HighTone Therapy Device

HiToP 1 touch

Instructions for use

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1 Introduction

1.1 Purpose

Electrotherapy with sinusoidal alternating currents.

1.2 Note concerning the operating personnel

The device is to be operated by healthcare professionals only.

1.3 Description of the unit

The **HiToP®1touch** is a medical product and is well suited for:

- knee arthrosis
- hip arthrosis
- lumbar spine syndrome
- cervical spine syndrome
- thoracic spine syndrome
- shoulder-arm syndrome
- tennis elbow
- pain following injuries and operations
- edema treatment
- Diabetic PNP

The **HiToP®1touch** is also well suited for:

- "refreshment treatment" for overall vitalisation
- muscle relaxation
- muscle training
- muscle stimulation (increase of energy consumption)
- rehabilitation

Also patients with varicose veins, metal implants, endoprothesis and open wounds (ulcus cruris) may be treated. Patients with cardiac pacemakers may be treated at the lower extremities.

The single channel HighTone Power Therapy device **HiToP®** (**Hi**gh **To**ne **P**ower) provides a therapy with medium frequency sine waves. The therapy is absolutely free of d.c. components. The frequency range used comprehends 3 octaves, the range being 4096 – 32768 Hz. The therapy frequency is scanned with a defined frequency. This method is called **SimulFAM®** which stands for **Simul**taneous **F**requency **A**mplitude **M**odulation. In the following, the basic method is divided into two different ones.

SimulFAM® *i*

A slow frequency scan of up to three octaves is realized. The minimum amplitude is passed with the minimum frequency. The maximum amplitude is passed with the maximum frequency. This therapy activates the metabolism of the body **without any effect of irritation**.

SimulFAM® *X*

A frequency scan of three octaves is realized. The frequency scan is realized with different speed (0.1 - 200 Hz). This therapy activates the metabolism in the body, thus having **an effect of irritation**.

1.4 Short operating instructions for SimulFAM® *i*

(1) Switch on the device with the mains switch in the back of the device. Now the device carries out an automatic check of all functions. If faultless, the device automatically shows the home screen.
(2) Connect the accessories to the respective socket on the back side of the device.
(3) The display shows the window with the settings of the last treatment.
(4) Select **SimulFAM® *i*** from the list of "More Therapies" or the favorites list.
(5) Apply the electrodes to the patient *(see chapter 5.2, Electrode Positioning).*
(6) Increase the current slowly using the **Intensity regulator.**
(7) The display shows the message: ***"Increase the intensity at 4096 Hz until you start to feel a prickling sensation and confirm with the button Continue. ".***
(8) Press the button "Continue" to accept the intensity at 4096 Hz.
(9) The display shows the message: ***"Increase the intensity at 16384 Hz until you start to feel a prickling sensation and confirm with the button Continue. ".***
(10) Press the button "Continue" to accept the intensity at 16384 Hz.
(11) The current frequency of the **SimulFAM® *i*** scan is shown on the display and the frequency is shown on the **SimulFAM® *i*** graph.
(12) A special tone marks the end of the treatment time.
(13) The current to the patient will decrease automatically.

1.5 Short operating instructions for SimulFAM® *X*

(1) Connect the device with the mains switch at the back of the device. The device will then carry out an automatic check of all functions. If faultless, the device automatically shows the home screen.
(2) Connect the accessories with the respective socket on the back side of the device.
(3) In the display you see the window with the settings of the last treatment.
(4) Select **SimulFAM® *X*** from the list of "More Therapies" or from the favorites list.
(5) Apply the electrodes to the patient *(see chapter 5.2, Position of the Electrodes).*
(6) Increase the current slowly with the **Intensity regulator** until the patient feels a tingling sensation.
(7) In case of a frequency scan the current stimulation frequency is shown. The frequency values increase and decrease every second.
(8) A special tone marks the end of the treatment time.
(9) The current to the patient will decrease automatically.

2 Start of Operation

2.1 Transport and Assembly

After unpacking check all components (unit with power cable, electrode connection cables and electrodes) for external integrity.
The unit may be placed on any flat surface. It must not be placed on the floor. Keep a wall distance of at least 20 cm. The device should neither be placed in front of radiators nor should it be covered by pillows or blankets while in operation. The device is not made for outdoor operation. Do not operate the device inside the transport bag.

2.1.1 Assembling

On delivery, the two feet for placing the appliance are kept into the corresponding holes. The feet are held by magnets. Remove the two feet and screw them clockwise into the holes provided on the bottom of the device.

Pull both feet well hand-tight so that the device has a good level and does not wobble.

2.1.2 Preparing for the transport

Unscrew both feet counter-clockwise from the holes in the lower part and slide them into the holes on the rear panel. The feet are secured against falling out during transport by magnets. For the transport use always the designated **HiToP® 1touch** transport bag. In this bag enough space for all the accessories is available. Also for the Aloe Vera contact spray a bottle holder is provided.

2.1.3 General Notes

The **HiToP® 1touch** corresponds to the regulations of EN 60601. It is a device of protection class I. Within the scope of the Medical Device Directive (MDD) the current stimulation device belongs to class IIa.

Warning!

The unit is not designed to be operated in places with the inherent risk of explosions. If it is used in dangerous areas of anesthesia departments, the

possibility of an explosion cannot be excluded.

If the patient and/or the patient cable is directly exposed to a radiator of a medical device for high frequency heat therapy, damage of the device or danger to the patient cannot be excluded. As a rule, a clearance distance of 3 m is sufficient.

2.2 Connection and Switch-On

The **HiToP® 1touch** is designed to be connected to a supply voltage of 100 to 240 V. It is not necessary to switch over the voltage – the device adjusts automatically to the right voltage.
Irrespective of the adjusted supply voltage, the device is appropriate for mains frequencies of 50 to 60 Hz.
Connect the **HiToP® 1touch** with the mains cable to a socket with protective ground. The protective ground must work correctly.
The **HiToP® 1touch** is switched on by the main switch on the back of the device.

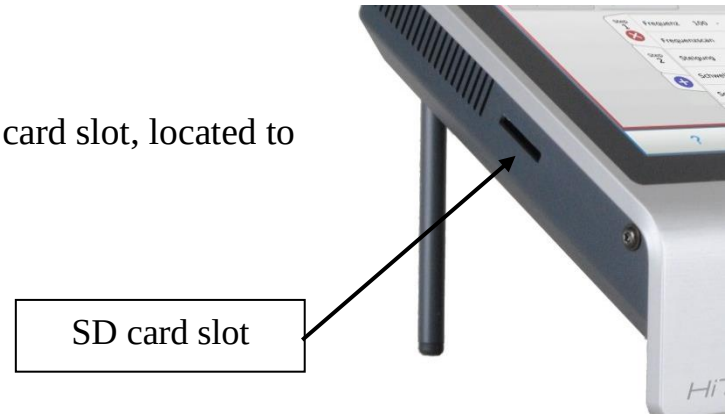
Warning!

To avoid the risk of electric shock, this equipment must only be connected to supply mains with protective earth.

Warning!

The device must not be placed in such a position that the mains input plug is inaccessible.

HiToP® 1touch is equipped with a SD card slot, located to the left of the display.



2.3 Placing out of order

In order to disconnect the device just disconnect it from the mains power supply. Before the disposal of the device, the electrodes should be cleaned one last time.

3 Operating

The **HiToP® 1touch** is equipped with a touch screen display, one on/off switch, one connecting plug for patient cables and the knob.

The **HiToP® 1touch** is being operated via the control panel of the large touch screen. The user will obtain explanations regarding the device's operation and functionality of individual elements via a direct help system during operation. Consequently, operation is explained in broad outline only.

3.1 Control Panel

3.1.1 Touch screen

The touch screen should be operated with a distinct pressure of the fingertip. Pointed objects are unsuited for operation and can destroy the touch screen.

Every button is clearly labelled. Optically, the user can differentiate operable buttons from non-operable buttons. In case of doubt the user can obtain further information via the direct help system.

The scrollbars are used like with a PC: press the slider and then move it into the desired direction.

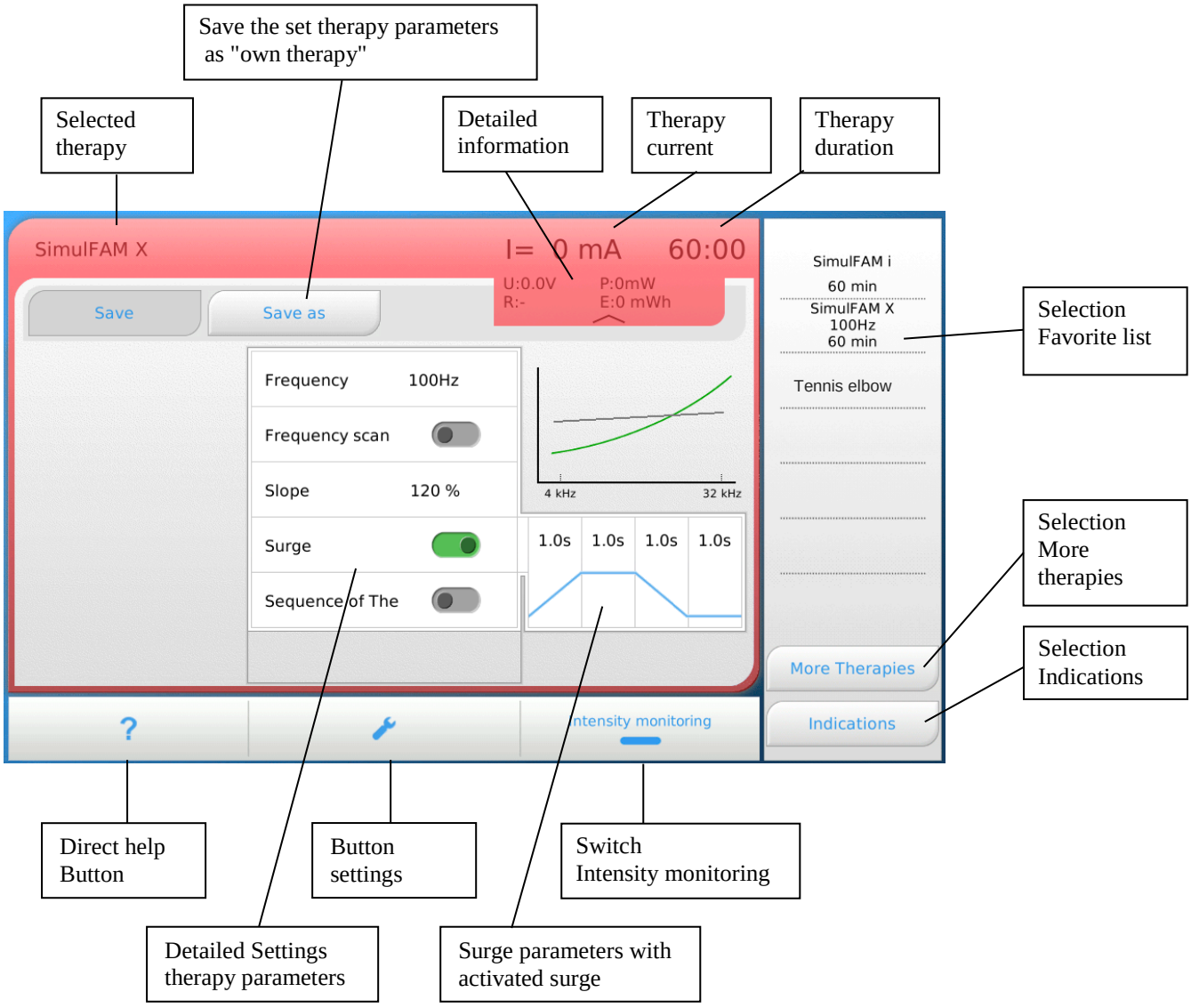
3.1.2 Intensity and modification knob

The intensity and modification knob is located on the front panel and is used as an intensity knob to adjust the output voltage as well as a modification controller for changing therapy parameters such as treatment duration or frequency.

The Knob will be used as a modification knob after pressing a button, such as the changeable frequency. When the button is pressed, it is provided with a blue border and the adjusting knob may be operated for 3 seconds.

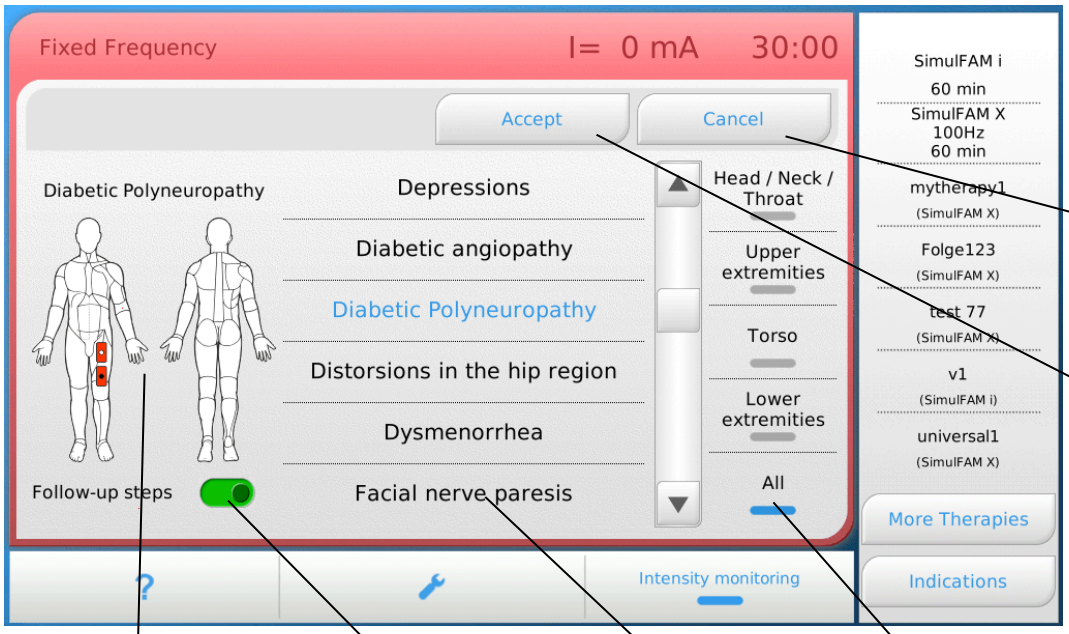
3.1.3 Home screen

After power-up, and ready for operation, the device displays the home screen.



3.1.4 Screen for selecting an indication

After pressing the button “Indications”, the device displays the following screen.



Return to the Home screen without accepting the indication.

Accept the selected indication and return to the home screen.

Indication image showing the electrode placement

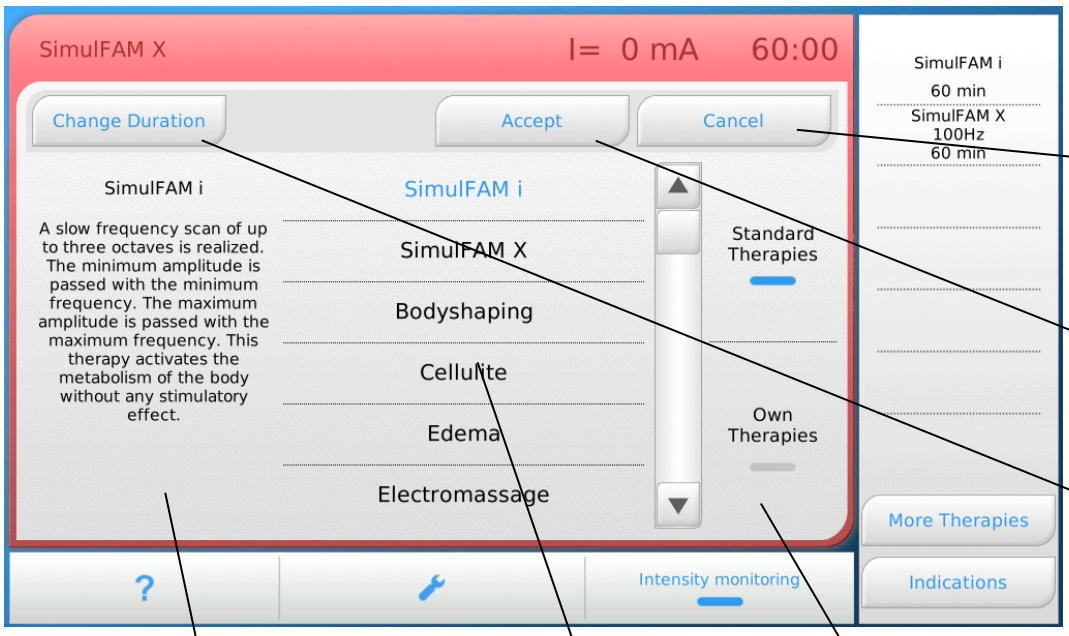
Switch for follow up steps on/off

Indications list in alphabetical order

Selection of treatment area to restrict the list.

3.1.5 Screen for selecting More Therapies (Standard Therapies)

After pressing the button “More Therapies”, and selection of “Standard Therapies” the device displays the following screen.



Return to the Home screen without accepting the own therapy.

Accept the selected therapy and return to the home screen.

Change the duration for the selected Standard Therapy

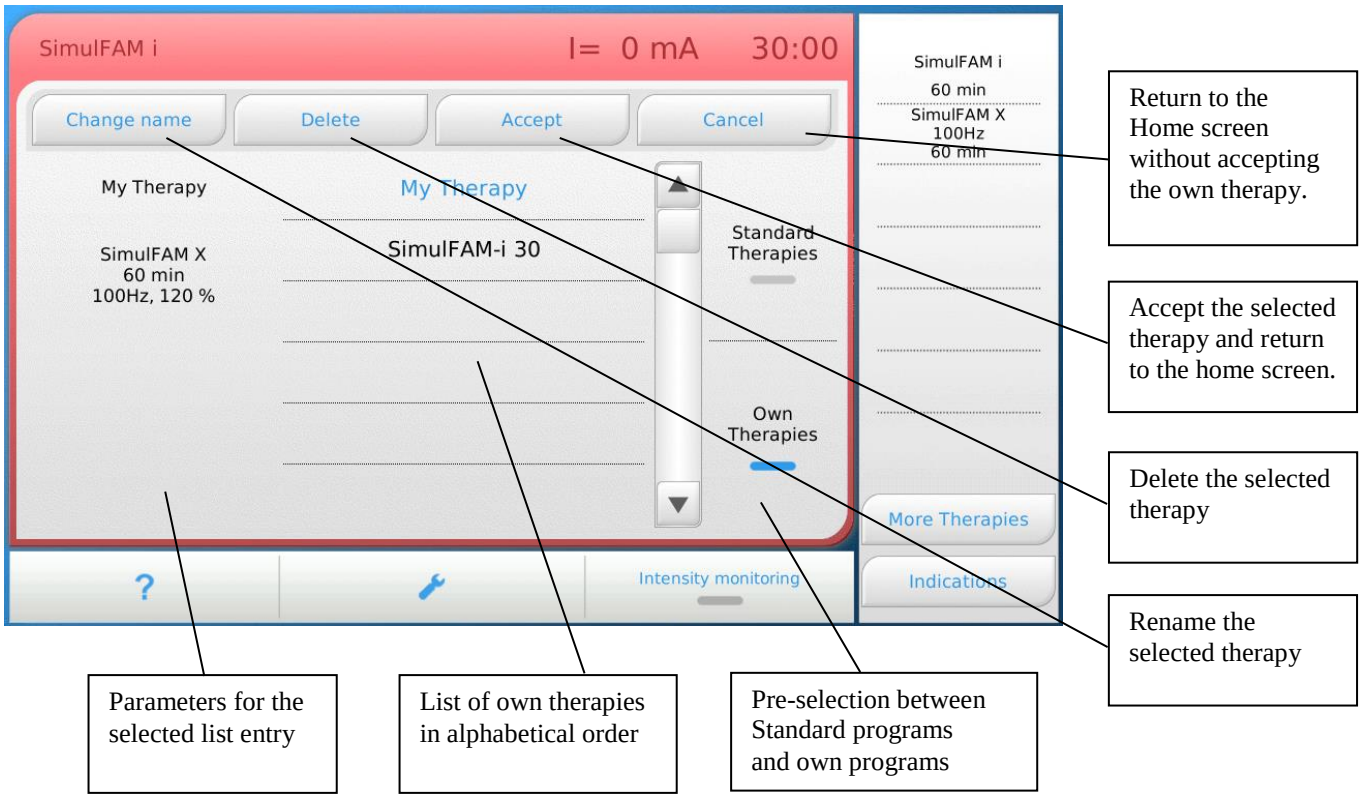
Information for the Standard Therapies

List of Standard Therapies in alphabetical order

Pre-selection between Standard Therapies and Own Therapies

3.1.6 Screen for selecting More Therapies (Own Therapies)

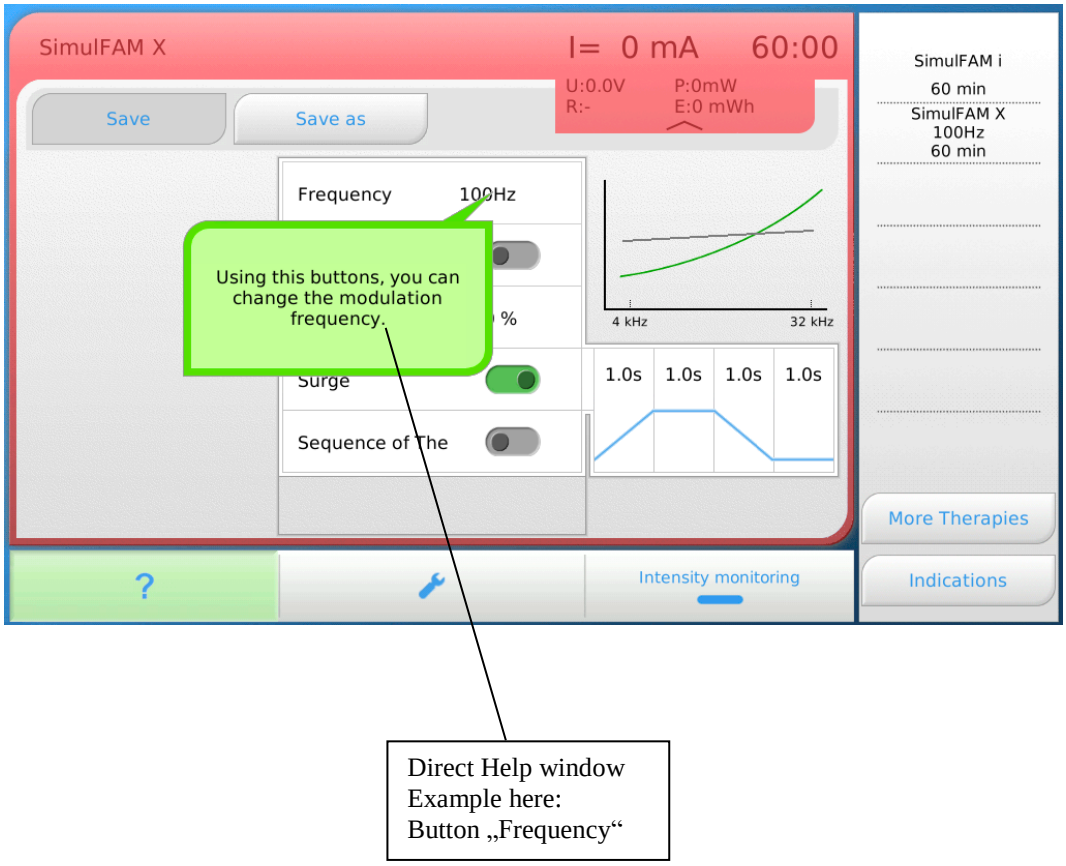
After pressing the button “More Therapies” and selection of “Own Therapies” the device displays the following screen.



3.2 Direct help

The user of **HiToP® 1touch** is guided on the screen. The direct help menu provides information about the selected buttons directly on the screen.

To start the direct help function, first touch the button "?" and then the button for which you desire information. A window opens where the information is shown. Touch to the help window in order to close it.



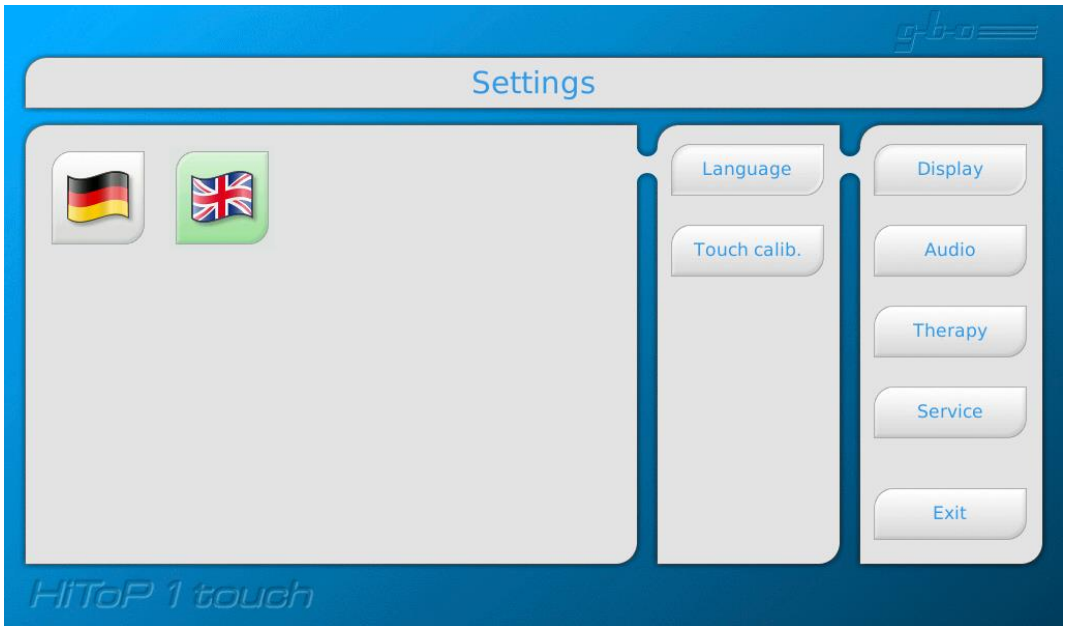
Direct Help window
Example here:
Button „Frequency"

!!	**Note!** Available buttons are indicated in white. Unavailable buttons are indicated in grey. If you push an unavailable button, information about the use of this button is shown on the screen automatically.

3.3 Settings

Using the Settings button to access the settings menu of the **HiToP® 1touch**. In this menu, parameters such as languages, output of different sounds, e.g. for the end of treatment and various treatment parameters are defined and may be changed.
Also the access to the service menu is located in the settings menu.

!!	**Note!** Only if no therapy is active, you can switch to the settings menu.



The following items are available in the Settings menu:

Display
- Setting the national language
- Calibration of the touch screen.

Audio
- Setting the system sounds like the end of therapy-tone, error tone, etc. The sounds can be heard and assigned to the corresponding functions. A sound can also be switched off.
- Repetition of the therapy end sound (Never, 2 Minutes, 10 Minutes)
- Breaks between the repeated therapy end sound (Yes/No)
- Repetition of the error sound (Never, 2 Minutes, 10 Minutes)
- Breaks between the repeated error sound (Yes/No)

Therapy

- Cable test to check Patient cables and the distribution cable for failures.
- Selection of Standard Therapies
- Frequency for Nerveblock
- Standard Duration for Indications

Service

- Software version
- Operation hour counter
- Different functions like device settings, favorites list and own Therapies may be reset to factory settings.
- Import/Export to compile a back-up of the data to a SD-Card. It may then be loaded to another device or reloaded to a replaced device.
- Access to the service mode. The service is reserved for service partners and helps in the search for faults in the hardware.

!!	**Note!** The basic settings for the duration of SimulFAM *i*, SimulFAM X and the Standard Therapies may be changed in the selection menu of "More Therapies"

Settings	Possible settings	Delivery status
Language	german english	german
Volume of sound and gong	0 – 100 %	40 %
Repetition of the therapy end sound	Never, 2 Minutes, 10 Minutes	Never
Breaks between the repeated therapy end sound	Yes/No	Yes
Repetition of the error sound	Never, 2 Minutes, 10 Minutes	Never
Breaks between the repeated error sound	Yes/No	Yes
Selection of Standard Therapies	Individually deselcetable	All on
Block frequency	4096 – 32768 Hz	12000 Hz
Standard Treatment time for Indications	10 – 90 Minutes	60 Minutes
Treatment time SimulFAM *i*	1 – 90 Minutes	60 Minutes
Treatment time SimulFAM *X*	1 – 90 Minutes	60 Minutes

3.4 Intensity monitoring

During the development of the **HiToP® 1touch** we have endeavored not only to offer you a High Tone Power Therapy device of a new generation with regard to its efficiency and operability, but also to set new standards with regard to the patient's safety.

The intensity is increased at open circuits, i.e. no patient is connected to the device:
If the initial voltage is increased at open circuit and no current is measured, the circuit will be switched off for the patient´s safety. An acoustic signal is given and the following message will be displayed:
"Therapy terminated by open loop detection …"

!! **Note!**
Please check the contact of the electrodes and the cables, resp., before you set the intensity anew.

Abrupt resistance changes in the electrode application could cause problems:

1. Two electrodes touch each other and form a shunt during treatment. If the patient moves during the therapy, that shunt can open and the patient becomes exposed to an unintended high intensity of current.
2. The electrodes are shorted-out by a conductive part, such as a metallic temple in case of a tinnitus treatment. If during the treatment that shunt is removed (e.g. the glasses are taken off) this abrupt resistance change also leads to a severe modification of the intensity of current.
3. Generally, please observe the notice regarding the electrode positioning *(see chapter 5.2)*.

We at gbo Medizintechnik AG expanded the device software by a special intensity monitoring routine in order to get the application problems mentioned under control. This safety circuit avoids an unintended high change in the intensity of current and switches off the circuit in such a case.

3.4.1 Deactivate intensity monitoring

!! **Note!**

- The intensity monitoring is automatically activated after each restart of the unit! The function can be manually deactivated with the button “Intensity monitoring” after starting the unit.
- Only deactivate the intensity monitoring as an exception, e. g. in case of the Big-Tast-Therapy!

1. Press the button ”Intensity monitoring“.
2. The blue bar which indicates Intensity monitoring is active will get grey.

!! **Note!**

- If the “Intensity monitoring” is deactivated, the bar in the button “Intensity monitoring” will be grey.
- The Intensity monitoring remains deactivated until it is modified manually into “on“ by pressing the button “Intensity monitoring”. Upon each **restart** of the device the Intensity monitoring is automatically activated.

4 Therapy

4.1 General guidelines for therapy

The **HiToP® 1touch** guides the user through the application of the therapy. With the direct help menu all buttons and their functions are explained directly on the screen.

On the right side of the screen therapy programs can be selected directly from this list of favorites or with the sub-menus “More Therapies” or “Indications”.

Select the desired program or indication. The direct help menu will give you information about the following steps of the therapy.

The HiToP®-therapy is a special treatment and it is very different from the classical electrotherapy. In the HiToP®-therapy, the application technique for the electrodes is more complicated and, typically, the treatment time is longer than in the classical electrotherapy. We talk about a holistic treatment. For this reason, the treatment suggestions in the list of indications are mostly structured in two steps. In the first step or main treatment, the treatment area is, in most cases, flooded with SimulFAM i transversally. In the Follow-Up therapy, treatment is often a whole body treatment or it is the treatment with SimulFAM X longitudinally. With this method, the therapeutic success which is accomplished by multi-circuit treatment using a multi-channel device (2 or 4-channel) can be achieved by providing a sequential treatment with the single channel HiToP® 1Touch.
Typically, you have to change the electrode placement after the first half of the treatment in order to start the Follow-Up treatment.

If such a treatment is not possible in the daily practice routine, the treatment can be switched to a single step treatment. In this case, only the main treatment step is used for the therapy. This therapy lasts as long as both steps of the Follow-Up therapy.

The time period of the treatment for the indications can be selected in the settings.

4.2 Selection of therapies

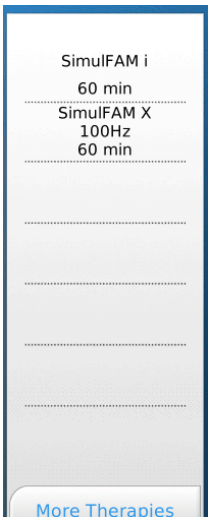
4.2.1 Selection of therapy by More Therapies

In this selection all pre-defined and all user-defined programs are filed. The selection is made from a list which is filtered. Thus, only pre-defined or user-defined currents can be displayed from the appropriate list and then selected.

4.2.2 Selection of therapy by indications

In **HiToP® 1touch** an indication menu is integrated. This provides a list of programs with indication pictures on which the electrode positioning is specified and pre-defined parameters (current form, possibly modulating frequency and duration). These treatment parameters are indicative and recommendations are in the responsibility of the treating physician.

4.2.3 Selection of therapy from the favorites list



The Favorites list can be filled by the user as desired. Thus, the users can define the order of his frequently used therapies by himself. Indications, own therapies and individual treatment settings may be transferred to the Favorites list. A simple push on the button loads the therapy from the favorite list as current therapy.

The Favorites list can be easily filled. Select a treatment from the list of indications, the list of other therapies or set the parameters individually. This therapy can now be stored by pressing and holding (≥ 2.5 seconds) the corresponding button on the right location of the favorites list. Entries which are no longer required can be easily deleted by pushing them away to the right.

4.2.4 Individual settings

At the home screen there is the possibility to change parameters for a selected current waveform within certain limits. The duration can be changed accordingly. The current form as newly generated can be directly applied. It can be stored in the Favorites list. There is also the possibility to save this modified current form as "Own Therapy" under a user-specified name. These self-defined therapies can then be retrieved by the use of the button "Other therapies" with the sub-selection "Own therapies".

!!	**Note!** After switching on the device the last-used therapy will be loaded automatically.

4.3 Setting SimulFAM *i*

If the current form SimulFAM i is selected with its frequencies of 4096 and 16384, the current intensity must be such that the patient feels a light tingling only. It is the aim of this setting to emit the maximum output during therapy. The high tone

frequencies of 4096 – 32768 Hz are being emitted as quarter tone steps every second. The current should be comfortable to the patient with all frequencies. There is no stimulation of the nerve or muscle, the patient feels a light tingling only. In general, the current form SimulFAM i is applied for whole body treatment however, it may also be used for a local lateral throughflow.

!!

Note!

- The amplitude values move on the determined threshold curve.
- Therapy time may also be modified during treatment.
- With the frequency button the frequency flow may be stopped and released upon new activation.
- The frequency set may be changed with the bar beneath the graphics.
- The intensity of SimulFAM i may also be changed during therapy.

4.4 Setting SimulFAM *X*

If the current form SimulFAM X is selected, the high tone frequencies are run through faster. The frequency run can be set between 0.1 Hz up to 200 Hz.
In contrast to SimulFAM i, with SimulFAM X we try to generate specifically a stimulation of the nerves and the muscles. E.g. with the frequency of 20 Hz you generate a muscle stimulation. Here the current is increased up to a range above threshold. Now the patient will show a stimulation of the muscle. Please choose a current intensity which turns the therapy well tolerable to the patient.

!!

Note!

- Therapy time can be modified during the treatment.

5 Electrodes

Single-pole electrodes are fit for all therapy currents. It is preferable to use large conductive rubber electrodes for the treatment of a large body area. In the very sensitive area of the head adhesive electrodes might be used. The electrodes must be plugged in to the unit through a patient cable which is connected to the distribution cable. The electrodes must be applied as described in chapter 5.2.

The electrode's size depends on the area to be streamed by the current. Under small electrodes the current is more concentrated and more localised than under large electrodes. The area to be treated depends on the clinical picture.

electrode	**area**	**maximum current**
conductive rubber electrode 80 mm x 120 mmm	95 cm^2	190 mA
conductive rubber electrode 115 mm x 175 mm	200 cm^2	300 mA
self-adhesive electrode 51 mm x 57 mm	29 cm^2	58 mA
self-adhesive electrode 50 mm x 104 mm	52 cm^2	104 mA

Table 1: Maximum currents for electrodes

5.1 Advise on self-adhesive electrodes

Adhesive electrodes have been used in combination with HiToP® therapy. gbo has always advised to use adhesive electrodes very carefully and only with adequate currents.
Experience has shown that the use of adhesive electrodes in combination with HiToP® therapy might cause problems due to misuse. Electrodes were used with currents that are too high or the electrodes were used for too many treatments (old and worn electrodes).
Consequently it might be possible that the adhesive electrodes get warm during the therapy and even heat up to a temperature that causes burns with the patient.

To avoid such situations gbo removed the adhesive electrodes from the standard accessory set and advises **to avoid the use of adhesive electrodes with HiToP® if possible.**

Yet, the use of adhesive electrodes might be necessary for special applications (e.g.: in the face). The therapist must then take special care and monitor that the adhesive electrodes are used correctly and do not heat up.

5.2 Electrode positioning

The position of the patient is very important. The therapy shall always be carried out while the patient is in a comfortable and relaxed position. The joints should be bended in a mid-position to allow both the flexor as well as the extensor muscles to be stimulated.

In general, the preparation and the application of the electrodes are carried out as follows:

1. Moisten the conductive rubber electrodes with contact spray to avoid current sensations on the skin. Apply two puffs of the spray to the electrodes and spread the liquid over the electrodes' surface.
2. Apply the electrodes to the patient.
3. Apply the elastic strap with Velcro in such a way that the electrode covers the skin all-over.
4. Connect the electrodes to the patient cable.
5. Connect the patient cable to the distribution cable.
6. Plug in the patient plug of the distribution cable to the socket on the back side of the unit.

Warning!

- Do not apply the electrodes on skin injuries. Even minor abrasions can cause a burning sensation to the patient. Consequently, the intensity of the current may be judged erroneously by the patient. If an electrode must be placed in spite of it all, it is advised to apply zinc ointment or white petrolatum to cover the affected parts of the skin.
- The electrodes must cover the skin all-over in order to avoid excessive local current densities. Otherwise, flush or even burns may show.
- During the therapy the patient must take off jewelry and eyeglasses.

Note!

- A current density of more than 2 mA/cm^2 on all electrode surfaces requires increased attention of the operator.

6 Maintenance

Functionality, reliability and safety characteristics of the **HiToP® 1touch** are guaranteed only if the device is handled in accordance with the operating instructions. Safety control, maintenance work, repair work and modifications must only be carried out by the manufacturer or by service agents authorized by him. In case of a failure, parts which influence the safety of the device must only be replaced by original spare parts of the manufacturer. The electric installation must correspond to the requirements in accordance with VDE/IEC. **The device does not contain any parts which require maintenance work by the user.**

Warning!

No parts of the device are allowed to be serviced while a patient is connected.

6.1 Safety Controls

The device is subject to the provisions of the Medical Device Directive. The safety controls have to be carried out on the basis of this directive. Thereby, the operator regulation has to be observed in particular.

Irrespective of the legal rules or beyond the scope of the Medical Device Directive, it is recommended to have the device checked at 12-months intervals by the manufacturer or by a maintenance service authorized by him.

The review shall consist at least of the following criteria:

- Electrical safety check in accordance with the test plan of the manufacturer
- Review of the device in respect of external integrity
- Review of all display and operating elements in respect of damages
- Review of all inscriptions in respect of immaculate legibility
- Review of power supply and all patient connecting cables
- Functional check

6.2 Disposal of the device and the accessories

According to the WEEE Directive 2002/96/EG (waste electrical and electronic equipment) this device must not be disposed of with the domestic waste. The device must be returned to the manufacturer for disposal. The manufacturer is committed to guarantee the disposal of all devices marketed. This is also indicated by the WEEE sign (crossed out waste container).

6.3 Cleaning and disinfection

6.3.1 Cleaning the Device

Clean the device with a damp cloth. Never use abrasive cleaners.

Fingerprints on the touchscreen should be cleaned with a dry cloth or some isopropanol.

Warning!

- Unplug the mains plug out of the socket prior to cleaning and disinfection.
- The device is not suited for heat sterilization or for the sterilization with gases.

The **HiToP® 1touch** is suited for wiping disinfection. Make sure that no liquids soak into the device. Under no circumstances the plug or socket must get wet. Do not sprinkle the device for cleaning or disinfection. The device is not suited for hot sterilisation or sterilisation with gases.

6.3.2 Cleaning the Elastic Bands

The elastic straps can be washed in a washing machine. Please observe the washing instructions of the instruction label or observe the washing instruction on the packaging.

6.3.3 Cleaning the Electrodes

You can clean the rubber electrodes after a treatment with some warm water (appr. 40°C) and soap suds on the conductive (black) side. Dry the electrodes with a cleaning cloth or let them air-dry. The cleaning process removes the film left by the Aloe spray or the contact spray and the electrodes will regain a good conductivity.

!!

Note!

The conductivity of the electrodes is optimized by the use of a certain amount of graphite. Consequently, when using and cleaning the electrodes, black color may come off.

6.3.4 Disinfecting the Electrodes

The rubber electrodes can be disinfected by spray/wipe disinfection. Spray onto the black side of the electrodes, leave to soak and wipe off with a lint free cloth. (Please follow the recommendations of the manufacturer.)
We recommend Bacillol-AF for the disinfection of the electrodes.

!!

Note!
The conductivity of the electrodes is optimized by the use of a certain amount of graphite. Consequently, when using and disinfecting the electrodes, black color may come off.

7 Warnings and Safety Precautions

Warning!

- For patients with implanted electronic device electrical stimulation treatment is to be carried out only after having checked any risks.
- Jewellery and eyeglasses have to be taken off during the treatment.
- Turn off cellular phones and radiophones or place them in a distance of 3 m from the device.
- Cardiac pacemakers are extremely vulnerable. Here the therapy should only be carried out under continuous pulse and ECG control.
  The lower extremities may be treated without control.
- If the patient and/or the patient cable is in the direct range of a high-frequency, short-wave or micro-wave therapeutic device, damage to the device or an injury to the patient cannot be excluded. Please keep a clearance of 3 m.
- A simultaneous connection of the patient to a high-frequency surgery device can lead to burns under the electrical stimulus electrodes.
- The unit is not designed to be operated in places with the inherent risk of explosions. If it is used in dangerous areas of anesthesia departments, the possibility of an explosion cannot be excluded.
- Application of electrodes near the thorax may increase the risk of cardiac fibrillation.
- In case of any visible failure contact gbo Medizintechnik AG or one of the service agencies authorized by gbo Medizintechnik AG immediately.

Note!

- A current density of more than 2 mA/cm^2 on all electrode surfaces requires a higher attention of the operator.

7.1 Contraindications

Contraindications for the use of HiToP® Therapy are:

- feverish systemic infections
- local bacterial infections
- pregnancy
- cardiac pacemakers

!!

Note!

For patients with cardiac pacemaker the treatment at the lower extremities is not contraindicated.

!!

Note!

Patients with organ transplantation who take immunesuppresive medications should not be treated with SimulFAM *i*.

!!

Note!

The above list is not exhaustive. In individual cases the attending doctor should decide on contraindications and criteria for the treatment.

!!

Note!

Patients with varicose veins, metallic implants and endoprotheses may be treated with HiToP® Therapy.

8 Explanation of the Pictographs used

CE – conformity sign

Follow instructions for use!

Caution

Application part ungrounded, protection degree Type BF.

This product complies with WEEE Directive 2002/96/EG (waste electrical and electronic equipment). Separate collection for electrical and electronic equipment. The waste removal at the end of the service life will be done by the manufacturer.

9 Technical Data

Mains voltage and frequency:	100 – 240 V, 50-60 Hz	
Power consumption:	max. 45 VA	
Output current:	max. 310 mA	
Output voltage:	max. 76 V	
Output power:	max. 5000 mW	
Patient resistance:	30 – 1500 Ω	
Applied part	Contact surfaces at the electrodes.	
Mode of operation:	continuous operation	
MDD device class:	IIa	
Protection degree:	I acc. to IEC 60601-1	
Protection class:	BF acc. to IEC 60601-1	
Protection against ingress of: liquids	IP X0	
Dimensions:	max. 27 cm x 24,5 cm x 6 cm (W x H x D)	
Weight:	2,44 kg without accessories	
Color:	aluminium natural anodized and grey RAL 7016	
Display:	10,1“ TFT LCD touch screen	
Environmental conditions:	operation of the device:	temperature range +10 °C ... +40 °C relative humidity of air 30 ... 75 %
	transport and storage:	temperature range +5 °C ... +50 °C relative humidity < 90 %, non condensing
Current types:	carrier frequency low frequency accuracy	4096 –32768 Hz Sinus wave 0.1 Hz – 200 Hz ± 10 %

By request of technical personnel gbo Medizintechnik AG can offer spare part lists and circuit diagrams.

The appliance inlet is used for all pin disconnection from the mains.

gbo Medizintechnik AG reserves the right to modify design and specifications without prior notice.

9.1 Current Types

The used currents in **HiToP® 1touch** are sinusodial alternating currents in the frequency range from 4096 – 32768 Hz.

The described alternating currents are modulated by frequencies in the range of 0.1 - 200 Hz.

The output current is free of dc parts.

The maximum output voltage is 76 V and the maximum current is 310 mA.
The maximum power is limited to 5000 mW. This correlates with the demands of the standard 60601-2-10 which describes a limitation of 100 mA at 500 Ω.

The valid impedance ranges from 30 Ω to 1500 Ω.

10 Accessories

Accessories included in **HiToP® 1touch (**027-0-0040):

1	distribution cable red, 150 cm
1	set of patient cables red (6 cables of 100 cm each)
2	conductive rubber electrodes, 115 mm x 175 mm
4	conductive rubber electrodes, 80 mm x 120 mm
6	elastic straps with Velcro, 70 cm
1	aloe Vera contact spray, bottle of 473 ml
1	Instructions for use
1	Transport bag for **HiToP® 1touch**

For the **HiToP® 1touch** we offer a large variety of accessories.

Specification	**Part number**
Distribution cable red, 150 cm	017-0-0030
Set of patient cables red (6 cables of 100 cm each)	017-0-0034
Conductive rubber electrode, 115 x 175 (package of 2)	017-0-0046
Conductive rubber electrode, 80 x 120 (package of 2)	017-0-0047
Elastic straps with Velcro, 70 cm (package of 2)	011-0-0033
Easy-fix electrodes, 80 mm x 120 mm (package of 2)	017-0-0062
Elastic straps with Velcro for easy-fix electrodes (package of 4)	017-0-0059
Aloe Vera contact spray, bottle of 473 ml	002-2-0073
Transport bag for **HiToP® 1touch**	027-0-0150
Device cart for **HiToP®** basic rack	026-0-3000
Tray for **HiToP® 1touch**	026-0-3030

For detailed information see the enclosed brochure "**HiToP® 1touch** and Accessories". This brochure is also available as a pdf-file by download on our website:
www.gbo-med.de.

!!

Note!

Use gbo original accessories only to guarantee the safe function of the unit.

11 Troubleshouting

Each problem that occurs during operation of the unit will be shown in a message window on top of the display and will be accompanied by an acoustic tone. Most of the problems can be solved by the instructions displayed.

In general:

1. The malfunction is shown on the display.
2. An acoustic signal is heard.
3. Follow the instructions on the display.

Suggestions:

- Turn off the unit and turn it on again.
- If the error occurs again, the device is not functioning. Please contact a service authorized by the manufacturer.

Further errors

symptom	**cause and action**
The device cannot be switched on, no display is shown.	Please check the mains plugs and sockets. If necessary contact your service agent or the manufacturer.
No acoustic signal is heard. (End of therapy…)	Please check the settings of the acoustic sound in the menu. The volume must be greater than 0.

Please contact your service agent or the manufacturer if the problems cannot be solved by the measures mentioned above.

Please note that the unit must be placed on a plane horizontal surface. The device should neither be placed in front of radiators nor should it be covered with pillows or blankets while in operation. Do not cover the ventilation slots on the bottom of the unit either.

12 Appendix A - Standard Programs

Program	Step 1	Step 2	Step 3	Loops	Duration
SimulFAM® *i*				-	Changeable in "More Therapies"
SimulFAM® *X*				-	Changeable in "More Therapies"
Reha	0,2 – 0,5 Hz			-	Changeable in "More Therapies"
Mobilisation	0,5 Hz 14 sec	1 – 8 Hz 21 sec		15	Changeable in "More Therapies"
Muscle pump	0,3 Hz			-	Changeable in "More Therapies"
Trauma	10 Hz 1/2 Bhz.	100 Hz 1/2 Bhz		-	Changeable in "More Therapies"
Lymphdrainage	0,3 10 min	10 Hz 10 min	10 – 30 Hz 10 min	1	Changeable in "More Therapies"
Edema	10 Hz			-	Changeable in "More Therapies"
Pain	90 - 112			-	Changeable in "More Therapies"
Universal	0,1 – 200 Hz			-	Changeable in "More Therapies"
Muscle Stimulation HTEMS	20 Hz 3s /3s /3s			-	Changeable in "More Therapies"
Synchr. Stim.	20 Hz 3s/3s/7s				Changeable in "More Therapies"
Lipolysis	2,5 – 3,5 Hz			-	Changeable in "More Therapies"
Cellulite	2,5 – 3,5 Hz 10 min	10 – 20 Hz 5 min		2	Changeable in "More Therapies"
Fatburning	2,5 – 3,5 Hz 8 min	10 - 30 HZ 2 min		3	Changeable in "More Therapies"
Bodyshaping	2,5 – 3,5 Hz 5 min	20 – 30 Hz 5/5/20 5 min	150 – 200 Hz 5 min	2	Changeable in "More Therapies"
Electro massage	0,5 – 3 Hz			-	Changeable in "More Therapies"
Shaking massage	3 – 10 Hz			-	Changeable in "More Therapies"
Sport	20 Hz 5s /5s /20s			-	Changeable in "More Therapies"

To facilitate the setting of the intensity with programs with very low frequencies the unit switches to a higher, more clearly perceptible frequency (1.5 Hz). The unit switches back to the "correct" frequency as soon as the intensity knob has not been used for more than 3 seconds.

13 Appendix B - EMC Hints

Comments according to the Medical Device Directive

The **HiToP® 1touch** is a mains operated current stimulation device of protection class **I**.

The device is in accordance with the EC Medical Device Directive (93/42/EEC) and therefore carries the CE-sign with the number of the ”notified body for medical devices”. The respective graphical symbol is placed on the type plate.

According to the Medical Device Directive, **HiToP® 1touch** is a device of class **IIa**.

The manufacturer is responsible for the security, operational reliability and functionality of the device under the following conditions only:

- the device is used in accordance with the user manual;
- the electrical installation of the location where the device will be used corresponds to the respective current requirements of electrical safety;
- the device is not used in hazardous environments and humid locations;
- the mountings, add-ons, internal adjustments, modifications or repairs are realized only by personnel authorized by the manufacturer;
- the operator regulation of this EC-directive is observed within the scope of the Medical Device Directive.

You may obtain technical support by the manufacturer or the dealers or service authorized by the manufacturer. The manufacturer projects a product life of 10 years.

HiToP® 1touch is an electronic device. Waste disposal is to be done according to the regulations for electronic devices. Consumables have to be disposed as residual waste.

On request, the manufacturer will provide you with further technical descriptions for all serviceable parts of the device, such as circuit diagrams, spare part lists and adjustment instructions as far as these are of use for the qualified technical staff of the user.

Comments on electromagnetic compatibility (EMC)
Medical electrical devices are subject to special precautions concerning the EMC. They must be installed and operated according to the EMC-advice given in the accompanying documents. In particular medical electrical devices may be influenced by portable and mobile RF-communication devices.

The manufacturer guarantees the conformity of the unit with the EMC-requirements only if accessories which are listed in the EC declaration of conformity are used. The use of other accessories may cause an increased emission of electromagnetic disturbances or may lead to a reduced electromagnetic immunity.

The unit must not be arranged physically close to other devices or stacked with them. If such an order is necessary nevertheless, the unit must be observed in order to check it for the intentional operation.

You find more EMC-comments in the chapter “Warnings and Safety Precautions” of this manual as well as the Technical Information on the next two pages.

In accordance with the EMC-regulations for medical products we are obliged by law to provide the following information.

Guidance and manufacturer's declaration — electromagnetic emissions

The equipment is intended for the use in the electromagnetic environment specified below. The customer or the user of the equipment should ensure the compliance with this stipulation		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions, CISPR 11	Group 1	The equipment 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.
RF emissions, CISPR 11	Class B	The equipment 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.
Harmonic emissions, IEC 61000-3-2 (*)	Class A	
Voltage fluctuation/flicker emissions, IEC 61000-3-3 (*)	complies	
(*) Note: For devices with a power consumption between 75 W and 1000 W only.		

Guidance and manufacturer's declaration — electromagnetic immunity

The equipment is intended for the use in the electromagnetic environment specified below. The customer or the user of the equipment should ensure the compliance with this stipulation.			
Immunity test	**IEC 60601- test level**	**Compliance level**	**Electromagnetic environment – guidance**
electrostatic discharge (ESD), IEC61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be made of wood, concrete or ceramic tiles. 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 differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	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_τ for ½ cycle (>95% dip) 40% U_τ for 5 cycles 60% dip) 70% U_τ for 25 cycles 30% dip) <95% U_τ for 5 s (>5% dip)	<5% U_τ for ½ cycle (>95% dip) 40% U_τ for 5 cycles 60% dip) 70% U_τ for 25 cycles 30% dip) <95% U_τ for 5 s (>5% dip)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment 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_τ is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration — electromagnetic immunity

The equipment is intended for the use in the electromagnetic environment specified below. The customer or the user of the equipment should ensure the compliance with this stipulation.			
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 equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
conducted RF, IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{eff}	$d=1.2\sqrt{P}$
radiated RF, IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d=1.2\sqrt{P}$ for 80 MHz to 800 MHz $d=2.3\sqrt{P}$ for 800 MHz to 2.5 GHz
			Where P is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Interference may occur in the vicinity of equipment marked with the following symbol: 

Recommended separation distances to portable and mobile RF communication equipment

The equipment is intended to be operated in an electromagnetic environment where radiated RF interference is controlled. The user can help to avoid interferences by meeting the minimum separation distances between portable and mobile RF communication equipment (transmitters) according to the maximum output power of the communication equipment.			
Rated power of the transmitter (W)	**Separation distance according to the transmission frequency (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

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