Read this manual before using the device

SUMMARY

MI-UBHS02-UK - Rev. 1.1 - August 2018
SW. 1.x

1 INTRODUCTION

1.1 What FAST model UBHS-02 is and how it works

This manual describes the function and use of the medical device model UBHS-02, hereafter referred to with its brand name FAST.

FAST is a therapeutic device and shall be used on medical prescription.

FAST is a *Low Intensity Pulsed Ultrasound* Stimulator for the Bone Growth

The ultrasound is an acoustic vibration with frequency above the human auditive level, thus the device is silent.

FAST is a medical device which, by means of an ultrasound transducer, applies to the area to be treated an ultrasound signal, whose SATA Acoustic intensity and frequency, is effective to accelerate the osteogenetic process therefore reducing the healing times.

The application of this ultrasound transducer is simple and does not require any assistance by specialized medical staff, as the patient can apply it on its own.

FAST is controlled by a microprocessor which ensures efficient device operation, and which immediately alerts the patient of malfunction or problems that may arise during therapy.

1.2 Who can use FAST

FAST must be used by people who understand and put into effect independently the instructions provided in this manual: otherwise, and if used on children, FAST can be used only under the supervision of people able to understand and put into effect the instructions provided in this manual.

1.3 Clinical indications

Main **indications** for use of FAST are:

- Recent fractures
- Non union
- Pseudoarthrosis
- Septic pseudoarthrosis

2 FAST COMPONENTS

Figure 1 - FAST components

FAST device is composed by the following parts:

- The signal generator ①;
- The transducer ②, applied part of the device
- The external power supply ③
- The armlet, with elastic strap ④
- A tube of gel.

2.1 Generator description

Figure 2 - FAST Generator

The generator is equipped with:

- A **display** that shows the following information:
- the battery charge status (Figure 2, ❶);
- the daily treatment timer (Figure 2, ❷);
- in the lowest part of the display (Figure 2, ❸) are shown all symbols related to the execution the treatment and the error messages.
- A **function button** (Figure 2, ❹), to start or pause the treatment.
- A **ON/OFF button** (Figure 2, ❺), marked with the symbol ⏻.
- A **RESET button** (Figure 2, ❻).

On the lower side of the device, there are three sockets:

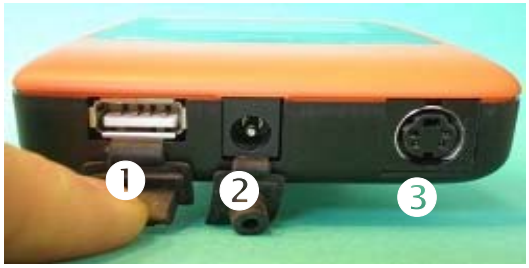


Figure 3 – lower side of FAST generator

- The **USB** socket (Figure 3, ❶) marked with the symbol .
- The **Power Supply** socket (Figure 3, ❷) marked with the symbol .
- The **Transducer** socket (Figure 3, ❸) marked with the symbol .

Normally USB (❶) and power supply sockets (❷) are covered with rubber cap, that should be removed only when the socket is used.

The rear side of the generator houses the data plate containing identification data and regulatory symbols.

2.2 Applied part – Ultrasound Transducer

The applied part of the device is an ultrasound transducer that must be applied directly onto the area to be treated, by means of the armlet, as described in chapter 3.1.

2.3 Gel for ultrasound transmission

The supplied gel tube contains the gel to be applied on the side without writings of the transducer, to form a 1-2 mm thick layer, before treatment.

The gel is necessary to allow the ultrasound transmission to the treatment area; **use only ultrasound gel supplied by the manufacturer.**

3 FAST OPERATION

FAST device can be used in two modes:

- **battery** mode, when the internal battery is fully charged, FAST can deliver up to 5 treatments;
- with **external power supply** that powers the device while recharge the internal battery.

Note: The battery must be fully charged before using the device for the first time, upon receipt.

3.1 Treatment execution

To perform the treatment proceed as follows:

1. Connect the transducer to the generator, inserting the connector into the appropriate socket; keep the arrow symbol/white dot on the connector facing upwards.
   Caution: handle the transducer carefully, as a fall may damage it.

2. Wear the armlet on the area to be treated and secure it with the elastic strap. The excess elastic strap can be cut by the user.

3. Open the orange cover by rotating it.

4. Apply the gel to the transducer surface (side with no writings) to form a 1-2 mm thick layer; spread the gel with a finger to obtain a uniform layer.

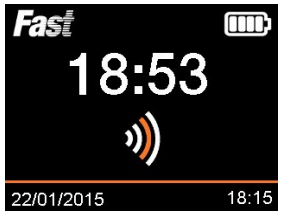
5. Insert the transducer inside the armlet so that the serial number is visible; then close the orange cover by rotating it.

6. Turn on the device by pressing on/off button (Figure 2, ❺) for two secs, until you hear a "beep", then release the button. The display lights up and the IGEA logo appears followed, after a few moments by the FAST logo.

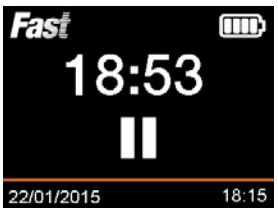
The device is now ready for treatment;

- The display shows the 20 minutes of treatment time along with the 'play' symbol (white triangle).
- The **'gel' symbol flashes** (for 10 secs) to remind the user **to apply ultrasound gel on the transducer before starting the treatment.**

7. To start the treatment **press the function button of the device** on the front panel, shown in the figure; the generator signals the start of treatment with a "beep".



During treatment, the display shows the remaining therapy time and the animation indicating the correct operation.



Pressing the function button, the treatment is paused; the remaining time is stopped and the pause symbol appears. To resume the treatment, press the function button again.

At the end of the daily treatment time, the display shows the symbol '√' and emits three long "beeps"; after 30 seconds, FAST turns off automatically.

8. Open the orange cover of the armlet and remove the transducer. Remove the armlet from the treatment site and clean all the parts from the remaining gel.

3.2 Therapy times

The user must perform therapy for the number of days indicated by the doctor who prescribed the therapy.

FAST provides a daily 20 minute treatment; any treatment of more than 20 minutes per day must be authorized by the doctor who prescribed the therapy.

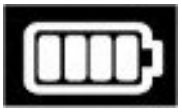
FAST allows a maximum of two treatments per day, which must be performed not consecutively and by midnight on the current day.

3.3 Battery monitoring and recharging

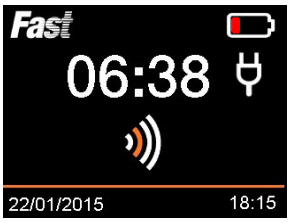
Battery charge status indicator is shown on the upper right corner of the display.

When the battery is fully charged, FAST can deliver up to five treatments.

If the device is on, waiting to start the treatment and the power supply is not connected, the generator will automatically turn off after two minutes of inactivity, to reduce battery consumption.

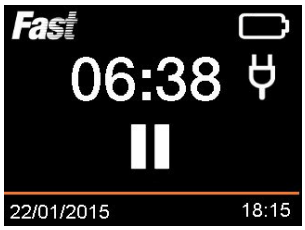


The battery symbol is characterized by several notches, which go out as the battery runs down.



The battery level decrease gradually until the **low battery** level; the red indicator and the plug symbol indicate the need to connect the external power supply to recharge the battery.

In the "low battery" condition, treatment delivery can continue.



If not recharged, the battery level decreases up to a **empty battery** level, indicated by the flashing empty battery symbol and by three repeated short "beeps". The generator automatically switches into pause mode and the treatment stops: **to continue the treatment connect the power supply and press the function button**.

Connect the power supply **first to the generator**, removing the protective cap (Figure 3, ❷), **then to a mains socket**.

When the power supply is conneceted, the battery charging process starts and a **flash symbol** appears next to battery status symbol.

Warning: the flash symbol does not appear in case of faulty power supply. Contact the technical service for assistance.

During the battery charging process, the battery charge status indicator moves from one level to next one until the process is finished. When the charging process is completed the full battery symbol is displayed. Disconnect power supply and insert the rubber cap into the power socket.

It is possible to recharge the battery even when FAST is turned off, connecting the power supply to the generator.

The battery charge status indicator is shown in the center of the display and is updated from one level to the next until the battery charging process is complete.

When the charging process is completed, the indicator shows the full battery symbol. Disconnect the power supply from the generator and insert the protective cap into the socket.

In case internal battery is faulty, the battery charging process is not possible and the display shows the battery symbol with a warning triangle in the middle: Contact the technical service.

In case of faulty battery, it is possible to carry out the treatment by connecting the external power supply. The generator, after a few seconds, automatically starts in “treatment mode” (the symbol "X" on the battery, indicates that the battery is faulty and is not charging).

At the end of the treatment, it is necessary to disconnect the power supply from the generator to switch off the device.

In case of faulty battery, it is not possible to turn on FAST in “calendar mode”.

- If the device is not used for long periods, the internal battery may be completely discharged: it is recommended to recharge the battery before starting the treatment.
- If the battery does not allow completing the treatment, fully recharge the battery: if the problem persists, contact the technical assistance service.
- For a better battery efficiency, always charge the battery in environments with temperatures below 40°C.

4 DEVICE CLEANING

The device shall be used in compliance with the normal rules of hygiene, and shall be cleaned regularly. The presence in the environment of use of hair, dust, and exposure to direct sunlight, even if it does not cause malfunction of the device, shall be avoided.

Before cleaning the generator and its parts, make sure that it is switched off and disconnected from the power supply. Handle the transducer carefully because a fall could damage it.

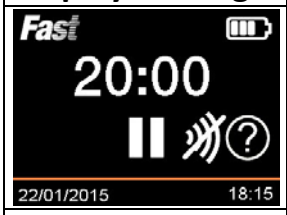
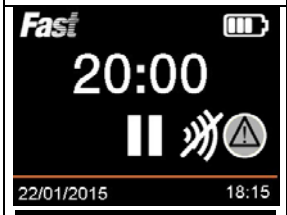
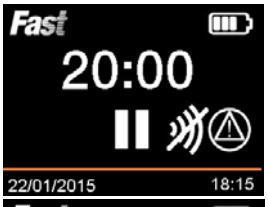
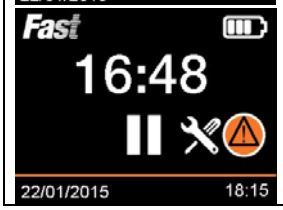
Accurately clean the transducer, as dirty applied parts could result in ineffective treatment.

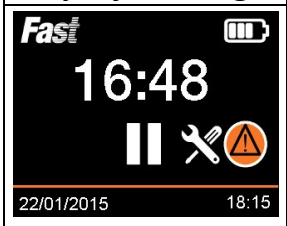
Clean the device **after each treatment** as indicated below:

- Clean the generator with a slightly damp cloth using water or a neutral detergent; do not use solvents or other aggressive detergents;
- Gently clean the transducer using a cloth moistened with water; do not use solvents or other aggressive detergents;
- Never use any spray products directly on the generator to avoid the risk of the liquid penetration;
- Never pour water or liquids of any type directly onto the generator;
- The elastic strap can be washed like an ordinary clothing.

5 ERROR MESSAGES AND TROUBLESHOOTING

If alarm conditions occur during the treatment, the treatment is interrupted and the anomaly is notified to the user by means of the visual and a**coustic messages** described below. When possible, restore the normal condition and restart the treatment by pressing the function button, otherwise contact the technical assistance service.

Display message	Acoustic signals	Problem and solution
	Three short “beeps” every 3 seconds	**Not Connected Transducer:** Check the connection of the transducer to the generator and press the function button to restart the treatment.
	Three short “beeps” every 3 seconds	**Treatment not allowed** FAST allows a maximum of two treatments per day*; if two treatments have already been carried out during the day, no other treatments are allowed. The generator switches off automatically after 30 seconds. ** The second treatment must be completed by midnight on the current day.*
	Three short “beeps” every 3 seconds	Maintenance Required: Maintenance is required; the generator switches off automatically after 30 seconds. Contact the technical assistance service**.**
  	Three short “beeps” every 3 seconds	**Detected fault:** FAST detects an anomaly in the transducer or generator operation and stops the treatment. - Check the presence of gel on the transducer, which must form a uniform layer 1-2 mm thick, then restart the treatment, pressing the function button. - If, after checking the presence of gels, the message remains, turn off the device, and contact the technical assistance service**.**

Display message	Acoustic signals	Problem and solution
 	Three short “beeps” every 3 seconds	**Anomaly detected** if the display shows in sequence these two messages, FAST detects an anomaly and after 5 seconds, it switches off automatically; **contact the technical assistance service.**
	\	**Damaged internal battery**: recharging is not possible: contact the technical assistance service.
	\	In case of damaged battery, it is possible to carry out the treatment by connecting the external power supply; in this case, the "X" symbol on the battery indicates that the battery does not charge.
⚠ **Block of the device**: Electromagnetic interference, such as active cellular phones or disturbance to the power supply system, can interfere with the normal FAST operation and cause the device to block. **To restore normal operation, press the RESET button**, on the left side of the generator, with a pointed object, and turn on the device. Be sure to remove the source of disturbance before continuing the treatment.		

⚠ The user must never make any service on the system. **The device technical assistance is exclusive pertinence of Manufacturer IGEA S.p.A.**

⚠ In case of failure, or in any case where repairs is necessary, the user should contact a service centre, authorized by IGEA S.p.A.

IGEA S.p.A. Authorized Service Centre: Tel. +39 059699600, Fax. + 39 059695778, e-mail: info@igeamedical.com

6 MANAGEMENT OF THE TREATMENT CALENDAR

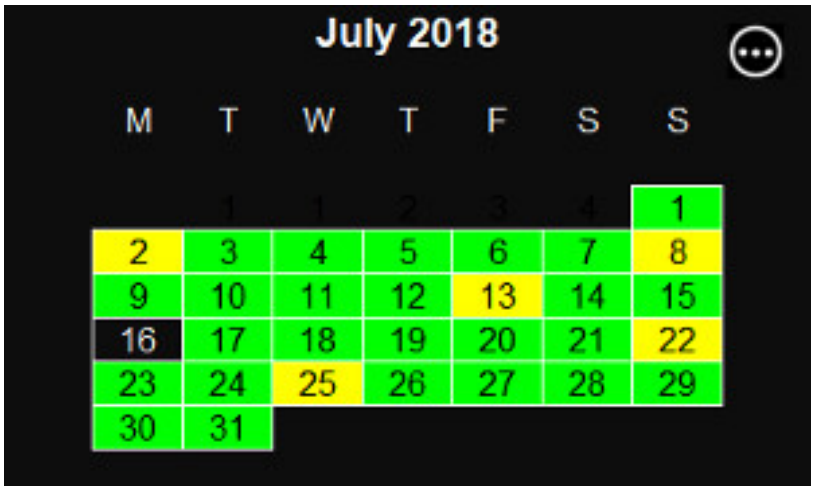


Figure 4 - Treatment Calendar

FAST is equipped with an internal memory that records data related to treatments performed for a period of up to 3 months, starting from the first day of treatment.

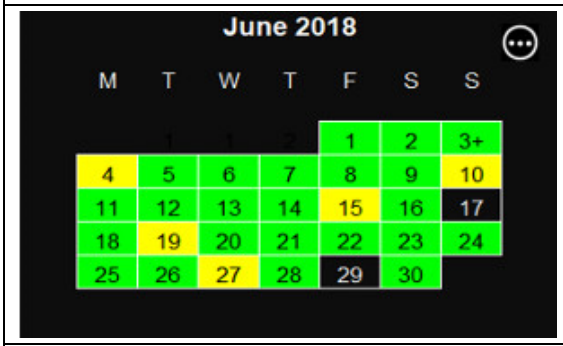
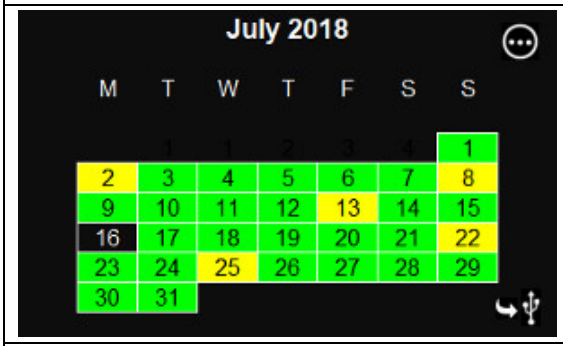
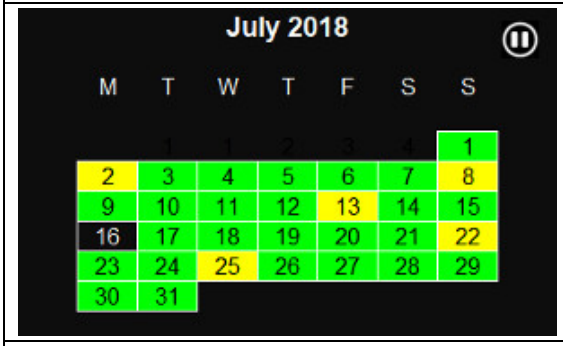
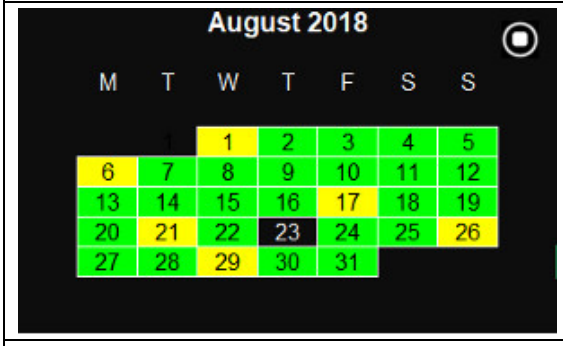
The day and duration of each treatment are recorded and displayed as a calendar, as shown in Figure 4, according to the following criteria:

- Day on **black background**: no treatment performed;
- Day on **yellow background**: treatment performed lasting less than 20 minutes;
- Day on **green background:** treatment performed correctly;
- Day on green **background** and **'+'symbol**: more than one treatment performed;

Treatment data are shown in read-only mode and cannot be changed by the user.

Note: At the end of the available memory space, the oldest data are overwritten by the latest treatment data. A maximum of 13 months can be displayed in sequence.

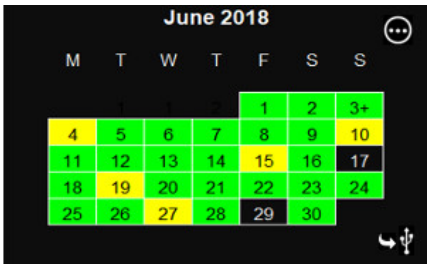
In order to enter in calendar mode, please proceed as follows:

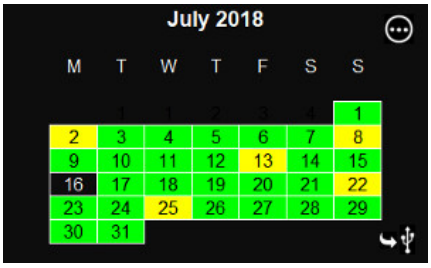
<table>
<tr><td> 
</td><td>1. Turn on the generator pressing the on/off button (Figure 2, ❺), for at least 5 secs until you hear a short ‘beep’ followed by a longer ‘beep’.
The display lights up, the IGEA logo appears followed, after a while, by the FAST logo.</td></tr>
<tr><td> 
</td><td>2. The display shows data recorded in first month of treatments, as shown in the image. In the right up corner, a small image with three dots means that other months are going to be displayed.</td></tr>
<tr><td> 
</td><td>3. After 5 secs, the display automatically switch to data of the treatments performed in the following month.</td></tr>
<tr><td> 
</td><td>4. Pressing function button, the sequence is paused (in the right up corner, a small image with pause symbol is displayed); press the function button again to restart the sequence.</td></tr>
<tr><td> 
</td><td>5. The sequence stops on the last month of treatment data (in the right up corner, a small image with stop symbol is displayed); pressing function button, the sequence restart from the beginning.</td></tr>
<tr><td colspan="2">6. Turn off the device in order to exit calendar mode.</td></tr>
</table>

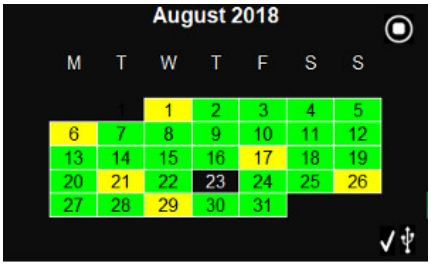
6.1 Treatment Data Export

The user can export treatments data on a USB pen drive. In order to do this, please proceed as follow:

1. Insert a USB pen drive into the USB socket (Figure 3, ❶).
2. Turn on the device in calendar mode, as above specified.







3. The symbol appears on the right down corner along with an arrow indicating the data has been saved on USB pen drive, in the file "**FastTrtLog.txt**". If the file already exists on USB pen drive, data are added to the existing ones.
4. After 5 seconds, the next month is displayed and data are saved on USB pen drive in the file FastTrtLog.txt"; this step is repeated for each displayed month.
5. Data saving ends when the display shows the last month of registered treatments and the symbol 'V' is shown next to the symbol .
6. Remove USB pen drive and analyse data with a PC; in case of Excel, please use the function "import data from file".

In case the user restarts the calendar sequence, pressing the function button and the USB pen drive is still connected to FAST, the treatment data will be saved again in the same file "FastTrtLog.txt", at the end of the previous data.

If the USB pen drive is not removed and FAST is turned on in "Treatment" mode, the connection of the USB pen drive is indicated by the symbol next to the battery symbol.
When the USB pen drive is removed from the generator, the symbol disappears.

7 SAFETY INSTRUCTIONS

7.1 Warning and Recommendations

Closely follow these instructions to ensure optimal and safe operation of the device:

- **Carefully read the present instructions manual before using FAST.**
- FAST must be used by people who understand and put into effect independently the instructions provided in this manual: otherwise, and if used on children, FAST can be used only under the supervision of people able to understand and put into effect the instructions provided in this manual.
- Keep the device away from children and pets, if any.
- Handle any parts of the device with care to prevent damage to the device; in particular, handle the transducer with care, avoiding impacts, violent blows or falls that could compromise the operation of the device.
- Place all parts of the device in the supplied box, after use.
- Before using the device, make sure that the display is sufficiently visible.
- Attention: connecting cables could cause strangulation hazard if incorrectly used.
- Do not attempt to disassemble or detach any part of the medical device. Do not open the device and or the service door on the back of the generator: use permitted only by authorized personnel!
- Do not put any part of the medical device into mouth in order to avoid any risk of suffocation.
- Do not over tighten the armlet elastic strap.
- Do not use the device in the presence of inflammable gases.
- Keep the device or its applied part (transducer) away from breathing system or other devices that use oxygen because.
- Do not handle any of the system components with wet hands, especially when connecting the power supply to the mains.
- Do not dip or splash any of the system's components with water or any other type of liquid. **In the event of the accidental immersion of the generator in liquids, it must no longer be used** and must be returned to an authorized assistance centre or manufacturer for checking/repairs.
- Do not connect any part of unit to other equipment or devices.
- Do not connect to FAST any part not intended for use and not supplied by the manufacturer.
- Do not cover the generator, for example with blankets, during the use or the charge, to allow aeration and avoid overheating of the device.
- Do not put the generator directly on the body during the charging of the battery.
- Clean regularly the transducer to prevent accumulation of dirt; use neutral detergents; do not use aggressive solvents or detergents.
- Clean the generator with a slightly damp cloth using water or a neutral detergent; do not use spray or flammable liquids. Switch off the device and disconnect the power supply before cleaning.

- Check the integrity of the transducer cable before each treatment session. If it is damaged, replace with a new transducer supplied by the manufacturer.
- Before use, always check for visible damage to the power supply case and cable; never use a damaged power. In case of damage, replace the power supply with a new one supplied by the manufacturer.
- Do not expose the generator that contains Li-Ion battery to heat sources and do not throw it into fire; danger of explosion!
- The internal battery must not be removed. Battery replacement is allowed only to personnel authorized by IGEA. Battery is a polluting waste and mast be disposed in compliance with waste material directives & local lows.
- The device is equipped with self-control mechanisms of the correct functioning; any anomaly that may occur is indicated by the system and is described in the instruction manual. Any malfunctions therefore do not affect therapeutic efficacy.
- Always ensure that the liquid gel complies with the use specifications and that the packaging bears CE marking.
- Use only the gel for ultrasound supplied by the manufacturer or authorized distributor.
- It is recommended not to use the device in concomitance with cellular phones or any devices potentially causing disturbance to the power supply.
- Position FAST so that disconnection from the power supply is easy to operate.
- ⚠ Warning: to recharge the battery use only the power supply provided; using a different device could damage the generator or battery or, worse still, cause harm to the user, for which the manufacturer cannot be held responsible.
- IGEA recommends repeating safe test at regular intervals not exceeding 24 months of use, to ensure that safety standards are consistently maintained. IGEA, in agreement with the client, is able to perform the recommended safe test.
- IGEA recommended a routine maintenance procedure for the operating parameters check at regular intervals not exceeding 24 months of use to ensure reliable performance; contact IGEA or an authorized assistance centre.

7.2 Contraindications and adverse effects

No adverse effects have been noted which might be attributable to the treatment with FAST. However, it is necessary to consider the following precautions:

- In case of wounds or skin lesions in the area of treatment, always inform the doctor who prescribed the therapy that will evaluate the opportunity to start or continue the therapy.
- If you know or think you are pregnant, always inform the doctor who prescribed the therapy who will evaluate the need to continue/interrupt it.
- FAST can be used in the presence of internal synthesis means. In case of plate, do not place the transducer directly on the plate, but on the side or on the side opposite to it, to prevent the ultrasound signal from being reflected.
- With active implantable devices, such as cardiac pacemakers, operation may be adversely affected by close exposure to the FAST device; therefore, evaluation during the treatment by attending cardiologist is recommended. In any case, do not make any therapy with direct application of the applied part on the thorax and keep the generator far from the thorax.
- The use of the device at the same time of the use of drugs do not normally presents contraindication. The doctor who prescribes the therapy should be informed by the patient for any medication.

7.3 Biological Safety

The safety and effectiveness of the FAST treatment system has been fully proved and all performed tests have demonstrated the complete absence of any negative treatment effects.

8 MANUFACTURER'S RESPONSIBILITY

The Manufacturer is responsible for the safety, reliability and performance of the device, only providing that:

- The device is used in conformity with user instructions in this manual.
- Modifications or repairs, or hardware or software updates have been performed directly by the manufacturer or by authorized qualified personnel only.
- The user or any unauthorized person do not open or tamper with the device in any way.
- The protective devices applied by the manufacturer are never removed from the device or its parts.
- The devices is used exclusively with the power supply supplied by IGEA or authorized distributor.
- The power supply is used exclusively for operation of FAST and in accordance with the terms specified in this manual.
- The user regularly makes all the necessary cleaning operations according to the instructions of the present manual.
- The user regularly perform, every 24 months, the safe test and the operating parameters check recommended by IGEA.

IGEA reserves the right to implement updates that improve the system performances without modifying pictures or instructions of the present manual.

For further details or updates, the user may contact the manufacturer or its local authorized dealer.

Manufacturer:

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9 TECHNICAL DATA

MANUFACTURER: IGEA S.p.A. Via Parmenide 10/A 41012 Carpi (MO) - ITALY

FAST, Model UBHS-02 complies with MDD 93/42 EEC and subsequent amendments and is CE$_{0051}$ marked under the control of IMQ

General information:

MDD 93/42 EEC classification : Device of Class IIa
IEC/EN 60601-1 classification : Device of class II - Applied part of type BF
Expected lifetime : 5 years
Generator plastic case : IP22 degree of protection
Ultrasound transducer case : IPX7 degree of protection

Battery Internally powered equipment: Li-Ion rechargeable battery - 3,7VDC - 1100mAh
FAST is isolated from the supply mains by means of a class II external power supply

External power supply used as battery recharger		**IGEA reserves the right to provide different models of power supply, tested and approved for the system according to the standard EN60601-1; use only the power supply provided directly by the manufacturer.*
Model*	MENB1010A0503B01	
Brand	SL Power and AULT	
Input power	100 - 240 V_{AC}	
Mains voltage	50 – 60 Hz	
Max. Input current	0,3 A	
Output voltage	5 VDC	
Max output current	2,0 A	
Short-circuit protection	Internal self-resetting protection - Continuous	
Insulation class	II	

Operating specification: Device not suitable for use in presence of anaesthetic mixes inflammable in contact with air, oxygen and nitrous oxide.

Operating specification:

Ultrasound frequency : 1.5 MHz ± 5%
Pulse width : 200 µsec ± 10%
Repetition rate : 1 KHz ± 10%
Duty factor : 20%
Effective radiating area (ERA): : 3,5 cm^2 ± 20%
Output power : 105 mW ± 20%
Effective Intensity Isata : 30 mW/cm^2 ± 30%
Beam non-uniformity ratio (BNR) : 3,8 ± 30%
Beam Type : Collimated

The essential performance of model UBHS-02 includes the following:

- Free from the display of incorrect numerical values associated with the therapy to be performed
- Free from the production of unwanted ultrasound output
- Free from the production of excessive ultrasound output
- Free from the production of unintended or excessive transducer assembly surface temperature

Environmental operating conditions:

Ambient temperature: 10 ÷ 35 °C
Relative humidity: 15% ÷ 93% (non-condensing)
Atmospheric pressure: 700 ÷ 1060hPa

Environmental conditions for transport and storage:

The system can be transported and stored at the following environmental conditions without risk of any deterioration. NOTE: After removing the device from its protective packaging it is considered that the environmental operating conditions are applicable for transport and storage between uses.

	Transport	**Storage**
Ambient temperature	-20 ÷ +70°C	10 ÷ 40°C
Relative humidity	10% ÷ 90% (non-condensing)	30% ÷ 75% (non-condensing)
Atmospheric pressure	500 ÷ 1060hPa	700 ÷ 1060hPa

End of Life Disposal

FAST mod. UBHS-02 and all its parts cannot be disposed of as urban waste but are subject to separate collection according to the procedures established by local authorities.

9.1 Electromagnetic Compatibility

FAST, model UBHS-02, has been tested and certified as complying with the regulations on electromagnetic compatibility of medical devices and has been found suitable for the "Home Healthcare Environment". FAST, model UBHS-02, can be used in conjunction with other electrical or electronic devices, if they also conform to current standards, without causing interference or interference. The following general requirements need to be observed:

- FAST should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the medical electrical equipment or medical electrical system should be observed to verify normal operation in the configuration in which it will be used;
- FAST needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this accompanying documents;
- The ultrasound transducer, applied part with cable of 1 meter length, is replaceable by the manufacturer only, and is likely to affect compliance of the device with the requirements of electromagnetic emission and immunity;
- The use of accessories, transducers and cables other than those specified and supplied by the manufacturer of model UBHS-02, may results in increased emissions or decreased immunity of the device and result in improper operation;
- Portable and mobile RF communications equipment, including peripherals such as antenna cables and external antennas, should be used no closer than 30 cm (12 inches) to any part of FAST, including cables. Otherwise, degradation of the performance of this medical device could result.

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">FAST, model UBHS-02 is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions Test</th><th>Compliance</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>RF Emissions
CISPR 11</td><td>Group 1</td><td>FAST, Model UBHS-02 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF Emissions
CISPR 11</td><td>Class B</td><td rowspan="3">FAST, Model UBHS-02 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations / flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Guidance and manufacturer's declaration – electromagnetic immunity

FAST, model UBHS-02 is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycles 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0,5 cycles 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the medical electrical equipment or medical electrical system requires continued operation during power mains interruptions, it is recommended that the medical electrical equipment or medical electrical system be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level

			Portable and mobile RF communications equipment should be used no closer to any part of the model UBHS-02, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1{,}2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).

Field strengths 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 higher 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.

[a] 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 the model UBHS-02 is used exceeds the applicable RF compliance level above, the UBHS-02 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the UBHS-02.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and model UBHS-02

FAST, model UBHS-02 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the model UBHS-02 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model UBHS-02 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	80 MHz to 800 MHz $d = 1{,}2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2{,}3\sqrt{P}$
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

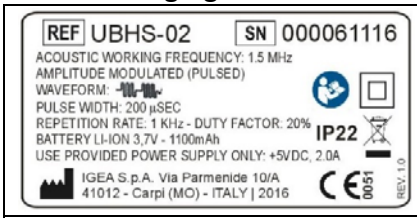
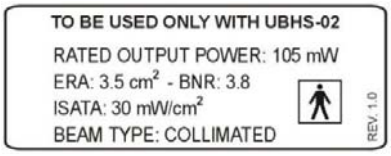
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher 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.

9.2 Markings

The following figure shows markings applied on generator and on applied part.

	Generator Data Plate, on the generator case
	Transducer Data Plate, on the transducer case
	Transducer serial number, engraved on the transducer surface.

9.3 Symbols

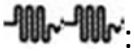
REF **Model:** this symbol specifies medical device model

SN **Serial Number**: this symbol specifies the medical device serial number, reported on the generator data plate. Please, note that this symbol is used on the ultrasound transducer cover also (as shown on figure above) and it represents the serial number of the ultrasound transducer alone.

Refer to instructions for use: this symbol indicates that user should read the instructions for use before using the device.

 **Type BF applied part:** applied part (ultrasound transducer) isolated from the rest of the appliance with a specific degree of protection against electrical hazards, specifically regards admissible leakage current.

 **Class II equipment:** appliance in which protection against electric shock does not rely on basic insulation only, but includes additional safety precautions such as double insulation.

 : this symbol indicates pulsed signal.

IP22 Degree of protection IP: this symbol informs the user that the device has a degree of protection against ingress of dust and liquids.

 **Manufacturer:** name and address of the manufacturer along with manufacturing year.

CE 0051 **CE Mark Symbol**: the device comply with European Directive for Medical Devices MDD 93/42/EEC and its revised version. The CE symbol is followed by the identification number of the notified body that checks conformity to the Essential Requirements of the Directive for applying the mark on the product.

 **Separated collection**: this device and its part cannot be disposed of as urban waste but are subject to separate collection according to the procedures established by local authorities.

 **Temperature limits for transport and storage**: symbol placed on the packaging of the device.

 **Atmospheric pressure limitation for transport and storage**: symbol placed on the packaging of the device.

 **Humidity limitation for transport and storage**: symbol placed on the packaging of the device.

 **Attention, consult the enclosed documents:** symbol placed on the packaging of the device, informing the user to consult the documents supplied with the device, as the user manual, for correct understanding and/or use of the device.

 **Fragile handle with care**: symbol placed on the packaging of the device.

REV. X.Y: this revision number is referred to marking's revision (it is printed in vertical mode).

⎓ **Continuous current:** on the power supply data plate indicates the provided power supply**.**

 **Alternate Current** (AC): on the power supply data plate indicates the required power supply**.**