

# User Guide



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## Definition and General Information

### What is the physiokey?

The **physiokey** is a transcutaneous electro stimulator with an individual dosing function. It is intended for delivering non-invasive therapy to the body's physiological systems via skin areas, in order to provide pain relief and functional restoration, as well as 'Key-phoresis', a form of iontophoresis.

The device generates low and medium frequency bipolar electric pulses. The shape of the bipolar electric pulses dynamically varies with the changing electrophysiological characteristics of the skin (capacitance and resistance). The device does not utilise a conductive media between the electrodes and the patient's skin.

### Intended Purpose

The **physiokey** is a non-invasive, electrotherapeutic, hand-held device that can be used to alleviate acute and chronic pain and to facilitate functional restoration and improvement.

### Contraindications

- Patients who have on-demand-type cardiac pacemaker or other electrically powered implant.
- Electrode placement over malignant tumours.
- Use over open wounds.
- Patients prone to seizures.
- Alcohol intoxication.
- Pregnancy.

## Cautions

The physio**key** electrodes should not make contact with wet skin. Natural body fluids, including sweat, are acceptable. Treatment with the physio**key** should not normally exceed 30 minutes in any specific area of the body and there should be, as a general rule, a minimum of 2 hours between treatment sessions, to avoid isolated cases of skin irritation. In most cases, application of the physio**key** is carried out by moving the device on the skin.

In some cases increased pain, muscle aches and other reactions may be associated with application of the physio**key**. These reactions will usually return to normal after a short time.

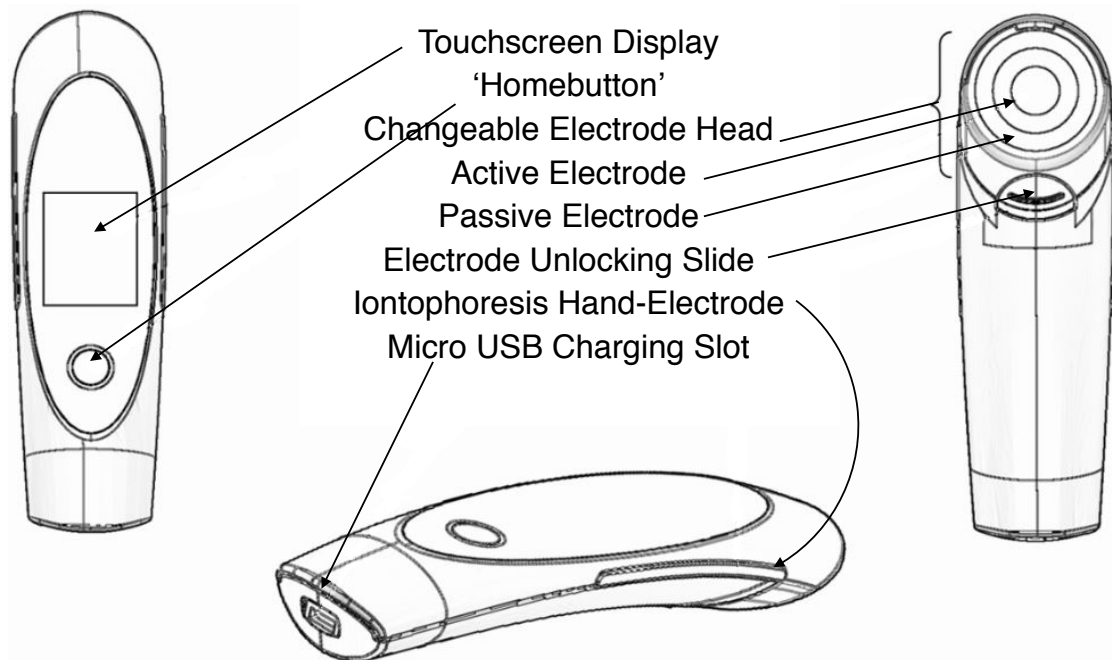
If symptoms persists, discontinue use of the physio**key** and consult your health professional.

## Safety

- Read these operating instructions before using your physio**key**.
- Keep device out of the reach of children.
- Protect from direct sunlight and do not immerse device in water or hold under running water.
- Recharge only with the with approved charger or recharge accessory.
- Do not use in presence of flammable substances.
- Do not dispose of device in domestic household waste.
- This device has no user-serviceable parts.
- The device is to be used only for its intended use.

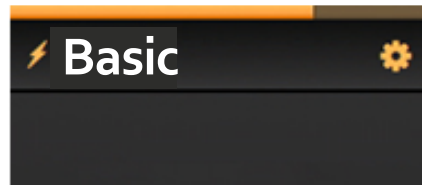
## physiokey Overview

This guide describes the features of your physiokey.



## Charging the physiokey

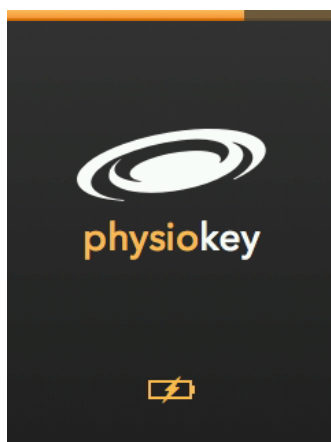
Make sure your physiokey is charged before use. Your physiokey shows you a battery-charge state icon during operation (here shown on the display).



When the battery no longer has enough charge to continue operation, the device will sound a warning tone. If the battery charge is too low, the device will no longer operate. Please connect it to a charger.

To charge your physiokey, turn the device off and plug the charger into an appropriate socket and connect it to the physiokey. Please note: operation during the charging phase is not possible. During charging, the screen shown below is displayed.

After a short time the display whilst in charging mode turns off to save energy and to speed up the charging process. To get information about the charge state, press the Home button to wake up the display.



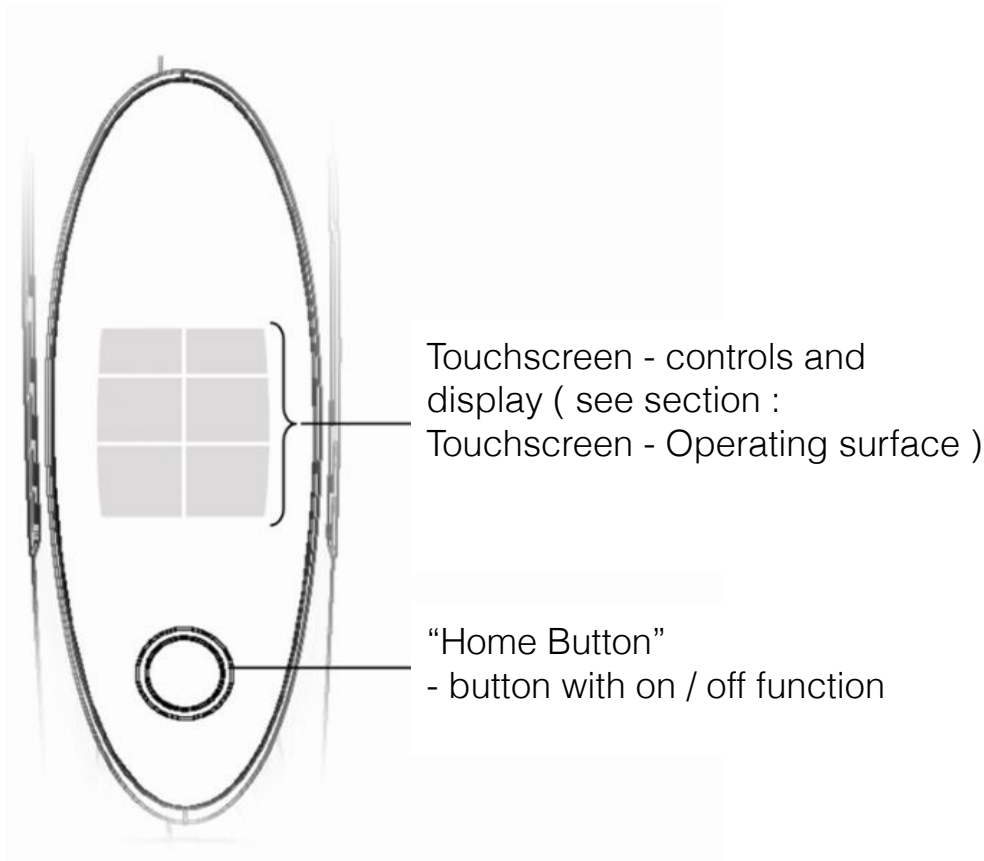
Device charging



Device fully charged

## physiokey Controls

The physiokey is controlled via the specially shaped control ellipse. The following controls are available:



The Home button is the only "physical" push button on the physiokey and has three functions:

1. Use the Home button to turn the unit *on*. Press the button for 2 seconds. To turn off, press the button again for 2 seconds. Please wait at least 15 seconds before you turn device on again.
2. The second function of the home button is to return to the main menu if the touch screen is active.
3. If the touch screen is inactive, it can be activated by a pressing the Home button.

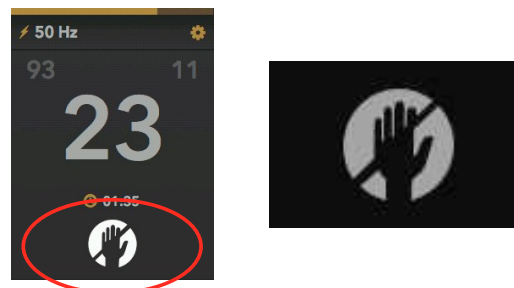
## physiokey Touchscreen

The touchscreen surface is located directly above the display. To change the energy level or the therapy mode, just lightly touch the designated symbol or word on the display.



## Inactive Display

In order to avoid accidental inputs, the touchscreen will become locked if not used for a period of time. If the screen is touched during this time the following symbol will appear at the bottom of the screen.



Pressing the Home button will activate the display again. Once the display is activated, pressing the Home button will return you to the main menu .

## Screen Lock-Out Times

After 4 seconds of inactivity, only the Plus and Minus keys can be used to change the energy levels of the device. After 9 seconds of inactivity the screen is fully locked and the darkened screen display is shown (see the image above). Pressing the Home button will activate the display again.

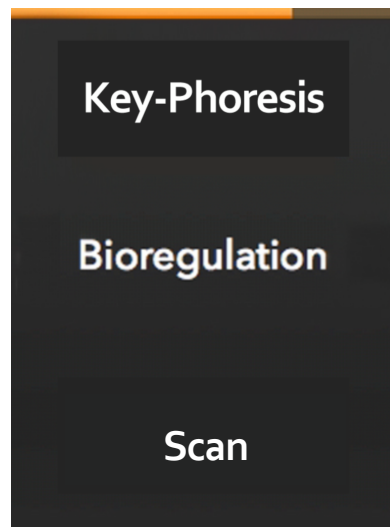


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## physiokey Operation Modes

Once the physiokey has been turned on, the main menu will show. From this menu, you have three choices available. Each choice has a significantly different application / therapy technique.

How to use the modes in detail is explained in training manuals or by attending training seminars. For more information visit [www.physiokey.com.au](http://www.physiokey.com.au).

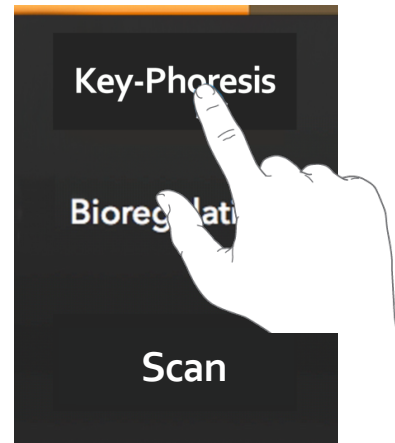


## Key-Phoresis Mode

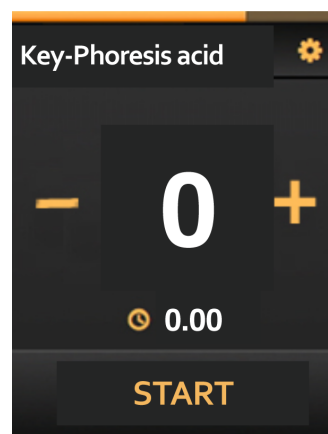
The Key-Phoresis mode is a specially modified form of iontophoresis, an electroplating-method of using a very weak direct current, an ion flux. In physiokey iontophoresis technology is refined and simplified.

The physiokey electrode is placed on the skin and the side electrode is the required counter-electrode. Please make sure that the skin of your hand is well moistened. This guarantees the best possible flow of ions.

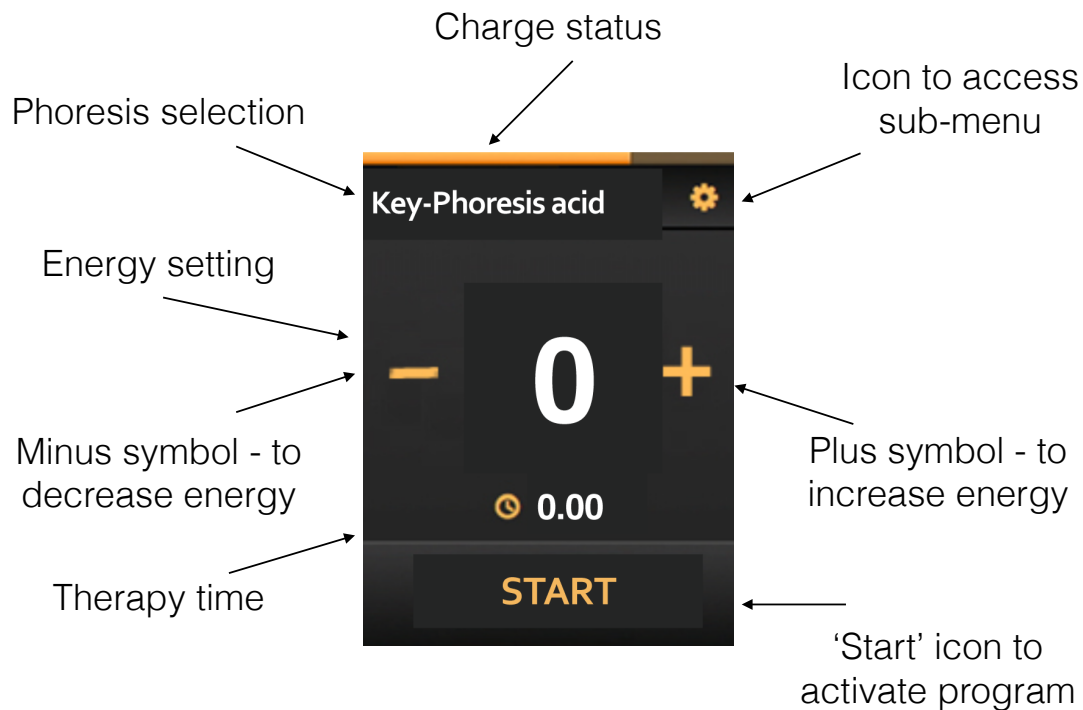
Key-Phoresis mode is activated by pressing the word "Key-Phoresis".



Then the therapy menu will show.



## Key-Phoresis Mode Overview



The Key-phoresis mode can be used for both acidic and alkaline creams and lotions. Please note that most creams and lotions are acidic. Alkaline creams and lotions are often labeled as such.

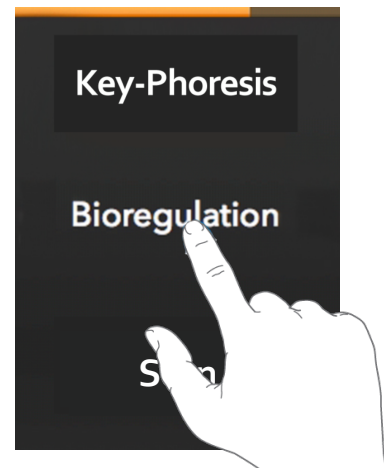
To use the Key-phoresis mode, the energy level should just be hardly noticeable or not at all. After selecting the energy levels, press "START". To stop the application, press "END".

How to use the Key-phoresis mode is explained in detail in training manuals or by attending training seminars. For more information visit [www.physiokey.com.au](http://www.physiokey.com.au).

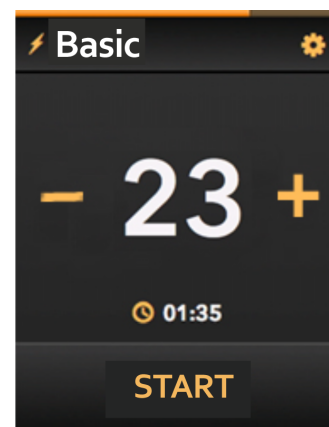
## Bioregulation Mode

The Bioregulation mode is for delivering non-invasive therapy to the body's physiological systems via skin areas, in order to provide pain relief and functional restoration.

The Bioregulation mode is activated by pressing the word "Bioregulation".



Then the therapy menu will appear.



## Bioregulation Mode Overview



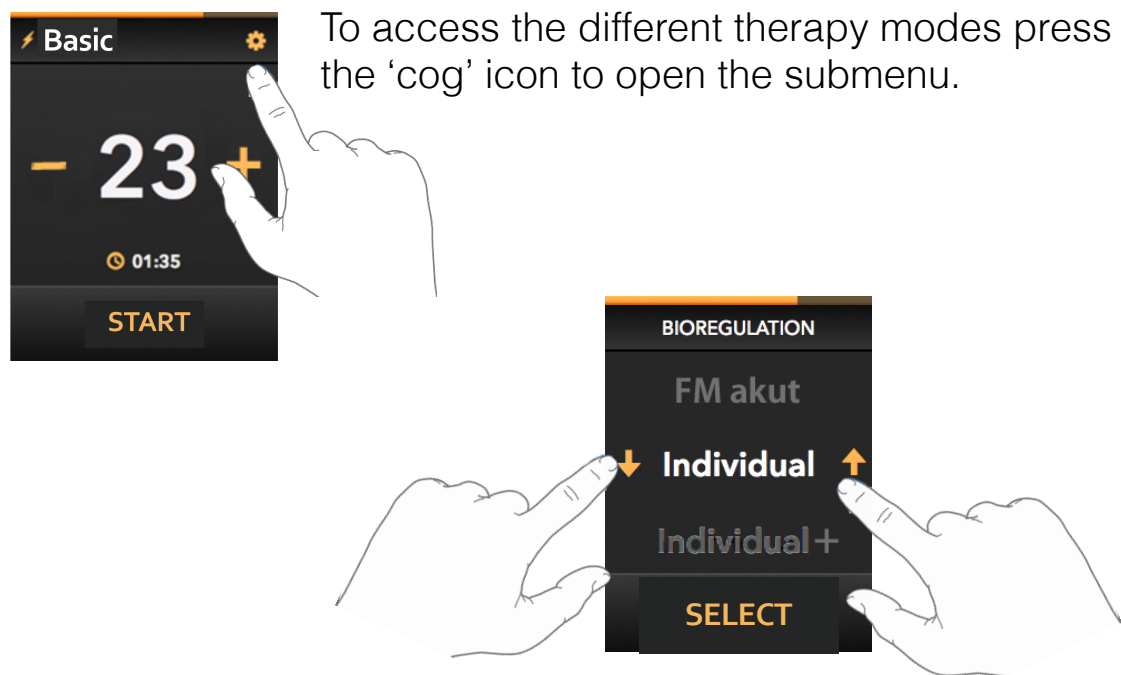
Use the Plus or Minus button to increase or decrease the energy level, indicated by the number in the middle. The energy level has a range of 1-99. For particular settings, refer to training manuals and seminar literature, but the energy level should be set to a comfortable level in most cases.

After switching on the physiokey, the therapy program in the Bioregulation mode is always initially set to "Basic" at energy level 1. This setting is used to locate painful areas on the skin for treatment.

## Changing Therapy Programs in Bioregulation Mode

With your physiokey you have a choice of different therapy modes at your disposal. The device provides maximum flexibility and provides therapy modes for a broad range of painful complaints, both acute and chronic.

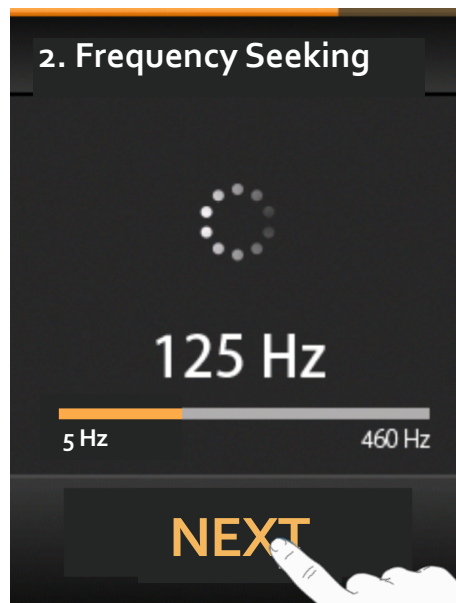
The various therapy modes are named according to the effect that is to be achieved. How to use the different therapy programs is explained in detail in training manuals or by attending training seminars. For more information visit [www.physiokey.com.au](http://www.physiokey.com.au).



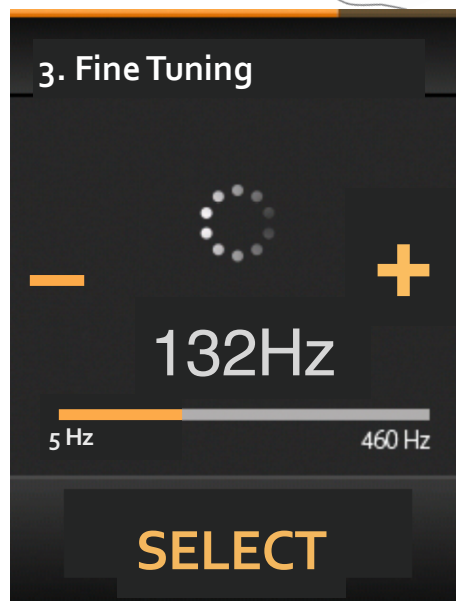
Use the arrow icons to highlight the therapy mode selection (it will be highlighted as it moves to the centre of the screen). Press "SELECT" to confirm the selection and save the therapy selection. While in other modes this stored selection will now automatically be recalled as soon as you press "START", allowing you to easily switch back and forth between two therapy modes.

## Individual+ Therapy Program

The Individual+ therapy program includes a special function to set a specific frequency. For this reason, with the selection of Individual+ the display screen will first show a frequency search function rather than the energy increase or decrease function.



In the Individual+ display screen, the pulse frequency is increased slowly from 5 Hz to 460 Hz cyclically. In the “frequency seeking” screen the pulse frequency is displayed in the centre of the screen as a number as well as with a rotating icon. Press the "NEXT" icon to accept the current frequency and move to the next screen to “fine tune” your selection.



In the Fine Tuning display screen, use the plus or minus icon to fine tune your frequency selection.

Press the "SELECT" icon to accept the frequency and it will be integrated into the custom+ program and displayed.

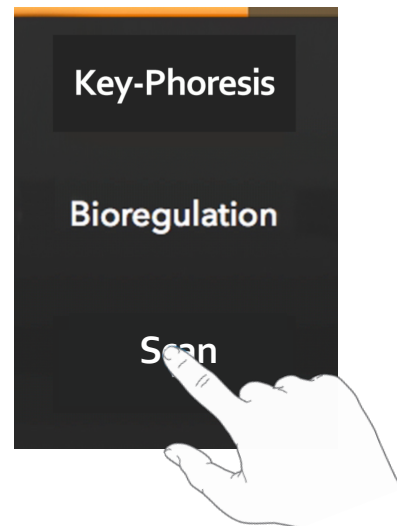
Once the frequency is set the energy can be increased or decreased as usual.

## Scan Mode

The Scan mode, allows the identification of optimal treatment points and individualised therapy through activity readings. The activity readings are used to give information for the location and duration of therapy.

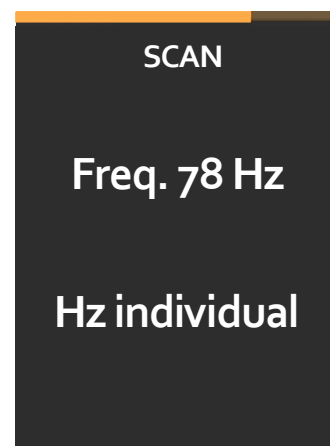
How to use the Scan mode is explained in detail in training manuals or by attending training seminars. For more information visit [www.physiokey.com.au](http://www.physiokey.com.au).

The SCAN mode is activated by pressing the word “Scan”.



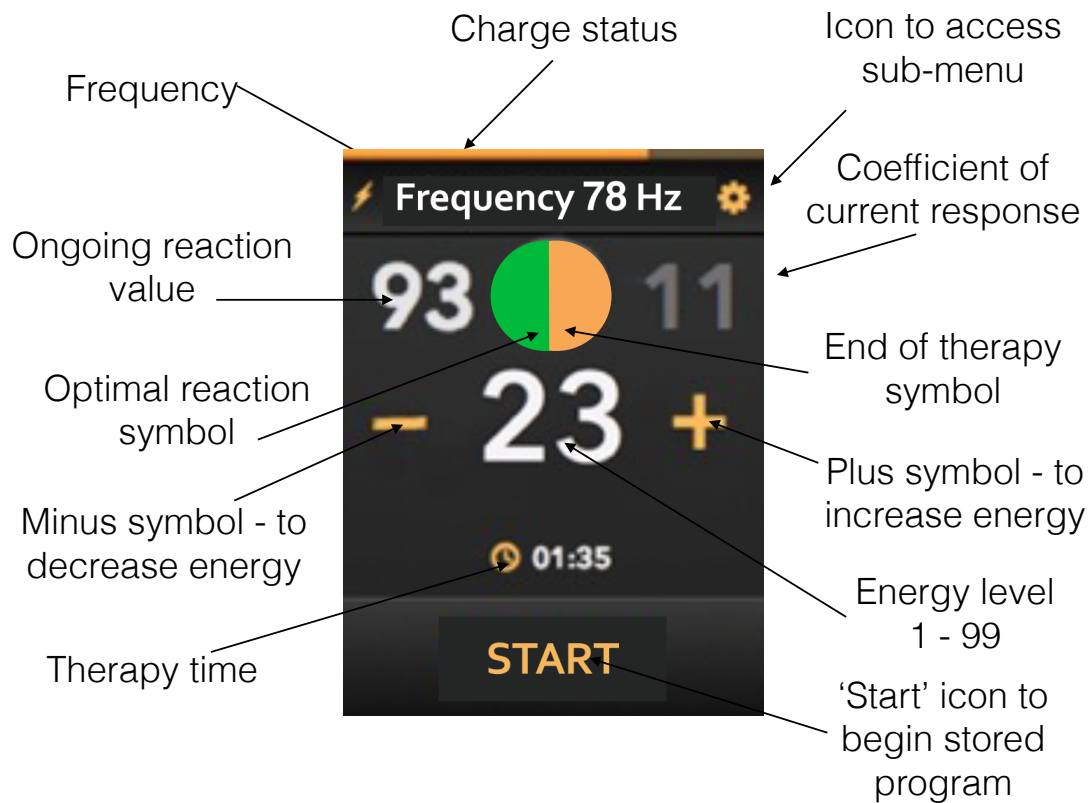
In the next screen you will be prompted to select either the basic 78 Hz scanning frequency or your own selection based on training recommendations.

Select the individual frequency by following the same steps as the Individual+ program (see page 15).





## Scan Mode Overview



Use the Plus or Minus button to increase or decrease the energy level, indicated by the number in the middle. The energy level has a range of 1-99. For particular settings, refer to training manuals and seminar literature, but the energy level should be set to a comfortable level in most cases.

When the energy level is set, the various measurements are automatically taken. The "Ongoing reaction" gives information available via the responsiveness of the tissue. The coefficient shows the "approach to zero" of the bipolar pulse wave packet.

The coloured icons in the middle indicate when the optimal reaction is reached (green), or when no more tissue attenuation change is to be expected (orange), signalling the end of therapy on an area.

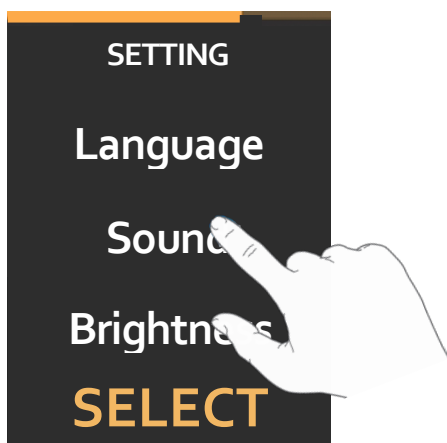
## Service Menu

The service menu is accessed via the main screen *as soon as the physiokey is turned on*. Once accessed the following settings can be changed:

- Language: English or German
- Sound: On or Off
- Brightness: 50 - 100%
- Touch Sensitivity: Default, +, ++, +++
- Patient Detection: High, Normal, Low



Pressing and holding the 'gear' icon as soon as the physiokey is turned on will take you to the Service menu



Select the setting you wish to adjust and once your choice is made, press the "select" icon

Press the Home button to return to the main screen.

## Technical Information

### Impulse shapes of different therapy modes

#### Bioregulation mode

<b>Basic:</b>	Default Frequency with other impulse parameters inactive.
<b>Sedation:</b>	High frequency combined with amplitude modulation
<b>Trigger:</b>	Low frequency with high intensity and amplitude modulation
<b>Activation:</b>	Low Frequency with other impulse parameters inactive.
<b>Relaxation:</b>	Different standard frequency with modified interval and intensity
<b>Harmonisation:</b>	Different standard frequency, high and low intensity interval
<b>FM Chronic:</b>	Low frequency modulation
<b>FM Acute:</b>	High frequency modulation
<b>Individual:</b>	Automatic intensity adjustment, variable time interval, frequency interval
<b>Individual+:</b>	Automatic intensity adjustment, variable time interval, frequency adjustable
<b>Memory</b>	Frequency modulation with with variable camping of impulse parameters

#### Key-phoresis mode

<b>Key-phoresis Acid:</b>	Key-phoresis with electroplating to produce an ion flow from - to +
<b>Key-phoresis Alkaline:</b>	Key-phoresis with electroplating to produce an ion flow from + to -

## Technical Data

### physiokey:

Dimensions:	185x51x28mm (LxBxH)
Weight:	150g
Operating temperature:	0 .... 40°C
Ambient humidity:	max. 93° non-condensing
Charging Voltage:	5V +/- 0.5V
Max. charging current:	500mA
Max. charging time:	180 min
Battery charge capacity	800mA
Typical operating time:	6h (depending on treatment mode and energy level)
Min. charge cycles:	500
Output values:	<p>a) Pulse mode: &lt;1 mA (rms) at 10kOhm (depending on operating mode) pulse energy max. &lt;200µJ / pulse at 10kOhm. Energy levels selectable in 100 steps</p> <p>b) Key-phoresis DC operation: max. 1.2 mA at 10kOhm <math>U_{max} M = 12.5 V</math></p>
Key-phoresis Acid	<p>Power level can be selected: in 100 steps:</p> <p>0 ... 1 mA 50 steps [20µA / step]</p> <p>1 ... 10mA 50 steps [180µA / step]</p>

## Classification

Your physiokey is a medical device. According to the EC Directive 93/42/EEC Annex IX, it has been classified as a Class IIa medical device and certified accordingly.  
TGA .....

## Icons and Symbols

Your physiokey contains the following icons and symbols:

