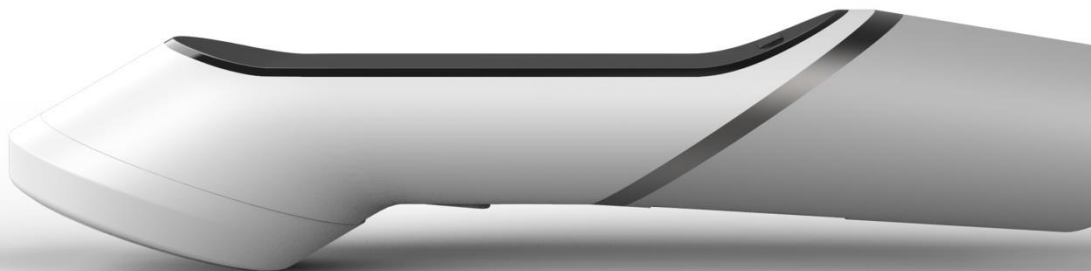




medkey



DE - Bedienungsanleitung
EN - Manual
FR - Manuel
IT - Manuale
ESP- Manual



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Definitions and general information

Purpose of the medkey

medkey is an adaptively regulated electrotherapy device.

The device uses (in the “bioregulation” and “diagnostic” modes) the process of non-invasive electrical nerve stimulation which has been established as a successful therapy for many years, through the electrode’s contact with the skin. This process is generally regarded as having very few side-effects.

The medkey can create a bidirectional (in “bioregulation”) and galvanic impulse form (in “key-phoresis”). The application of galvanic currents with medkey is used exclusively for the application of topical applications under the skin (see chapter “Key-phoresis mode”).

The application of the bipolar impulse form is discussed below:

The bipolar impulses in bioregulation serve the following indications and areas of application:

Indications

Indications for the medkey are acute and chronic pain, muscular and other organic dysfunctions (in terms of restrictions in functionality) including muscular imbalances (in terms of restrictions in the functionality of muscle pairs) as well as disorders or restrictions to the blood circulation in relation to microcirculation in the tissue for the areas of application:

Areas of application

- Nervous system
- Musculoskeletal system
- Digestive tract
- Urogenital area

The product can be used on patients of all age groups. Use on children up to the age of 5, however, is reserved exclusively to experts who have been given the appropriate training. The recommended treatment time using the device is a few minutes up to a maximum of one hour.

The medkey is a medical product. It can be used by medical professionals as well as at home by laypersons who have been trained in its use by a medical professional.

Contraindications and areas in which use is prohibited

medkey may not be used in the following cases:

- Use prohibited on injured skin (e.g. open wounds and/or wounds which have not yet completely healed)
- Use prohibited in bodily orifices
- Use prohibited on carriers of active implants (e.g. cardiac pacemakers)
- Use prohibited in the area of the uterus with pregnant women
- Use prohibited on patients with cardiac arrhythmia
- Use prohibited on patients with malignant diseases without consultation with a doctor
- No use on patients who suffer from epilepsy

Side-effects

The **medkey** is associated with very few side-effects. The following cases can be regarded as side-effects, however:

Symptom intensification: Symptoms may intensify during the treatment period, as the body is “dynamised”. These may include stronger pain, muscle aches and other reactions in isolated cases. In most cases, they fade away after a short time. Should they last longer, please interrupt the treatment for a few days and, if necessary, consult a doctor.

The stainless steels of the electrodes in the exchangeable heads contain small traces of nickel. Patients with a pronounced nickel allergy may therefore experience skin irritation. In this case, healthcare professionals must decide on whether the therapy should be continued or alternative treatment options should be used.

Safety instructions

- Read the instructions on use (this document) before you use the device for the first time.
- Only use the **medkey** for its intended purpose.
- The medkey must be kept in such a way that it is inaccessible to children and may not be used by children.
- Do not submerge the **medkey** in water or hold it under flowing water.
- The device must be checked for integrity before use (handpiece, tablet, base station and power pack (incl. cable)) and otherwise sent in for repair.
- With regard to electromagnetic compatibility (EMC), the device also fulfils the stricter requirements regarding “home environment”, which also apply to many doctors’ and therapists’ practices.
- Not suitable for use in intensive care units
- Portable HF communication devices (radios) of all types must not be operated at a distance of less than 30 cm from the device. An exception is charging a mobile phone on the base station.
- In exceptionally rare cases of high EMC interference, however the system may switch itself off. In such a case, restart the device to continue the therapy.
- To increase the data security on keypad, we recommend that you only establish the WiFi connection briefly for the use of the following functions: Updates (operating instructions and software) and access to the Media Library.
- Only the power packs that are provided by the manufacturer may be used.

Commissioning, instruction, safety inspection (STK) and medical devices book, service life

Ensure that your medkey is fully charged before using it for the first time. Otherwise, the displays on the charging status may not be correct later on.

The use of the device requires instruction. You can receive instruction on how to use the **medkey** either from your medical device consultant or through the **KeyAkademie** seminars (subject to payment) or an individually booked in-house training course (subject to payment). A medical device book (MPB) is available from Keytec. The device is subject to a safety inspection (STK). The safety inspection (STK) can only be carried out by professional staff who have been trained in the use of the device. A protocol template is printed on the second page of the MPB. When used at home, the treating therapist is responsible for the instruction and safety inspection (STK) obligations and is required to have been instructed by Keytec. The service life of the **medkey** is 10 years.

Product description

The medkey consists of the following components:

- Handpiece (appliance) including standard changeable head
- Instructions for use
- Base station for inductive charging including power pack

The medkey is delivered in a transport case that has space for all these elements.

Optional components (changeable heads, keypad and adhesive pads)

The medkey can be supplemented with optional components (changeable heads and adhesive pads) as regards the specific focal points for its application. The changeable heads consist of the connection to the appliance and the treatment electrodes with their different configurations. The electrodes of the adhesive pads are integrated into the textile and adhesive gel. All treatments according to the intended purpose can be carried out with the standard equipment. Improved access to the body and certain regions can be achieved with the optional components, however.

Standard changeable head: Basic equipment for all applications



Highpro Scanner changeable head: All applications, also for transfer of motion patterns in connection with keypad

Trigger changeable head: Treatment of the smallest structures, also muscle cords, tendon courses, trigger points.



Matrix changeable head: Specialised for fascia therapy and treatment of connective tissue.

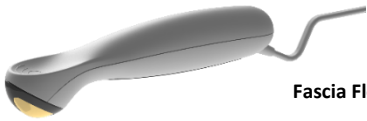
Comb changeable head: For treatment of hairy areas.



Connector cable: Adhesive pad connection

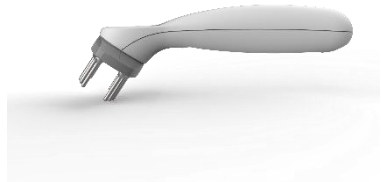
Adhesive pads: For sticking to the skin





Fascia Flow changeable head: For the treatment of fascia and trigger points.

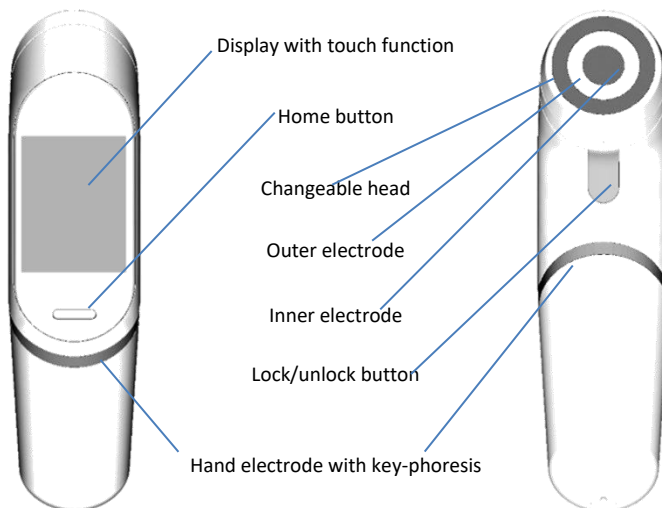
Hand Comb changeable head: For treatment of hairy areas



keypad (tablet PC) including separate charger: For connection with the medkey handpiece (see page 10)

Use

Description of the appliance (handpiece)



Explanation of the function of the Home button

The Home button is the only “physical” pushbutton on the medkey, and has 4 functions:

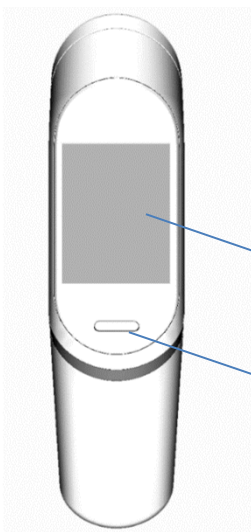
1. **Switch on and off:** With the Home button you switch the device on. To do so, press the button for two seconds. By pressing the button again for two seconds, the device is switched off again. The logo is shown on the screen when both switching the device on and switching it off. Please wait at least 15 seconds before switching the device on again.
2. **Activating the display:** If the touchscreen is inactive, you can activate it by pressing the Home button briefly once.
3. **Return to the main menu:** By pressing once briefly, if the touchscreen is active, you will exit the therapy mode and return to the main menu.
4. **Reset/recalibration:** Is carried out with a blue screen, see “Recalibration” section.

Explanation of the touchscreen

The display of the medkey has a touchscreen control. If you want to change the energy level or the therapy mode, simply press the respective symbol or item on the display. In this description, “press” is often used to describe a symbol/item. Light touching is often sufficient, however. In general, touching the item triggers the intended function directly, and is confirmed by an acoustic and vibrating feedback if you have activated these functions (default setting).

PLEASE NOTE: Using the touchscreen successfully is a matter of practice makes perfect.

You will get used to it quickly, though.



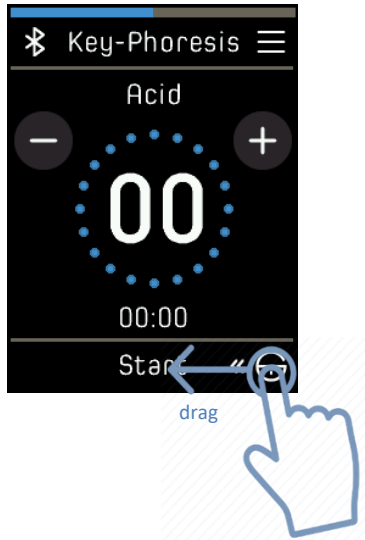
The medkey is controlled via the oval control ellipse. This control ellipse is designed in such a way that accidental changes to the device settings during use are pretty much excluded. The following controls are available:

Touchscreen control and display
(see section: Touchscreen control)

Home button with on/off function

Inactive display

To prevent accidental entries via the touchscreen, the touch function can be switched off if it is not to be used for a specific period of time. To do this, drag the lock symbol to the centre of the display.



Briefly press the Home button once to reactivate the touchscreen display. If the display is activated, pressing the Home button once always returns you to the main menu.

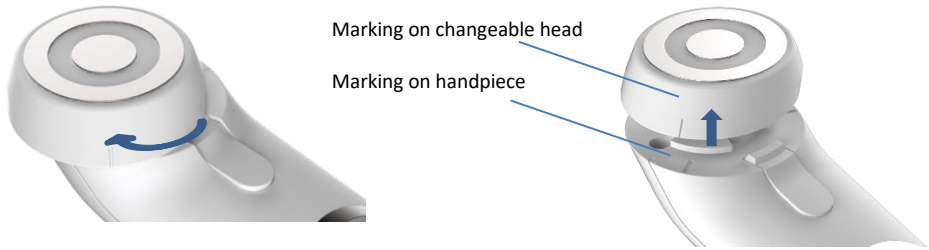
Replacing the changeable head

The electrode on the bottom of the medkey is attached to a changeable head. This changeable head can be replaced by specific optional changeable heads.

To replace the changeable head, press the lock/unlock button.



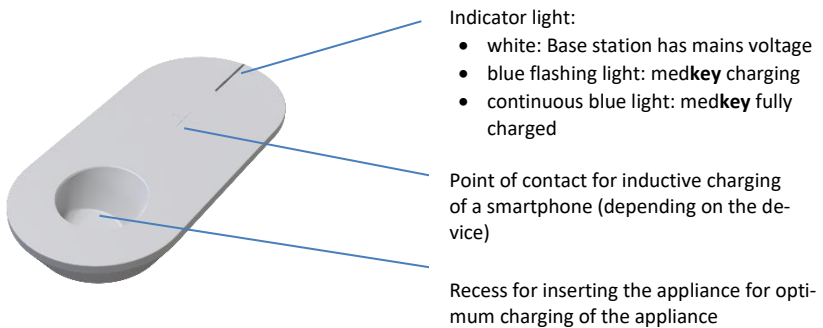
Turn the changeable head by approx. 60 degrees (left or right) and lift it out of its socket. To use another changeable head, place the marking on the changeable head on the marking on the handheld device and turn it towards the unlocking head until it clicks into place.



Description of the base station

The base station is used to charge your medkey handpiece. The exact procedure can be found in the chapter “Charging the medkey handpiece”.

Base station alone:



Base station with inserted appliance:



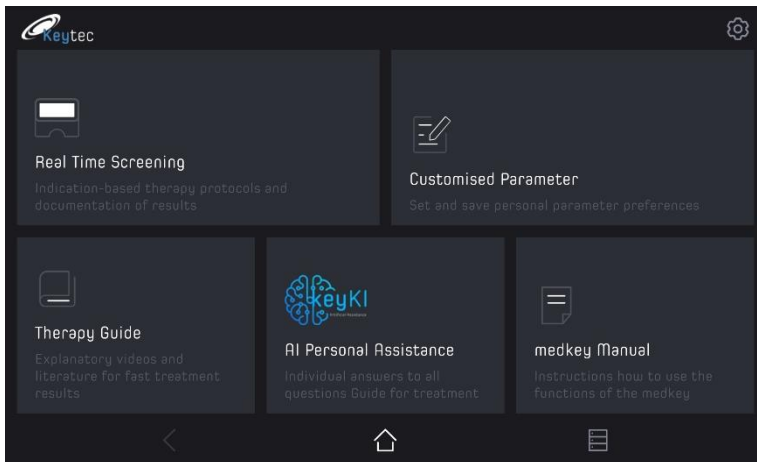
Base station with a (simultaneously) charging smartphone:

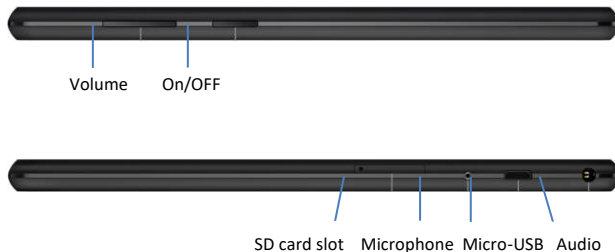


For further information on technical data, e.g. performance parameters, see the chapter “Technical data”. Power is supplied via the supplied power pack (see chapter “Technical data”).

Description of the optional **keypad** (tablet PC)

The **keypad** is a tablet computer which supports the use and application on the patient. You can make use of the large screen to conveniently set various parameters. In addition, the **keypad** offers you the option of displaying the progress of the therapy and documenting various parameters (also see the **Key-pad** mode chapter). To be able to use this range of functions, a corresponding application is preinstalled on the **keypad**. Please make sure that the Bluetooth and WiFi functions are activated. A use and treatment is also guaranteed at all times without the **keypad**, whose functions serve as an additional benefit.





Please only charge the **keypad** with the original power pack which is supplied.

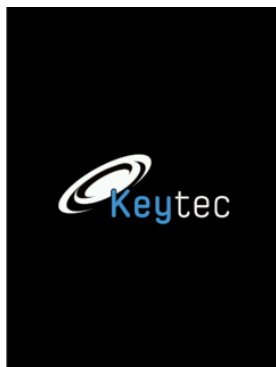
Caution! Please take care not to mix up the power packs; due to the different connectors, the power pack of the tablet does not fit into the base station. Do not use force.

When you switch on the **keypad** for the first time, an initialisation process opens. Please follow the instructions on the screen. Here, you specify the language of the app, establish the connection to the **medkey** handpiece, set the Wi-Fi connection, confirm the terms of use and set a password.

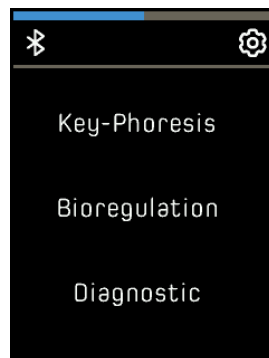
Please note that the information provided in the **keypad** is intended to make your work easier. It does not constitute diagnostic or therapeutic guidelines and is no substitute for an assessment by an appropriately trained specialist. All documentation obligations must be carried out by the therapist, regardless of the use of the tablet.

Therapy modes of the medkey

Press the Home button for approx. two seconds to switch on the **medkey**. The device will now start up. The main menu appears.



After approx. two seconds the display shows the main menu.



Three therapy modes are available to you in the main menu.

Key-phoresis mode

Select the **key-phoresis** mode by touching the corresponding item in the main menu.

Key-phoresis is a special form of application using the characteristics of direct current. This enables the application of the galvanic procedure, during which a low direct current is produced.

In the case of phoresis, the **medkey** is used as an aid in the case of topical applications. Please note their instructions for use as well as indications and contraindications of the topical application. Please take note of them for both the intended purpose and instructions for use. Also note the indications and contraindications of the topical application.

The changeable head is placed on the skin, the hand electrode (see diagram in chapter “Use” on page 6) is required as a counter-electrode. You touch this automatically when using the device, your contact allows the effect of the electrode to start. To close the circle, there must be skin contact, and ideally, the skin (including the hand) should be slightly moisturised.

You will not generally feel the key-phoresis. The required effect is still achieved, though.

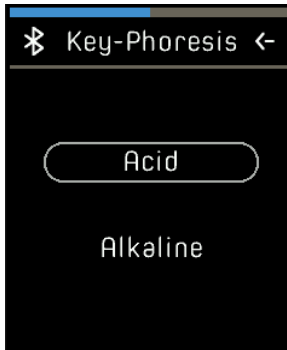
It is also possible for the patient to operate the device themselves for the duration of the **key-phoresis**. You can activate the **key-phoresis** by pressing the item.

Overview of key-phoresis mode



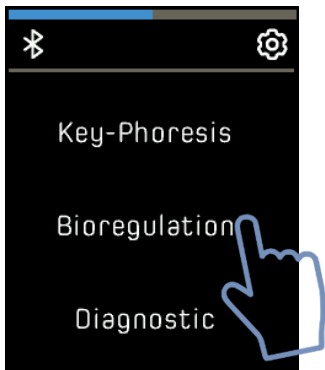
To perform **key**-phoresis, increase the energy level first by pressing the plus button. Touch the minus button to reduce the energy. The energy level is indicated by the number in the centre. You can choose from 1-99 for the energy setting. The energy should be barely noticeable or not noticeable at all. After selecting the energy level, press “Start”. The timer starts to run when the power is transmitted. If you want to stop the application, press “Finish”.

The **key**-phoresis allows for two different flow directions depending on the pH value of the topical application. To change this setting from alkaline to acidic, press the menu symbol. ☰
The screen then switches to another submenu. The two setting options are now available to you, which you can carry out by touching the respective item. The most recent active setting is highlighted with a border.

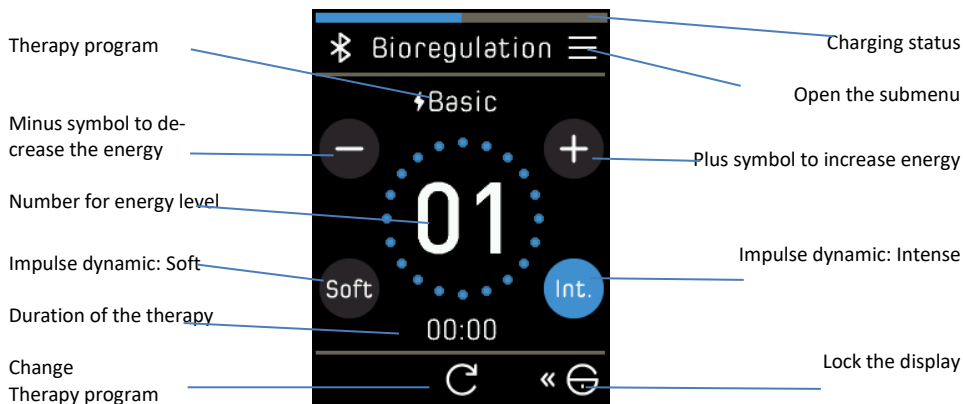


Bioregulation mode

Select the Bioregulation mode by touching the corresponding item in the main menu.





Overview of Bioregulation mode




If the lightning symbol is displayed in front of a therapy program, the output energy is applied at the electrodes. The timer begins running when skin contact is established.

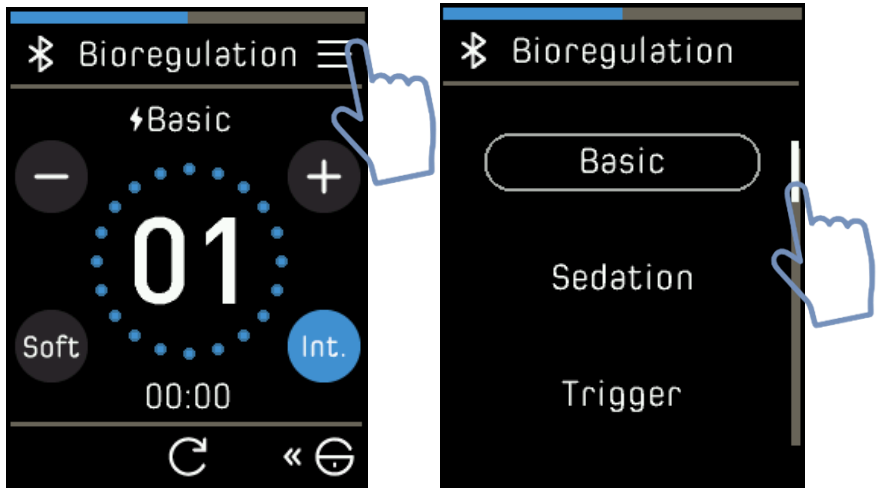
Press the plus or minus button to increase or decrease the energy setting. Pressing the buttons is confirmed with a haptic feedback if you have activated this function (default setting). The energy level is indicated by the number in the centre. You can choose from 1-99 for the energy setting. In most cases, however, it should be set so that it feels comfortable. The basic treatment can also be carried out in this setting. After switching on the **medkey**, the therapy program in the Bioregulation mode is always set to "Basic", with the energy level of 1.


The previously-selected therapy program is activated by pressing the arrow symbol . You can see this by the name in the top (e.g. Triggering).


Pressing the arrow symbol  again returns you to the basic setting.

Changing the saved therapy program

With your medkey, a wide range of different therapy programs are available to you. This way, the device offers maximum flexibility. The different therapy programs are named according to the effect to be achieved. For the programs you wish to select in specific cases, please refer to the seminar documentation. You make your selection by pressing the menu  symbol, and therefore opening another submenu.



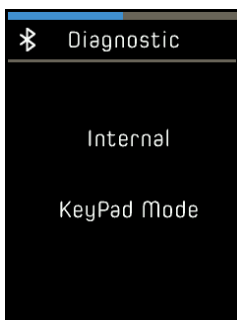
It is possible to go up and down the therapies list with the scroll function. By pressing on the item, you confirm the selection and select this form of therapy. This form of therapy will now be called up automatically as soon as you press on the arrow symbol . This function is also available in the Diagnostic mode. This means you can quickly access the selected form of therapy.

You can quickly switch between the individual bioregulation modes by clicking on the arrow symbol  once or multiple times.

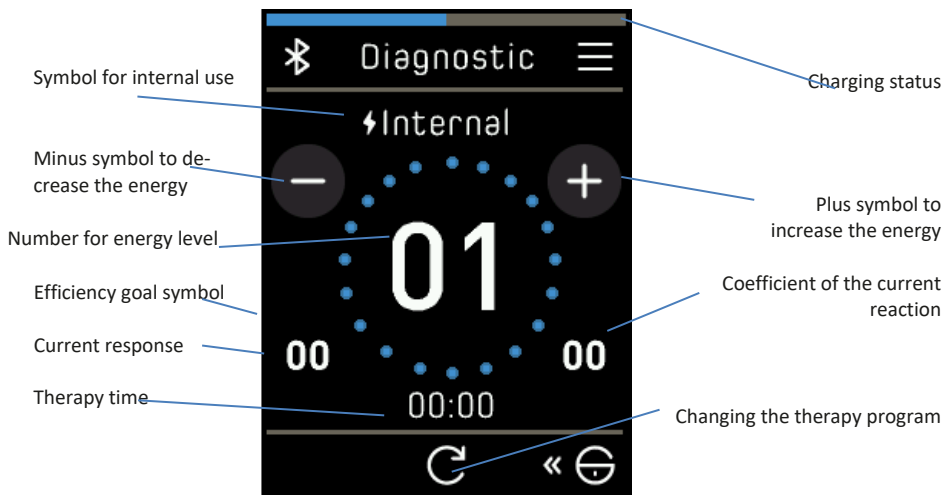
Diagnostic mode

The Diagnostic mode works in the same way as the Bioregulation mode. Additional measurement data can be shown on the display with the use of the Diagnostic mode, however. This way, asymmetries can be identified more precisely and objectively. This mode also enables application of a therapy while the dynamics can be displayed according to the acquired values. You will also be shown when the therapy can be ended. Please refer to the seminar content for information on therapy in the Diagnostic mode.

You can activate the Diagnostic mode by pressing the corresponding item in the main menu. A submenu then opens, in which you can choose whether you only want to carry out the diagnostic mode with the medkeyhandpiece or if you wish to perform the extensive diagnosis with the keypad.

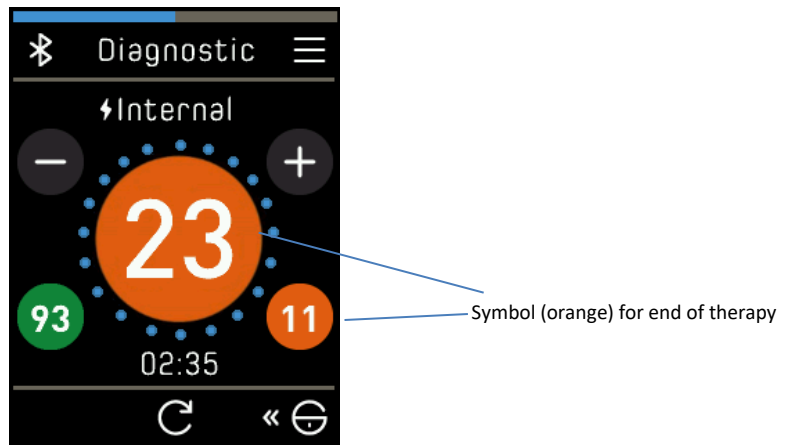


Overview in Diagnostic mode (internal)



Press the plus or minus button to increase or decrease the energy setting. As confirmation of pressing the button, you will receive acoustic and haptic feedback, if you have activated these functions (default setting). The energy level is indicated by the number in the centre. You can choose from 1-99 for the energy setting. When the energy is set, the various measured values are called up automatically.

The “ongoing reaction” provides information about the readiness of the tissue to react. The coefficient indicates the “zero flow paths” in the bipolar impulse wave package.



The centre circle turns green for a short time when the Efficiency goal is reached. Then, the left side with the current reaction also turns green permanently.

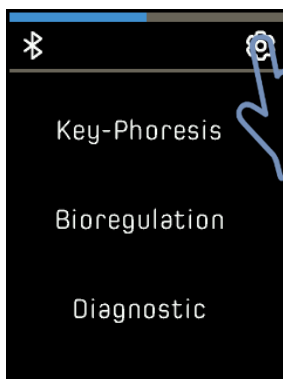
The centre circle turns orange if further therapy does not promise additional dynamics. Then, the right-hand side with the coefficient of the current reaction also turns orange permanently. At this point, the therapy can be ended.

Keypad mode (if optional keypad available)

Pairing of the medkey and keypad

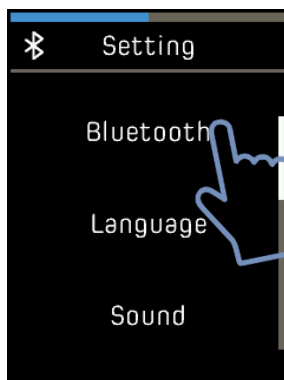
Individual therapy settings can be made in the **keypad** (tablet PC) and data from the Diagnostic mode can be transferred and saved via Bluetooth. The **keypad** is operated via the touch display. To ensure a smooth process, you should make sure that the **keypad** is connected to both your **medkey** and to the internet via the WiFi function.

To do this, the following steps are necessary:



Open the Settings menu on the main screen.

Press the Bluetooth function.



Select "Bluetooth on" and then click on the arrow in the top right.



The following symbols in the top left show the current Bluetooth status:



Bluetooth is grey: Bluetooth is switched off.



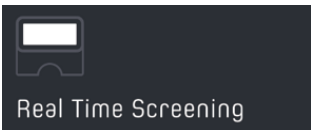
Bluetooth is white: Bluetooth is switched on but not connected.



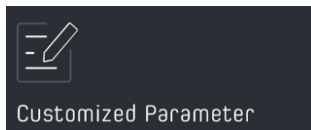
Bluetooth is white with 2 triangles: Bluetooth is switched on and connected.

If no connection is established or an error message appears in the **keypad**, please switch off the Bluetooth function in the **medkey** handpiece and in the **keypad** first, then switch it on again and repeat the process.

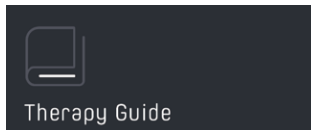
As soon as the connection to the **medkey** handpiece is established, the following functions are available to you via the **keypad**:



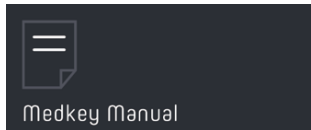
With the real-time screening, the numerical values from the diagnostic mode can be transferred to the **keypad** and saved (see point 1).



With the customer-specific parameters, the programs Personnel 1 to 3 can be programmed with individual parameter settings and, after confirmation, saved on the **medkey** handpiece under the freely-nameable designations (see point 2).



Explanatory and application images and videos as well as digital literature are available in the Media Library.



In this section, this instruction manual is provided in digital form.

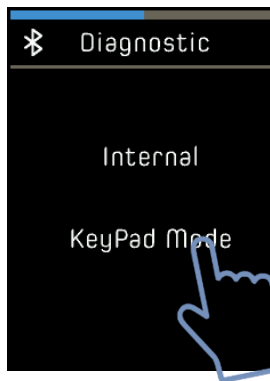
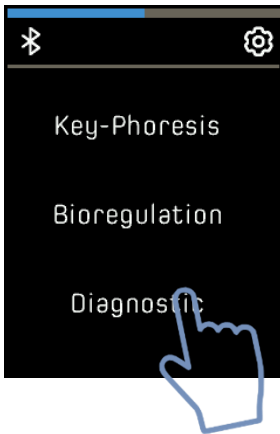


Support for finding required information from the instruction for use through voice command (voice input) and voice output as well as visual output.

Real-time screening

The real-time screening gives you the option of displaying the data collected on the medkey handpiece on the larger display of the keypad. At the same time, values obtained in this way can be stored in a database. To use these functions, please ensure that the Bluetooth connection between the medkey handpiece and the keypad is established and that the keypad is connected to the internet. Also please make sure that the Highpro Scanner changeable head is connected to your medkey handpiece.

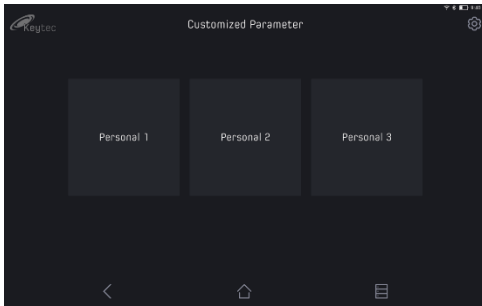
Select the “Diagnostics” setting and then the “keypad mode”.



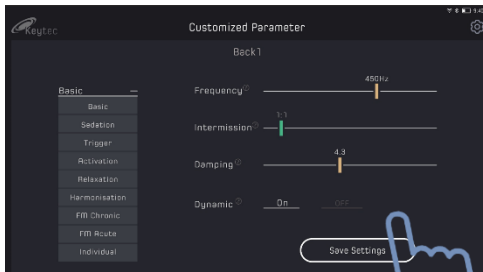
You can continue to work in the keypad mode as described in the chapter “Diagnostic mode”.

Customer-specific parameters

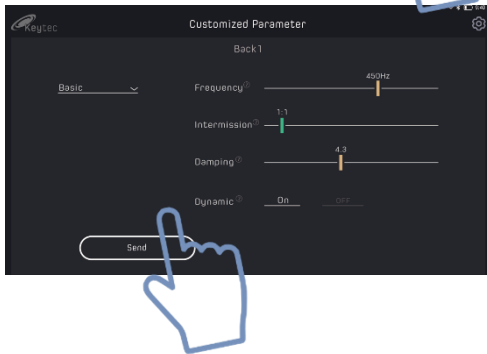
Your medkey handpiece offers you the option to save up to three individual parameter combinations. To increase the user friendliness, these parameters can be set on the keypad and transferred to the medkey handpiece after confirmation. To use this function, please open the “Customer-specific parameters” menu on your keypad. You can then make parameter changes to each fixed program, as far as this is physically/technically possible.



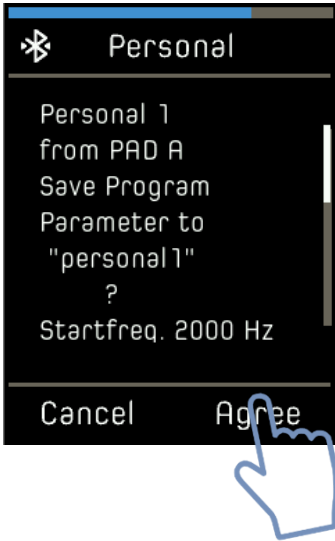
If the submenu is open, select the item (Personnel 1-3) under which you want to save the new setting.



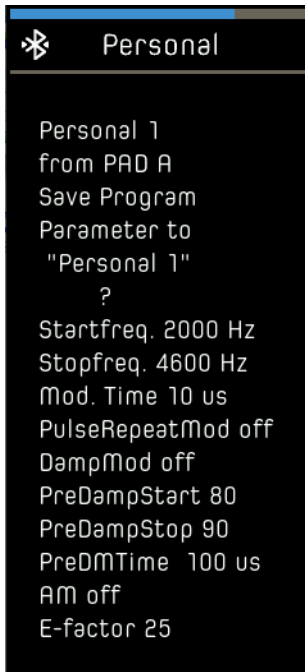
In the submenu that follows, you make your personal parameter selection and then click on "save".



After that, forward these settings to the medkey- handpiece by clicking "send".



The various parameters are now summarised for you on your **medkey** handpiece. In confirming this summary with “yes”, your individual parameters will be stored in the storage location that you have selected and are available to you straight away.

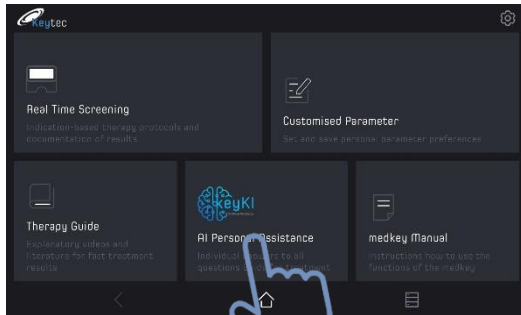


If you find that the displayed values do not correspond to the desired values, please press “no”. Next, repeat the process on the **keypad** and send the data to your **medkey** again.

KeyKI

1. Start KeyKI

Open the KeyKI application in the main menu.



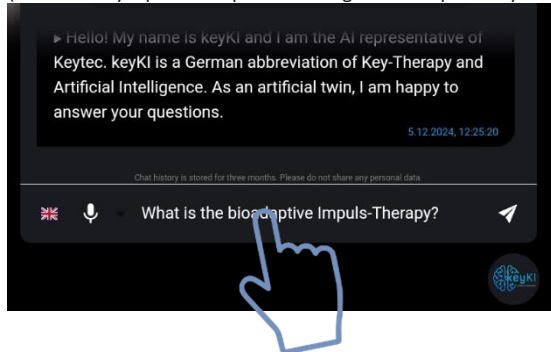
2. Accept the terms of use

Read and accept the displayed terms of use.

3. Enter a question

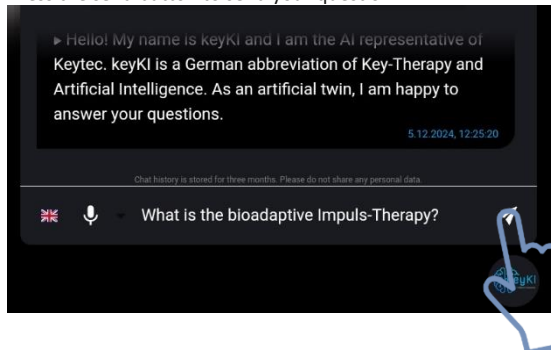
Enter user-related questions in the input field.

(Alternatively: Speak the question using the microphone symbol)



4. Send question

Press the send button to send your question.



5. Receive information

KeyKI provides acoustically matching information from a closed data set.

Additional video clips are displayed on the right-hand side of the screen containing relevant content for the question asked.

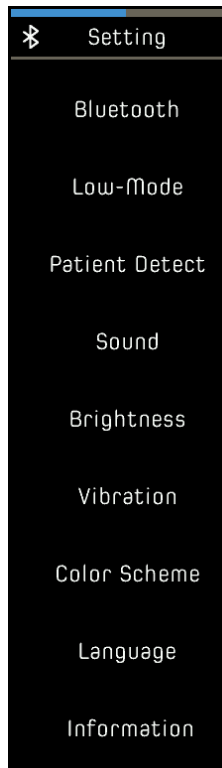
The information provided by KeyKI contains the information that is also contained in the operating instructions or other Keytec documentation for the respective product. This information therefore does not constitute diagnostic or therapeutic instructions and does not replace the assessment or responsibility of appropriately trained specialist personnel.

Device settings: The Settings menu

The settings menu can be called up from the main menu by pressing the gearwheel symbol in the top right.

With the scroll function on the right-hand margin, the respective settings can be displayed from the list and called up with a click. The following properties can be changed:

- **Bluetooth on/off**
- **Low mode:** This determines the scaling of the energy setting. If the patient is hypersensitive, the initial value (normal mode) can be set to 50% - 10% of the initial value, whereby the scale (1-99) remains unchanged.
- **Patient recognition:** The following three sensitivity settings can be selected for the patient recognition:
 - High: Quick recognition may cause the device to keep running after application on some patients.
 - Medium: Recommended setting; optimum recognition for most patients.
 - Low: Recognition takes place after light pressure is applied. Recommended for excessive measured values
- **Sound:** The sound can be switched on or off. Warning signals such as “low battery” cannot be deactivated. The selection is made using two buttons for “Sound on” and “Sound off”.
- **Brightness:** The maximum brightness of the display can be adjusted in a range of 40 % - 100 %. The selection is adjusted with + and –
- **Vibration:** The vibration feedback can be switched on or off. The selection is made using the “Vibration on” and “Vibration off” buttons. Please note that the completion of the therapy assistance may not be possible if the vibration is switched off.
- **Colour scheme:** Two colour schemes can be selected: a black background with white lettering or a white background with dark lettering.
- **Language:** You can choose between English, German and various other languages. The selection of a language is confirmed with a “click”.
- **Information:** Here, the installed firmware version and the serial number of the device are displayed as additional information. If the Highpro Scanner changeable head is connected, you will also find information on its firmware and serial number there (lines: HPS).



Charging the medkey handpiece

Display of the battery status

Your medkey shows you the battery charging status during the operation with a symbol (shown here on the display after starting the pre-setting):

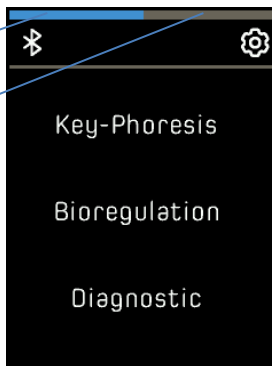
Battery charging status (charging bar):

Blue* = residual energy
(* in the light colour scheme: dark grey)

Light grey = used energy

When the charging bar for the remaining residual energy appears in **orange**, this means that the battery must be charged.

No new treatment of a patient should be started before the battery has been recharged.



Charging the handpiece in the base station

The base station is an inductive charger at the same time. If this is connected to the mains via the supplied power pack, the medkeyhandpiece is charged each time it is placed in the base station.

Always place the handpiece in the base station when it is not being used for treatment on patients. This prevents an insufficient battery charge, which would make it necessary to charge the battery in the base station before treating a patient.

PLEASE NOTE

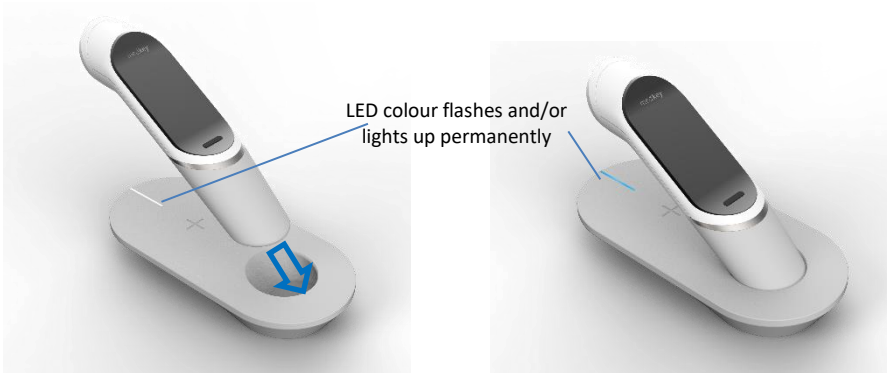
- Place the base station on a stable, even surface to make sure that it is sufficiently stable.
- The base station may only be used for charging within the intended temperature range of 0 to 30 °C. Otherwise, the battery may be damaged.
- Only charge the medkey handpiece using the accompanying base station and the supplied power pack! Never connect a power pack which is faulty or from a different manufacturer!
- Do not leave the medkey handpiece switched on unnecessarily.
- Do not switch the medkey handpiece on and off too often in succession.

During the charging process, the displays shown below appear on the display. In the charging mode, however, the display light switches off to save energy and speed up the charging process. The display can be reactivated using the Home button.

The blue LED on the charging station flashes during the charging process. When the battery is fully charged, the blue LED on the charging station lights up continuously.

**PLEASE
NOTE**

If the LED strip does not change from white to blue even though the medkey handpiece is placed in the slot, please check the exact position of the handpiece in the base station.



medkey charging



medkey fully charged

Information about a low battery charge during a treatment

If the battery charge falls below a certain level during a treatment, an acoustic signal (“beep”) is emitted. Based on previous experience, a treatment can still be completed, but a recharge of the batteries should be carried out in the charging station before a new treatment. After further discharging, e.g. as part of the treatment currently taking place, the charging bar also appears in orange (see description above) and the frequency of the acoustic signal increases.

If a new treatment has been started (contrary to the above recommendation to only complete the treatment when the first warning signal occurs), the handpiece may switch off during the therapeutic application; this switch-off is associated with a comparatively longer acoustic signal and the vibration of the handpiece.

It is then necessary for the handpiece to be recharged immediately in the base station.

In very rare cases, it is possible that none of the listed warnings regarding the charging status have been issued before or at the start of therapy and that the device may switch off before the end of therapy due to particularly high energy consumption and particularly long therapy. However, such a case has not yet occurred in any previous examinations.

The above advice should still always be followed to ensure that the handpiece is charged in good time by placing it in the charging cradle.

Prevention of a complete shutdown to protect the battery against destructive deep discharge

If the charging does not take place after the automatic switch-off because the battery charge is too low, and a possible attempt is made to switch the device on again, the battery will protect itself through its integrated electronic circuitry. In this case, the battery would be protected against a destructive deep discharge, but can only be reactivated for use by the manufacturer.

Battery performance

The battery was specially selected to meet the requirements of the **medkey**. It is permanently installed in the **medkey** handpiece and **cannot be removed**.

Depending on the therapy modes used and the energy level, the usable time for therapies between the full charging and the requirement for charging described above should be at least 1 hour. If the use time is significantly shorter, this indicates that the battery is reaching the end of its service life. You should ask the manufacturer to replace the battery (subject to a charge).

Care, cleaning and storage

Your **medkey** has been designed so that it is robust and durable. Nevertheless, we strongly recommend you handle your **medkey** with the same degree of care you would afford to any other technical device. Insufficient or incorrect care and cleaning may void the guarantee and warranty.

The **medkey and the exchangeable electrode** must be cleaned and disinfected after each therapy session. The base station should also be cleaned/disinfected at regular intervals.

Please proceed as follows:

- Switch off the **medkey**handpiece after each use.
- Apply cleaning agent and then disinfectant to a microfibre cloth slightly moistened with water or (for disinfection) with a microfibre cloth soaked in disinfectant.
- Gently wipe the device down with the cloth.
- Remove and wipe down the changeable head.
- Clean the device underneath the support surface of the changeable head
- Wipe with a damp cloth which is free of cleaning agent / disinfectant.
- Disconnect the base station from the power pack and clean/disinfect surfaces in the same way.

Isopropyl alcohol is to be used for the disinfection. Alternative procedures are only permitted following a consultation, and if they correspond to the recommendations of the Robert-Koch-Institute (Germany) and/or other national requirements.

Please note that the **medkey** is not entirely waterproof. For this reason, all parts should only be handled with a piece of cloth that has been moistened with cleaning agent

Ensure that no humidity penetrates into the interior of the device. Residues of external materials or substances must be removed completely.

Adhesive electrodes: Multiple use of the same adhesive electrodes may only occur on the same person.

Use:

1. Clean and dry the areas to be treated. Remove dirt, grease, creams, etc.
2. Remove 2 of the adhesive electrodes from the base foil and connect the electrode cables via the connector cable
3. Place the adhesive electrodes on the skin at the intended location. Make sure that it lies crease-free.
4. Select the required therapy mode on the Key-series device and set the energy level so that you feel comfortable.
5. At the end of therapy, switch off the Key-series device and disconnect the connector cable from the adhesive electrodes.
6. Carefully remove the adhesive electrodes from the skin and stick them onto the base foil until they are ready for reuse. Do not pull on the cable!
7. Store at room temperature. Protect against excessive moisture.

Store your **medkey** in the base station and only use the transport case for transport.

PLEASE
NOTE

!!!

Always place the medkey handpiece in the case with the display facing downwards. This serves to protect the display from scratches and prevents unwanted discharge.

!!!

Error messages and how to manage them

Your **medkey** has various self-test and monitoring mechanisms. These monitor both the installed hardware and the function of the firmware.

Error	Possible cause and rectification
Device displays a blue screen with errors	<p>If an error is detected by the monitoring mechanism, the application will be interrupted immediately and a blue screen with an error message is displayed.</p> <p>The device switches off automatically after 3 seconds with an acoustic interval signal. Press the Home button if you wish to view the error message for a longer time.</p> <p>If the display of your medkey is blue when you switch it on or during the treatment, you can recalibrate the device (see below) and return it to its default setting.</p>
Device does not switch on, <i>or</i> Device switches itself off automatically	<p>If the battery is too low, the device can no longer be operated. Check the battery level. To do this, place the device in the base station. If the charging screen appears, the battery is charging. Treatment is only possible again when the battery is sufficiently charged.</p> <p>If the battery is not charged, it will attempt to protect itself from deep discharge. This protection can only be removed by the manufacturer (subject to a charge). Under certain conditions, however, even this protection may not be effective, which can lead to the battery becoming faulty.</p>
Display only turns on briefly	<p>Display: Temperature Error</p> <p>The use temperature of medkey is exceeded or fallen below. Wait until the device has warmed up or cooled down. Only switch it on again afterwards.</p>
Unintended start of patient recognition	<p>Restart the device and open the settings menu. Select the "Patient recognition" entry from the list. In the new submenu, select the "Low" setting by clicking on it. This makes the patient detection less sensitive. The new value is accepted with the arrow button in the top right. After pressing the Home button, the device can be used as usual again.</p>
Patient recognition does not start	<p>Restart the device and open the settings menu. Select the "Patient recognition" entry from the list. In the new screen, select the setting "high". This makes the patient recognition more sensitive. The new value is accepted with the arrow button in the top right. After pressing the Home button, the device can be used as usual again.</p>

Damage

In case of visible damage to the device, stop using the **medkey** immediately. It is recommended to return the device to the manufacturer to have it checked.

Recalibration

CAUTION! Only recalibrate the device when the battery is fully charged!

If a blue screen appears with the words “go to service or reset device”, this means that a recalibration is required first. Restart the device. Press the Home button again and hold it for at least 10 seconds until an acoustic signal occurs along with a blue screen. Release the Home button and wait for the device to shut down automatically.

CAUTION! Before switching on the device again, make sure that there is no contact between the electrodes and the patient, you or any other conductive objects!

Switch on the device and wait for the device to calibrate automatically. This may take several minutes.

CAUTION! At this time, there must be no contact between the electrodes and the patient, you or any other conductive objects!

After the calibration has been completed, the settings menu is automatically displayed. Here, you can make the settings you require, such as the language. After pressing the Home button, the device can be used as usual.

Service, repairs and safety inspections (STK)

Contact the manufacturer if

- your **medkey** does not work properly and the measures in the chapter “Error messages and how to manage them” do not lead to success.
- the battery capacity of your **medkey**handpiece has fallen below one hour of treatment time (see “Charging the **medkey** handpiece”). The battery can only be replaced by the manufacturer.

Apart from the tests (see below), which have to be carried out by the user and a battery change when the battery capacity is no longer sufficient and/or a deep discharge has occurred (see p. 24 et seq., “Charging the **medkey** handpiece”), the **medkey** is maintenance-free for its entire service life.

Type of test	Component to be tested
Visual inspection	Instruction for use available Display readable Housing parts properly connected Housing without damage Contacting under exchangeable head undamaged Free of residues Side electrodes firmly attached Charging contact not damaged
Function testing	Display functional Touchpanel functional Impuls perceptible (Bioregulation) Changeable head connection free-running
Functional test optional components	Changeable heads clean and functional

Within the scope of the Medical Device Operator Ordinance (only operators in Germany), a medical device log (book) must also be kept, whereby the form attached by Keytec can be used as a template.

Loss of guarantee and warranty

The guarantee does not apply to wearing parts and consumables. Among others, the following actions lead to loss of guarantee and warranty

- Opening the **medkey** handpiece or optional accessories.
- Manipulating the internal hardware or firmware of the device.
- Combining the **medkey** with *non-original-manufacturer* technical equipment.
- Connecting the **medkey** with a *non-original manufacturer* charger (power pack).
- The improper use of the device.
- Gross negligence in connection with the use of the device (water ingress into the casing, dropping, etc.).

Return and disposal

Since the **medkey** handpiece is equipped with a rechargeable battery, please dispose of the entire device at a collection point which is part of the general take-back and recycling system. Do not open the device. The manufacturer is also obliged to take back the device.

Free collection points and/or acceptance points for used electrical equipment are available in your local area. Their address details should be available from your local council or municipal authority. If your **medkey** contains personal data, you are responsible for deleting such data before you hand it in. For further information, visit www.elektrogesetz.de.

KeyAkademie events

The seminars, workshops, live chats and webinars provided by KeyAkademie serve the purpose of sharing experiences with colleagues and learning about the electrotherapy treatment options with your medkey.

For further information on dates and locations, visit www.keyakademie.de.

Attachment: Contact details and technical information

Contact details

Manufacturer:	Keytec GmbH Steppacher Str. 32a 86420 Diedorf Germany
Contact partner Service, repair:	Keytec GmbH Charlottenburger Allee 23a 52068 Aachen Germany
Tel:	+49 241 - 913 88 95 - 0
Email:	info@keyserie.com
Internet:	www.keyserie.com

Explanations of the electrical current output of the different therapy modes

Key-phoresis mode

Acidic key-phoresis:	Galvanic with iontophoresis characteristic for the addition of acidic topical applications. Charge equalisation from - to +
Alkaline key-phoresis:	Galvanic with iontophoresis characteristic for the addition of alkaline topical applications. Charge equalisation from + to -

Bioregulation mode

Basic:	Standard frequency - all other parameters inactive
Calming:	High frequency combined with amplitude modulation
Triggering:	Low frequency with high intensity and amplitude modulation
Activation:	Low frequency with damping
Relaxation:	Deviating standard frequency with changed time interval and intensity
Harmonisation:	Deviating standard frequency with high time interval and low intensity
FM Chronic:	Low frequency modulation
FM Acute:	High frequency modulation
Customised:	Frequency modulation with constantly changing pulse bundles
Reorganisation:	Increased frequency with extended time interval
Dynamic:	Flowing changing between a variety of the above-mentioned programs

Using the optional **keypad**, three “personnel programs” can be programmed by the user based on the above-mentioned programs (see the chapter “**keypad mode**”).

Technical data

Appliance (medkey handpiece)

Dimensions:	19.5 x 5.5 x 3.8 cm (L x W x H)
Weight:	approx. 220 gr
Ambient temperature:	Use: 0°C to 30°C Storage: -25°C to 45°C
Ambient humidity:	max. 93% rel. humidity, non-condensing
Ambient air pressure:	700hPa...1060hPa
Protection class:	IP 44
Power supply:	Li-battery 3.7V nominal 4.2V final charging current
Charging current:	5 V +/- 0.5 V
max. charging current:	1200 mA
max. charging time:	210 min
Battery charging capacity:	1400 mAh 5.2 Wh
Operating time type:	6 h (depending on treatment mode and energy level)
min. charging cycles:	500
Energy output:	a) Pulse mode: < 10 mA (rms) at 10 kOhm (depending on operating mode) Max. pulse energy < 1 mJ/pulse at 10 kOhm Energy level selectable in 100 steps b) Key-phoresis DC operation: max. 1.2 mA at 10 kOhm $U_{max} \leq 12.5 V$ Current level selectable: in 100 steps 0 ... 1 mA 50 steps [20 µA/step] 1 ... 10 mA 50 steps [180 µA/step]

Power pack (HNP12-USBL6)

The medkey handpiece is charged inductively, a power pack is connected to the base station (see the section "Charging the medkey handpiece"). Only use an intact and original power pack.

Symbols and pictograms

The following symbols and icons can be found on your medkey handpiece and the base station:


Base station type plate:

Manufacturer

 **Keytec GmbH,**
Steppacher Str. 32 a | 86420 Diedorf

Product name

Recycling (return of recyclable materials)

 Basisstation medkey #705/805
Bestandteil gemäß Bedienungsanleitung, nur zum Gebrauch mit medkey!

CE certification

 **CE**
0123


Notified body

Year of manufacture



2021
1234

Leistung:

In: 5 V  2,4 A
Out: 2 x 6 Watt

Performance (input/output)

Serial number



SN

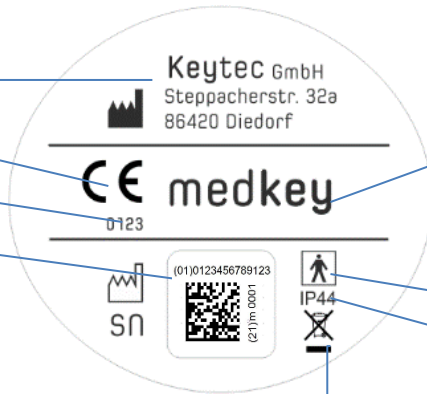
Appliance type plate:

Manufacturer

CE certification

Notified body

QR code with legible year of manufacture and serial number



Product name

Appliance BF

IP classification

Recycling (return of recyclable materials)

Caution! Note the instructions on use!



Results of EMC tests carried out

Emission tests in accordance with:

Norm: CISPR 11

Class: B

Group: 1

Mains Terminal Disturbance Voltage	150 kHz – 30 MHz	passed
Electromagnetic Radiation Disturbance	30 MHz – 1 GHz	passed
3-2 Harmonics:		passed
3-3 Flicker:		passed

Immunity Tests and their Test-Levels IEC 61000-

4-2 Electrostatic Discharge (ESD):	Contact Discharge: + 8 kV	passed
Air Discharge: +15 kV	passed	
4-3 Electromagnetic Field:	10 V/m up to 2.7 GHz (and 3 V/m up to 6 GHz for ETSI standard)	passed
4-4 Burst:	no signal lines in EUT	
Main Inputs/Outputs: + 2 kV		passed

4-5 Surge:	no PE in EUT Line to Line + 1 kV	passed
4-6 Conducted RF:	3 V/m performed up to 80 MHz plus ISM test	passed
4-8 Power frequency magnetic field:	30 A/m	passed
Voltage dip and short interruptions	in accordance to EN 60601-1-2: 2015	passed

Interference immunity of coverings

Tabelle 9 – Prüffestlegungen für die STÖRFESTIGKEIT von UMHÖLLUNGEN gegenüber hochfrequenten drahtlosen Kommunikationseinrichtungen

Prüffrequenz MHz	Frequenzband ^a MHz	Funkdienst ^a	Modulation ^b	Maximale Leistung W	Entfernung m	STÖRFESTIGKEITS- PROFPEGEL V/m
385	380 bis 390	TETRA 400	Pulsmodulation ^b 18 Hz	1,8	0,3	27
450	430 bis 470	GMRS 460, FRS 460	FM ^c ± 5 kHz Hub 1 kHz Sinus	2	0,3	28
710	704 bis 787	LTE Band 13, 17	Pulsmodulation ^b 217 Hz	0,2	0,3	9
745						
780						
810	800 bis 960	GSM 900/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5	Pulsmodulation ^b 18 Hz	2	0,3	28
870						
930						
1 720	1 700 bis 1 990	GSM 1900; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulsmodulation ^b 217 Hz	2	0,3	28
1 845						
1 970						
2 450	2 400 bis 2 570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulsmodulation ^b 217 Hz	2	0,3	28
5 240	5 100 bis 5 800	WLAN 802.11 a/n	Pulsmodulation ^b 217 Hz	0,2	0,3	9
5 500						
5 785						



medkey

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