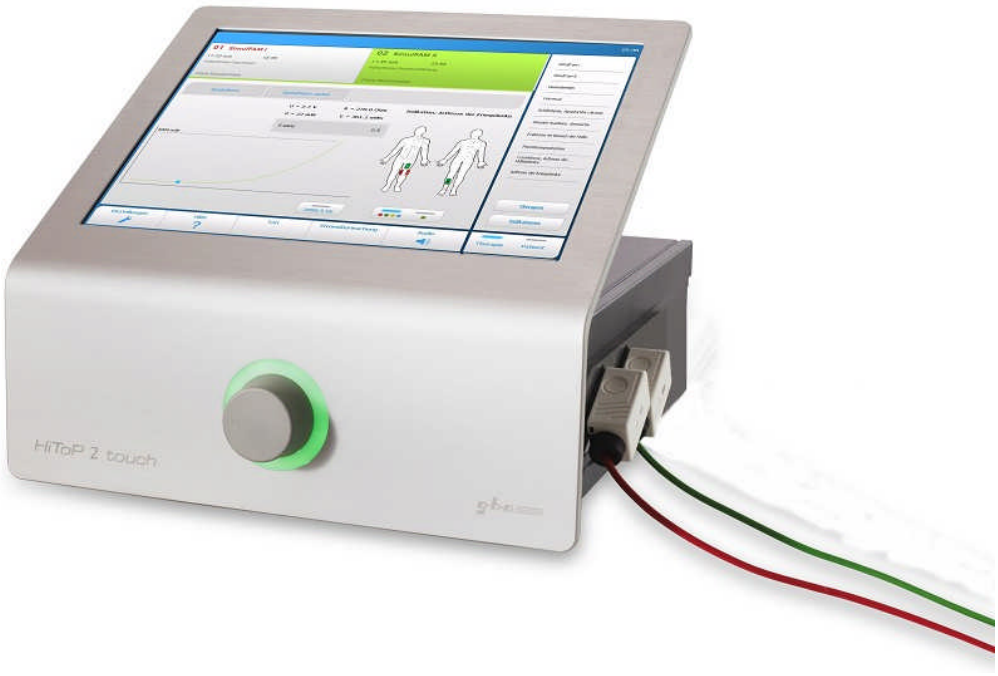
HighTone Therapy Device



HiToP 2 touch

User Manual

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Warnings and safety precautions

Warning!
Warnings which have to be observed by all means!

Caution!
Observe the instructions for use!

Note!
Information that will facilitate your work.

1 Introduction

1.1 Purpose

Electrotherapy with sinusoidal alternating currents.

1.2 Note concerning the operating personnel

The device is only to be operated by healthcare professionals.

1.3 Description of the unit

The **HiToP®2 touch** 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®2 touch** 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, endoprotheses and open wounds (ulcus cruris) may be treated. Patients with cardiac pacemakers may be treated at the lower extremities.

The 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. There are two channels available. 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®** for **Simul**tanous **F**requency **A**mplitude **M**odulation. In the following, the basic method is divided into two different ones.

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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 automatic check ends with an acoustic signal.
(2) Connect the accessories to the respective socket on the right side of the device.
(3) The display shows the window with the settings of the last treatment.
(4) Select **SimulFAM® *i*** from the favorites' list.
(5) Apply the electrodes to the patient *(see chapter 5.2, Electrode Positioning).* Select the channel with the channel buttons. The active channel will show up in the channel color.
(6) Increase the current slowly using the **Intensity regulator.**
(7) The display shows the message: ***"Increase the intensity at 4096 Hz until you feel a tingling 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 feel a tingling sensation and confirm with the button Continue".***
(10) Press the button "Continue" to accept the intensity at 16384 Hz.
(11) The bar display **SimulFAM® *i*** shows the frequency scan.
(12) A special tone marks the end of the treatment time.
(13) The current to the patient will decrease automatically.

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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 automatic check ends with the acoustic signal.
(2) Connect the accessories with the respective socket on the right 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 favourites' list.
(5) Apply the electrodes to the patient *(see chapter 5.2, Position of the Electrodes).* Select a channel with the channel buttons. The active channel shows up in the color of the channel.
(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.

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2 Start of Operation

2.1 Transport and Assembly

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.

For maximum usability there is a special device cart and also a special **HiToP®** bed available (see chapter 10, Accessories) which matches in design and function with the **HiToP®2 touch**. This device cart is perfect for the placement of the unit and various accessories. With the device cart the **HiToP®2 touch** is mobile and always ready for use. The device cart can easily be moved next to the patient for treatment. With the **HiToP®** bed patients as well as health care professionals benefit from functions like faster application of patient cables and electrodes, heated surface of the bed and the possibility to warm up the electrodes.

The **HiToP®2 touch** corresponds to the regulations DIN 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®2 touch** is designed for the connection 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®2 touch** with the mains cable to a socket with protective ground. The protective ground must work correctly.
The **HiToP®2 touch** is switched on by the main switch on the back of the device.

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Warning!

It is only allowed to connect USB-Sticks for data backup and update! ***Never*** connect a PC or another USB-device to this connector!

Only headphones are allowed to be connected to the headphone output. It is not allowed to connect active loudspeakers with a connection to the mains.

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

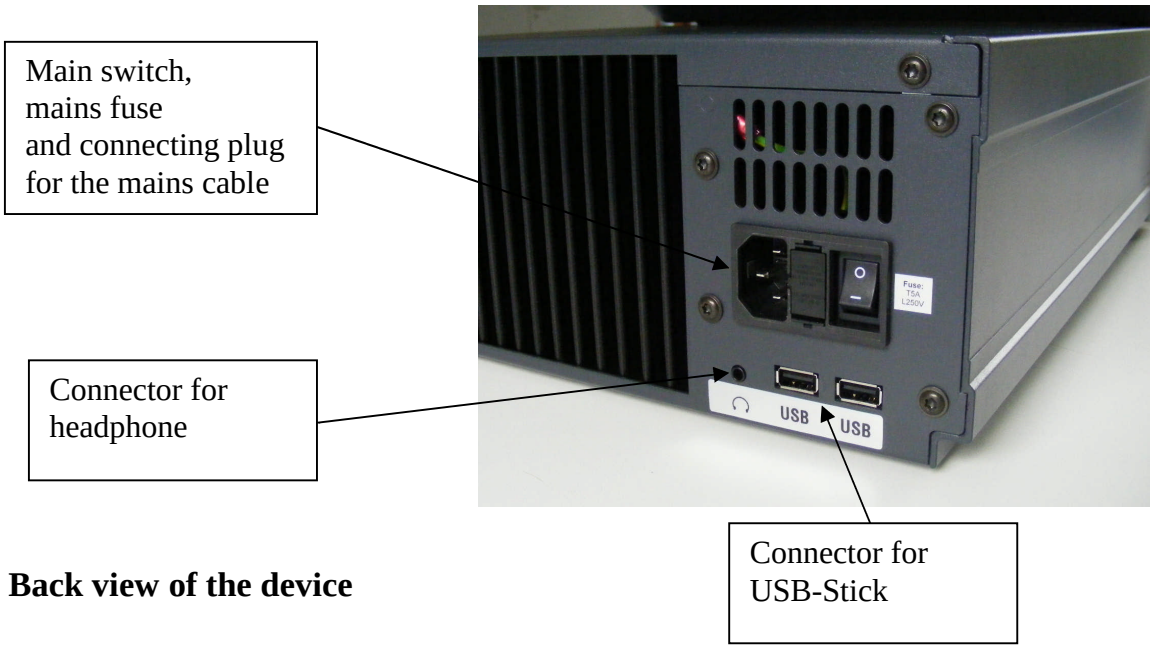

Figure 1: Back view of the device

2.3 Placing out of operation

In order to place the device out of operation just disconnect it from the mains power supply. No other measures are to be taken.

3 Operating

The **HiToP®2 touch** is equipped with a touch screen display, one on/off switch, two connecting plugs for patient cables and the intensity regulator.

The **HiToP®2 touch** 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

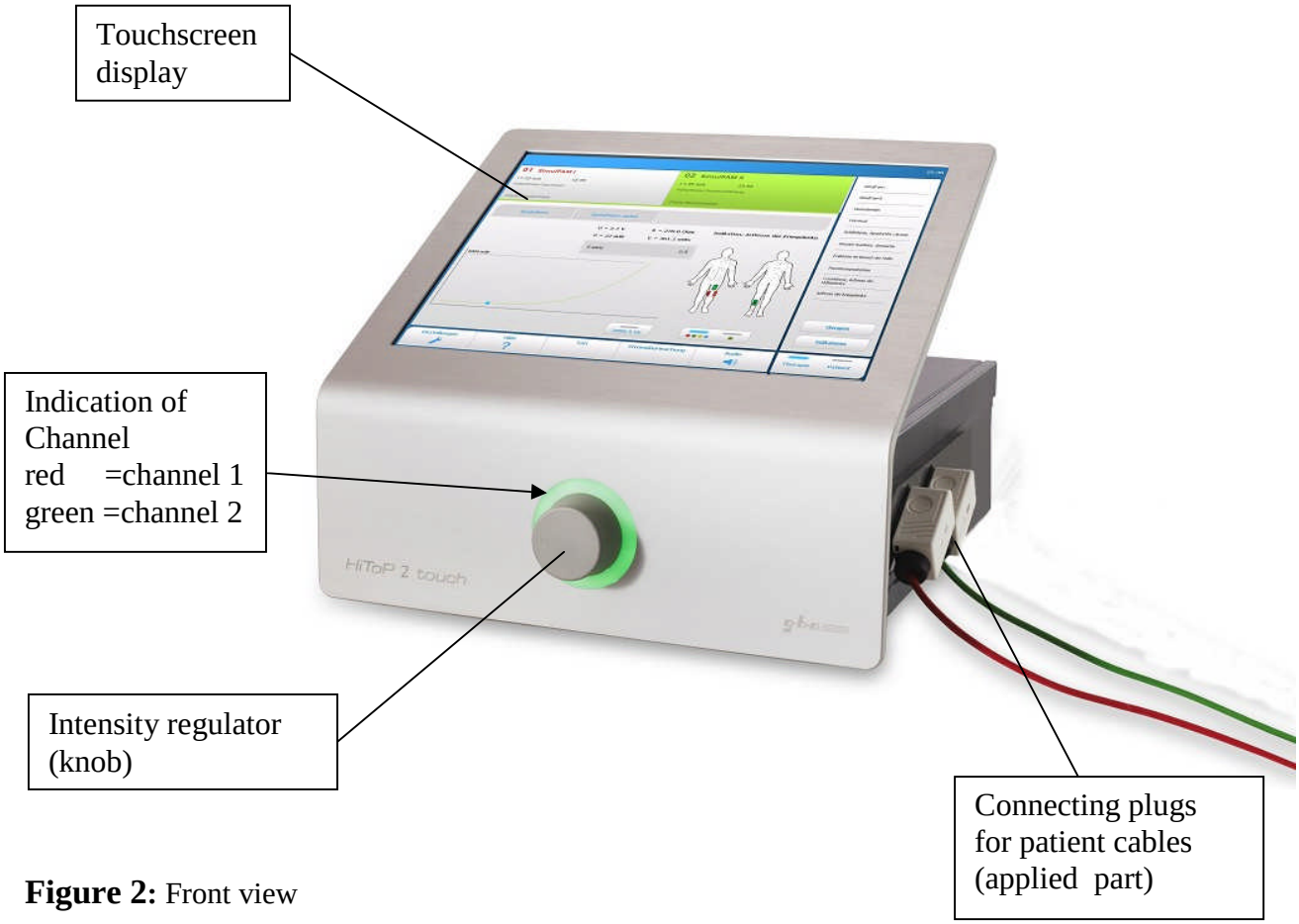

Figure 2: Front view

3.1.1 Touch screen

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

Every button is clearly labeled. Through the optics, the user can differentiate operating buttons from non-operating buttons. In case of doubt the user can obtain further information via the direct help system.

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In order to adjust numerical data the arrow keys may either be pressed repeatedly or pressed constantly for automatic increase/decrease of the value.

The scrollbars are used like with a PC: press the scrollbar and then pull into the desired direction.

3.1.2 Intensity regulator

During the therapy the output voltage is set with the **Intensity regulator.** The current increases by turning the intensity regulator clockwise and it is reduced by turning it counter-clockwise. The current intensity is shown in mA on the display. In order to reach the desired intensity the user might have to turn the regulator clockwise for more than one rotation.

!!

Note!

In the event that the intensity is set to 5000 mW while turning the button, the unit initiates a counterforce to the knob to signal to the user that the limit is reached.

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3.2 Direct help menu

The user of the **HiToP®2 touch** is guided on the screen. The direct help menu provides information about the selected buttons directly on the screen.

To open the direct help menu, first touch the „?“-button on the screen and then the button about which you desire information. A new window opens where the information is shown. Touch the “X”-button in order to close this window.

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

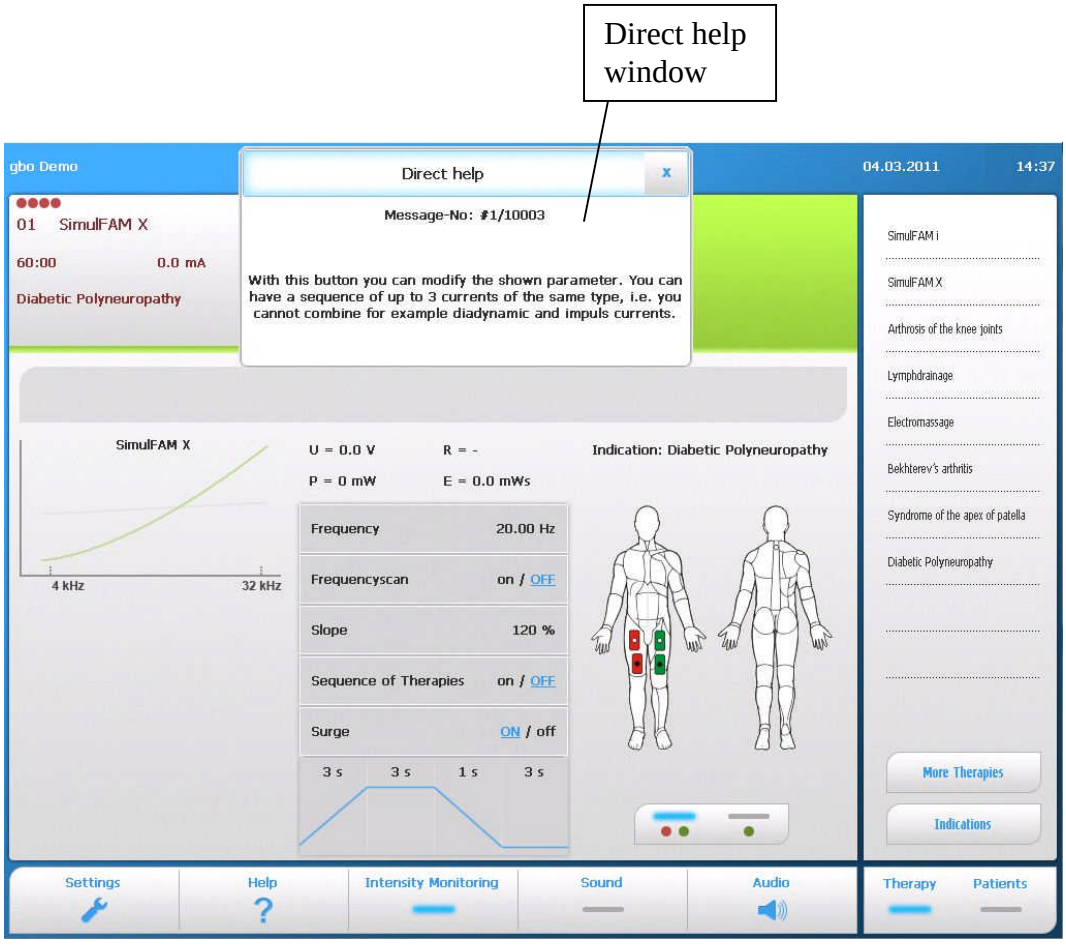
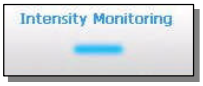


Figure 3: Direct help menu as shown on the display

3.3 Intensity monitoring



During the development of the **HiToP®2 touch** 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 channel will be switched off for the patient´s safety. An acoustic signal is given and the following message will be displayed: Therapy terminated by Intensity Monitoring in channel 1. Please check for insufficiently attached electrodes or disconnected patient cables.

!! **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 respective channel in such a case. On the display a note for the respective channel is shown (in case of the example mentioned: channel 1).

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3.3.1 Deactivate intensity monitoring

!! **Note!**

- The intensity monitoring is automatically activated for all channels 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. Select the respective channel with the channel buttons.
2. Press the button ”Intensity monitoring“.
3. 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 for one channel 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.

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3.4 Settings

The device **HiToP®2 touch** has a setting menu which is activated by pressing the setting button. This can be done only when the therapy is not yet active.

You find the following items in the settings menu:

Service	You get into the Service menu. This item is reserved for service personnel only and helps to locate failures within the hardware.
Cable test	Patient cables and the distribution cable may be checked for failures.
Audio	Here you can load your own music which the patient may listen to during therapy. When delivered an album with music for relaxation is pre-installed. In order to install music the respective music data must be converted into the .Ogg (Ogg-Vorbis) format. The data converted must then be loaded onto an USB stick into a HiToP_Audio folder. With the function “Audio import“ music titles may then be allocated to one of max. 8 albums.
Display	You may change the language, date format and time format. Also time and date may be set here.
Sounds	You may change system sounds like the sound signaling the end of the therapy etc.. You may listen to the sounds and allocate them to the respective functions.
System information	The software version is shown.
Delete patient	Patients may be deleted.
User	There is the possibility to compile different users. Each user gets his own language, he may store his own therapies and his list of favorites will fill up according to the therapies used by him.
Therapy	Personal therapies may be redefined or deleted. You can define basic settings for the treatment time of SimulFAM i and SimulFAM X.
Import/Export	You can compile a back up of the data. It may then be loaded to another device. A new language version may be loaded. A software update may easily be installed in this sub-menu. A USB stick is used for the transfer of the data. The USB stick must be placed in the back side of the unit.

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3.5 Music Playback (Audio)

With the unit **HiToP®2 touch** you may listen to music titles over a head set connected to the back side of the unit. Upon delivery an album with relaxation music is pre-installed and can directly be selected and listened to. If you press the button “audio” a flyout will open up. Now you can select an album and adjust the volume within the flyout. By pressing the button Play/Pause you can start and stop the playback.
Additional albums may be loaded in the menu “Audio” in the settings. (*See chapter* ***Fehler! Verweisquelle konnte nicht gefunden werden.***)

3.6 Sound

HighTone Therapy comprises a frequency range from 4096 Hz to 32768 Hz. The lower part of this frequency range lies within the audible range. In order to make clear to the user or patient, respectively, the kind of frequencies they are treated with it is possible to make these frequencies audible on the internal loudspeaker. If you press the button “sound” a flyout will open up. Now you can switch on the tone and also the volume may be adjusted in this flyout.

!! **NOTE!**
The activated sound is indicated by a blue bar within the button.

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4 Therapy

The **HiToP®2 touch** 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 favourites or with the sub-menues “More Therapies” or “Indications”.

First, choose the channel you want to use and then you can select the desired program or indication. The direct help menu will give you information about the following steps of the therapy.

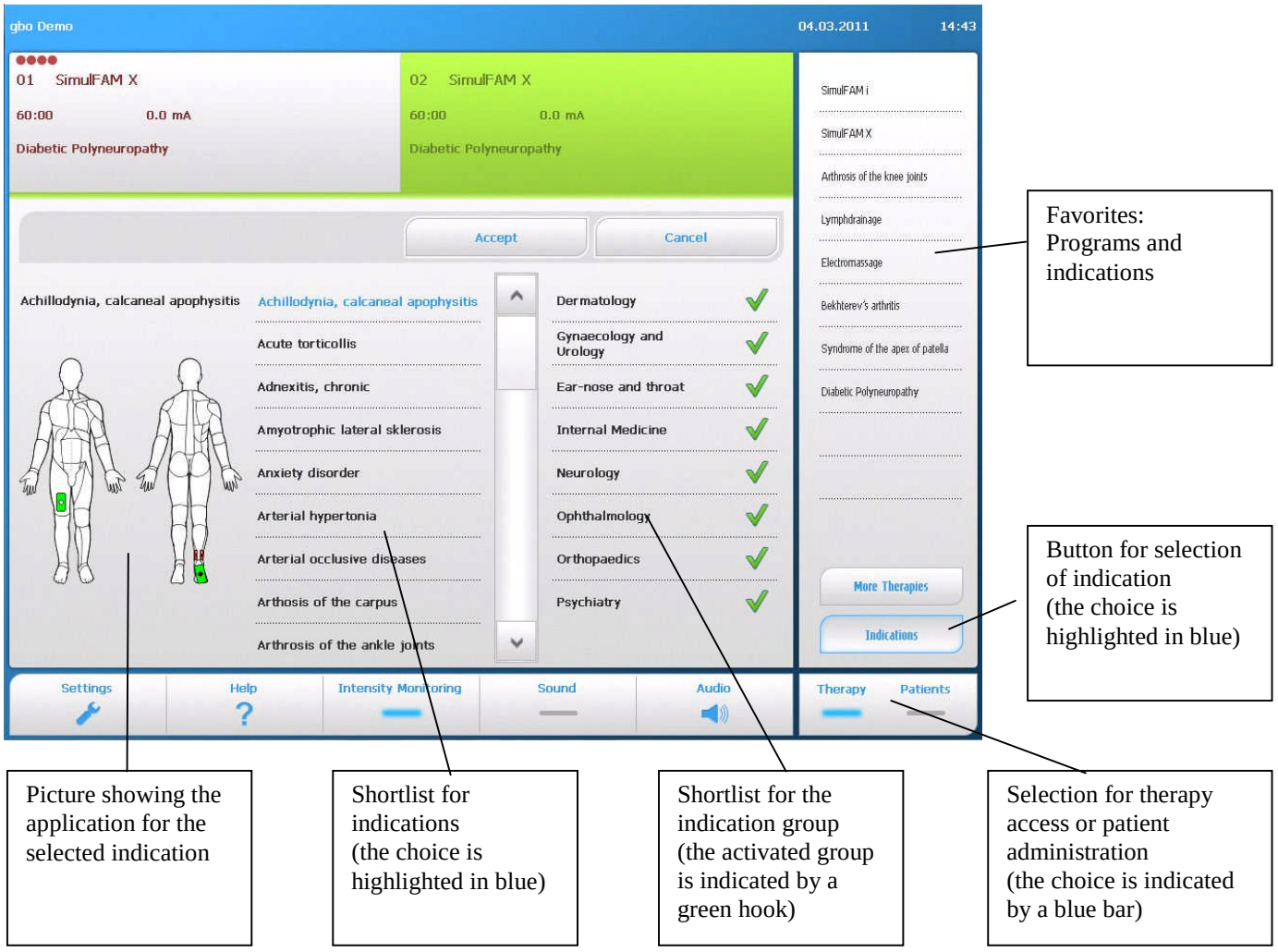

Figure 4: Touchscreen with selected indication

4.1 Frequently used therapies and indications (favourites)

Frequently used functions are directly accessible on the front screen. To this purpose, the eleven most used therapies are listed on the right side. From here, they can directly be selected.

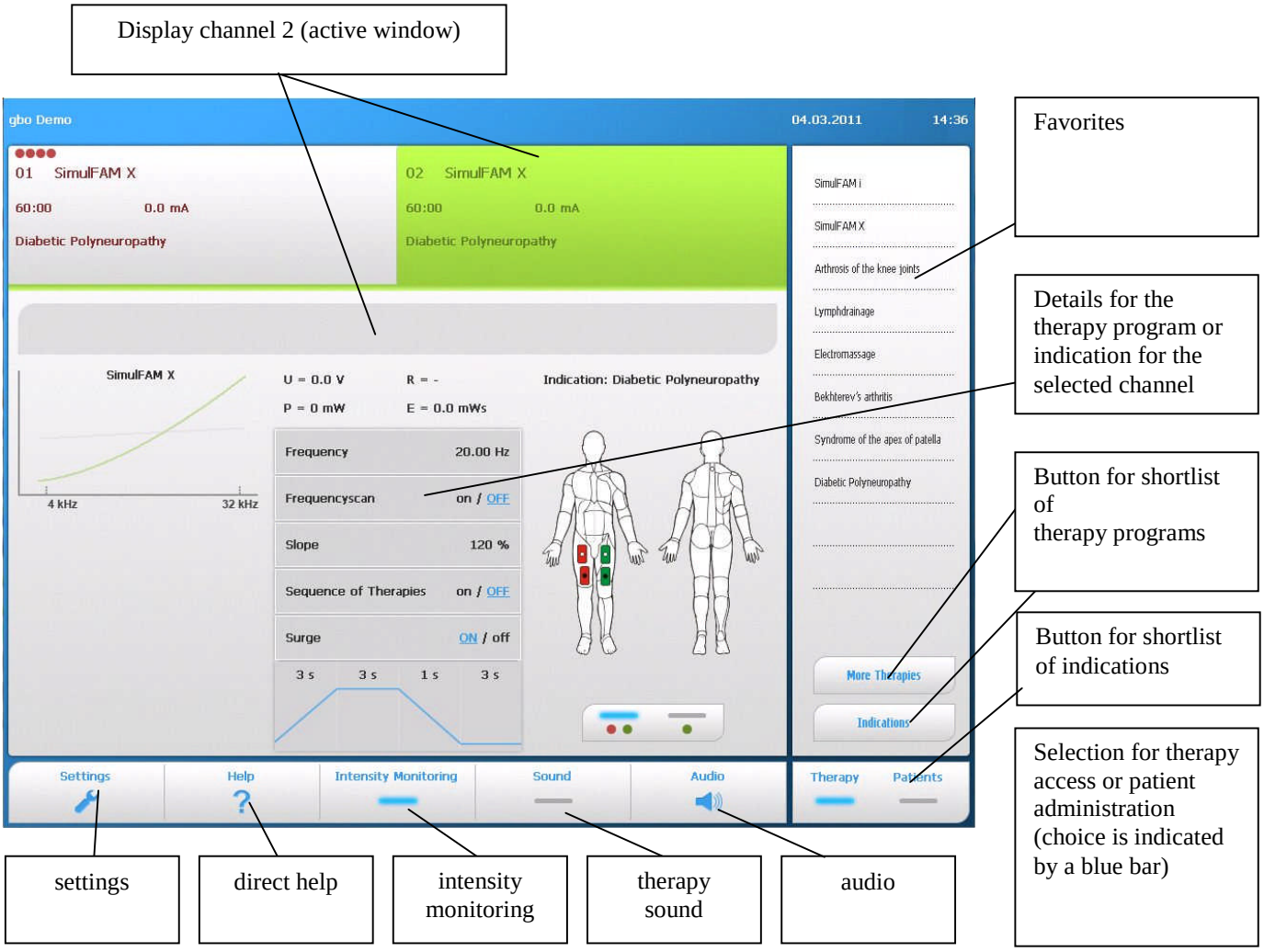

Figure 5: View of Touch screen display

The user can recall typically used therapies with only one touch. Additional therapies can either be recalled according to a patient's name, i.e. via log book, or by referring to indications or the name of the therapy.

4.2 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 threshold curve determined.
- 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.

4.2.1 Setting of f-sens

If both intensity values at 4096 Hz and 16384 Hz are set and the therapy is started, the calculated value for f-sens is indicated. This value indicates the relation of the current value at 16384 Hz relative to the current value at 4096 Hz.
As already mentioned above the patient should feel a tingling during the therapy with all 72 frequencies running. In the event that the tingling cannot be felt equally, it can be improved with a change in f-sens. When pressing the button f-sens, the device will switch into a faster run with a lower amount of frequencies. With the aid of the arrow key you can set the upper and the lower frequencies equally.
After a short timeout the regular frequency scan will restart. Now one can judge whether the adjustment improved which means that with all frequencies almost an identical current feeling is perceived.

4.3 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 01 Hz up to 200 Hz.

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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.

4.4 Working with the patients

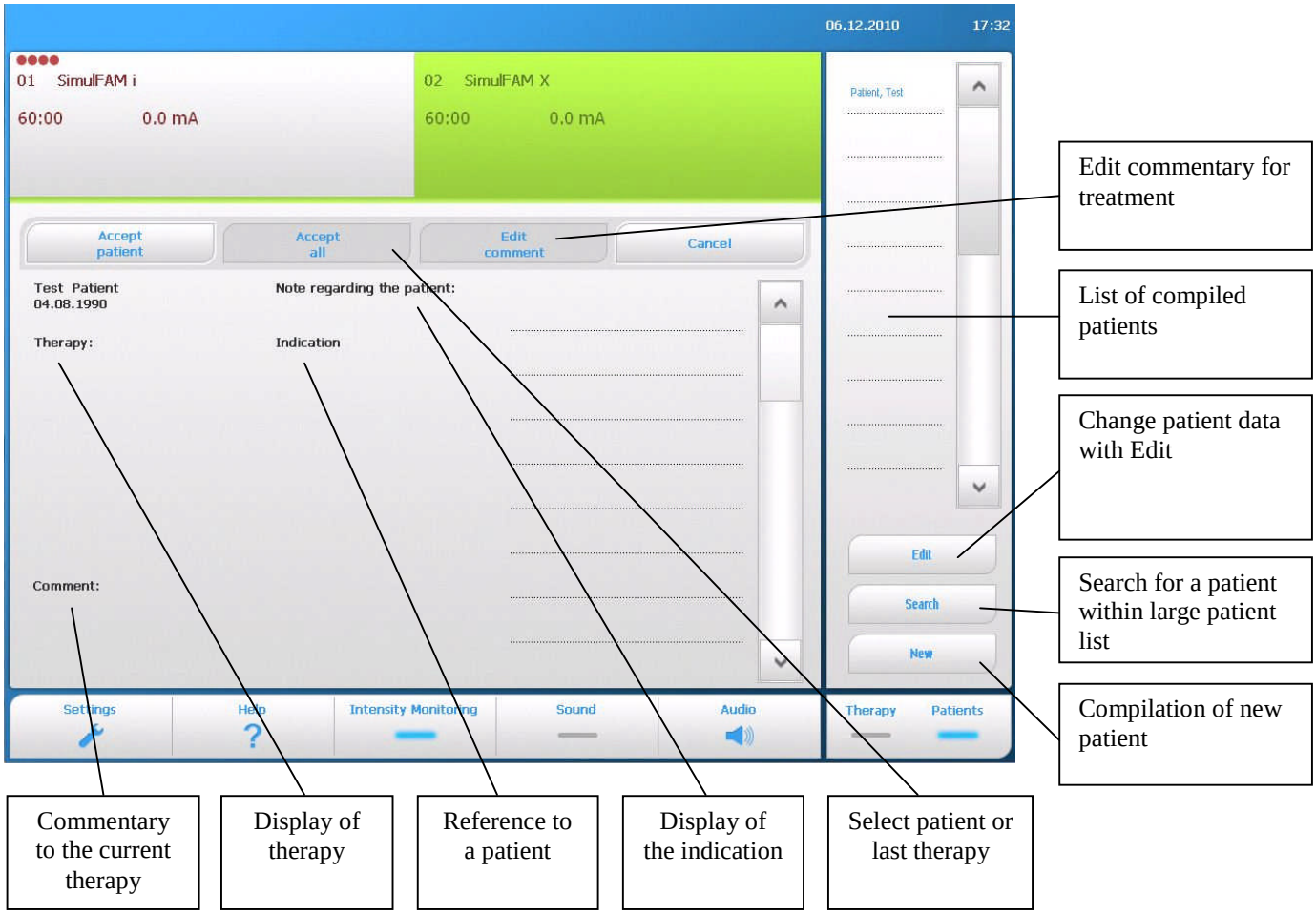

Figure 6: View touch screen-display select patient

4.4.1 Compilation of new patient

If you choose the button “patient“ and then the button “new“ you get to the virtual keyboard for the compilation of a new patient. Mandatory are the first name, last

name and date of birth of the patient. The year must be entered with 4 digits. You may also add a special reference when compiling a new patient. This reference may help the health care professional to correctly evaluate the contraindications. An example for a reference: “Patient carries heart pacemaker”. When all mandatory fields are filled the patient may be filed with the aid of the button “New”.

4.4.2 Load patient file for therapy

If you wish to assign the therapy data to a patient, the patient must be loaded prior to the start of the therapy. To this purpose you choose a patient already compiled from the list of patients. Upon selection of the patient you get into the patient logbook (see Figure 6 on page 20). From this list a patient can now be loaded for a therapy. When pressing the button “Accept patient“ the patient is loaded into all 4 channels and the therapy can be started.

4.4.3 Patient logbook

After the therapy time a logbook entry is created for each patient loaded (see Figure 6 on page 20). Here the time of the treatment as well as the therapy data are documented. These are the current form for channels 1-4, the max. energy emited per channel, the sum of energy for the entire treatment and, if necessary, the indication (only if an indication was chosen for the treatment). For each therapy it is possible to add a comment to the logbook either during the treatment or after.

The therapy conducted last may easily be applied by pressing the button “Accept all”. I.e. all therapy parameters of the last therapy are accepted.

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5 Electrodes

Single-pole electrodes are fit for all therapy currents. It is preferrable 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.

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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 eldtrodes and spread the liquid over the electrode's surface.
2. Apply the electrodes to the patient.
3. Apply the elastic strap with Velcro in such a way that the electrode fits 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 respective channel socket 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. If an electrode has to be placed nontheless, it is advised to apply zinc ointment or vaseline 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 over 2 mA/cm^2 on all electrode surfaces requires increased attention of the operator.

5.3 Multiple longitudinal (whole-) body treatments in parallel

As a rule, in whole-body treatment the longitudinal current flow is realized with two pairs of electrodes, one each applied to the hands and feet. One electrode is placed in the neck.

Principally–independent of the physiological effect of such a therapy– multiple parallel and overlapping longitudinal current flows with the two channels of **HiToP® 2 touch** can be realized. Here, due to physical principles, on the device's side it cannot be excluded that the patient experiences current sensations when further channels are added. Thus, please see the following note:

!!

Note!

If a second electric circuit is added in parallel to the first longitudinal body treatment, which overlaps the first circuit for a large area of activity, the total resistance in the first circuit is reduced suddenly at the moment of turning on the second circuit. This rapid change in the resistance causes a sudden current increase, which in the end may lead to a current sensation or– with acivated current monitoring - to the cutting off of one channel. This can be avoided as follows:

- First activate the circuit which passes the smaller part of the body and only after that you activate the whole body treatment.

This note is only applicable for current circuits overlapping in a significantly large area. As a matter of cause local therapies of small body regions, e.g. the knee, conducted during a whole-body treatment are not concerned by this.

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6 Maintenance

Functionality, reliability and safety characteristics of the **HiToP®2 touch** 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 done by the user.**

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 service agency authorized by him.

The check shall consist at least of the following criteria:
- Electrical safety check in accordance with the test plan of the manufacturer
- Check of the device in respect of external integrity
- Check of all display and operating elements in respect of damages
- Check of all inscriptions in respect of immacutate legibility
- Check 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).

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6.3 Cleaning, Disinfection and Care

6.3.1 Cleaning the Device

For cleaning and disinfection of the current stimulation device and its accessories there should not be used any agents containing higher portions of phenol derivatives, alcohol, compounds of chlorine or peracetic acid. It is recommended to use disinfectants on aldehyde basis. Never use an abrasive. Fingerprints on the touchscreen should be cleaned with a dry cloth or some isopropanol.

Warning!

- **Prior to cleaning or disinfection, unplug the mains plug out of the socket!**
- **The device is not suited for heat sterilization or for the sterilization with gases.**

The **HiToP®2 touch** 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.

6.3.2 Cleaning the Elastic Straps

The eleastic straps can be washed in a washing machine. Please observe the washing instructions of the instruction label.

6.3.3 Cleaning the Electrodes

You can clean the rubber electrodes after a treatment with some warm water (appr. 40°C) and a 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 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.

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6.3.4 Disinfecting the Electrodes

The rubber electrodes can be disinfected by a 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.

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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, a 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.
- In case of a short circuit the lithium battery contained in the device can explode. Only service staff should change the battery.
- 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 over 2 mA/cm^2 on all electrode surfaces requires a higher attention of the operator.

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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 immunsuppresive 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 criterias for the treatment.

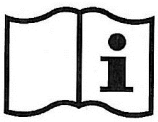
!!

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 operating instructions!

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.

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9 Technical Data

Mains voltage and frequency:	100 – 240 V, 50-60 Hz	
Power consumption*:	max. 200 VA bei 230 V: max. 1.65 A	
Mains fuse :	T 5A L 230V bei 230 V: T1.6 A	
Output current:	max. 310 mA per channel	
Output voltage:	max. 76 V per channel	
Output power:	max. 5000 mW per channel	
Patient resistance:	30 -1500Ω	
Mode of operation:	continuous operation	
MDD device class:	IIa	
Protection degree:	I acc. to IEC 601	
Protection class:	BF acc. to IEC 601	
Protection against ingress of: liquids	IP X0	
Dimensions:	max. 35 cm x 29 cm x 35 cm (W x H x D)	
Weight:	11 kg without accessories	
Color:	aluminium natural anodized and grey RAL 7016	
Display:	15“ TFT LCD Touchscreen	
Battery:	CR 2032	
Environmental conditions:	operation of the device:	temperature range +10 °C ... +40 °C relative humidity of air 30 ... 75 %
	transport and storage:	temperature range -10°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 mains connector is used for all-pin disconnection from the mains power supply.

The exchange of the battery is described in the service manual.

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

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9.1 Current Types

The used currents in **HiToP®2 touch** 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 per channel is 76 V and the maximum current is 310 mA. The maximum power per channel is limited to 5000 mW. This correlates with the demands of the standard 60601-2-10 which describes a limitation of 100 mA at 500Ω.

The valid impedance ranges from 30Ω to 1500Ω.

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10 Accessories

Accessories included:

HiToP®2 touch	2	distribution cable with color coding, 150 cm	part number
	2	set of patient cables with color coding (6 cables of 100 cm each)	
	6	conductive rubber electrodes, 115 mm x 175 mm	027-0-0010
	4	conductive rubber electrodes, 80 mm x 120 mm	
	10	elastic straps with Velcro, 70 cm	
	4	easy-fix electrodes, 80 mm x 120 mm	
	4	elastic straps with Velcro for easy-fix electrodes	
	1	aloe vera contact spray, bottle of 473 ml	
	1	headphones for integrated player	

For the **HiToP®2 touch** we offer a large variety of accessories.

Specification	**part number**
distribution cable I (red), 150 cm	017-0-0030
distribution cable II (green), 150 cm	017-0-0031
set of patient cables I (red) (6 cables of 100 cm each)	017-0-0034
set of patient cables II (green) (6 cables of 100 cm each)	017-0-0035
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	011-0-0033
easy-fix electrodes, 80 mm x 120 mm	017-0-0062
elastic straps with Velcro for easy-fix electrodes	017-0-0059
aloe vera contact spray, bottle of 473 ml	002-2-0073
headphones	017-0-0039

For detailed information see the enclosed brochure "**HiToP®2 touch** 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.

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For the **HiToP®2 touch**, following additional accessories are available:

specification	part number
device cart for **HiToP® touch**	026-0-2000
bed for **HiToP® touch**	027-0-1000

Figure 7:

HiToP®2 touch with accessories, device cart and bed

11 Troubleshouting

Each problem that occurs during operation of the unit will be shown in a message window on top of the display and also signalized 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.

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12 Appendix

Comments according to the Medical Device Directive

The **HiToP®2 touch** 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®2 touch** 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®2 touch 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.

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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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