* during 5 periods 70% *Ur* during 25 periods <5% *Ur* during 5 s	Compliant to the specified levels Compliant	The quality of the supply voltage should correspond to one characteristic for a typical commercial or hospital environment. If the user of the **BLEPHASTEAM®** requires a continuous function of the appliance also during interruptions of the power supply, it is recommended to supply the **BLEPHASTEAM®** out of an uninterruptible power supply or batteries
Power frequency (50/60 Hz) magnetic fields acc. to IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic for commercial or hospital environments

NOTE: *Ur* is the voltage of the alternative supply voltage before the application of the test level

Table 10: Guidance on manufacturer declaration - electromagnetic immunity

CAUTIONS

Note:
If spots or marks appear on the screen, that means potential defects occurs and the mask and potential electrical interference is present with the system. If present, discontinue the use of the device until you contact Laboratoires THEA or your authorized Laboratoires THEA dealer for technical support.
In order to avoid Hight level of ESD discharge, it is recommended not to touch the mask with your hands during treatment.

Interference may occur in the vicinity of equipment marked with the following symbol:

10. CONTACT

If you have technical problems with our product, please contact the **BLEPHASTEAM®** service Line. We require the following information in order to provide you with the necessary assistance:

- Serial number of your **BLEPHASTEAM®** unit

France	Laboratoires THEA Clermont-Ferrand	www.laboratoires-thea.com	+334 73 98 14 36