

TECHNICAL HANDBOOK

Technical specifications and Safety instructions



VERSION 3.1 - 02.07.2019

!!!CONFIDENTIAL!!!

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General Information

Special note for this instruction manual



Carefully read this instruction manual and follow all instructions. This will insure the reliable operation and longevity of your device.

List of warning symbols and key words in this instruction manual



DANGER!

Warning of immediate life-threatening consequences!

WARNING!

Warning of possible life-threatening consequences and/or serious, irreversible injuries!



WARNING!

Warning of danger of electric shock!



CAUTION!

Follow instructions to avoid injury and damage!

ATTENTION!

Follow instructions to avoid damage!



NOTICE!

Further reading on use of device!



NOTICE!

Follow instructions from the manual!

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Disclaimer:

BCR-Therapie system used in **BCR Premium** device is a Holistic and Alternative therapy system and do not serve as a substitute for professional medical advice, examination, diagnosis or treatment.

Brief Description

The device *BCR Premium* (production code *MSTU 100*) is a therapy system of the electrotherapy category *Biological Cell Regulation (BCR)* for the generation of micro currents and LED-light and belongs in the category of 'electrotherapy devices' and 'LED light therapy devices'. It is the latest development of microcurrent devices by Dr. Schwab Gesellschaft für Technologieberatung mbH / GERMANY.

Dr. Schwab Gesellschaft für Technologieberatung mbH has more than 20 years of experience with the development and production of microcurrent devices for market leading brands like Power2Cell and its predecessors.

The microcurrent- and light parameters are determined by programs, which are loaded into the device via a USB data storage medium.

A main area of use for the application of microcurrent is in the field of Preventive Healthcare, Pain, Wound Healing, Sports and Beauty.



Please refer to the section 'Further Information on Treatment' of this manual for more detailed information.

DECLARATION OF CONFORMITY



Declaration of Conformity

Manufacturer: Dr. Schwab Gesellschaft für

Technologieberatung mbH

Address: Max Planck Strasse 13

85716 Unterschleissheim

Germany

Declare our responsibility that the

Product: Microcurrent Therapy Unit for Preventive

Healthcare and Beauty

Trademark: BCR Therapie (Singapore) Pte Ltd

10 Jalan Besar, #07-10 Sim Lim Tower

Singapore 208787

Model(s): BCR Premium - MSTU100

Is confirmed to comply with the requirements set out in the Council Directive on the Approximation of the Laws of the Member States relating to Electromagnetic Compatibility 2014/30/EU, Low Voltage Directive 2014/35/EC and RoHS 2 Directive 2011/65/EU

The measurements were carried out in accredited laboratories.

For the evaluation of above mentioned Council Directives for Electromagnetic Compatibility were consulted:

EMC: EN 60601-1-2:2015

Safety: EN 60601-1:2006 + Cor.:2010 + A1:2013

EN 60950-1:2006 + A11:2009 + A1:2010 + A12:2011 +

AC:2011 + A2:2011

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Authorised signature

Dr. Gunther Schwab 2019.08.05

Responsibility of the user

This product is designed in a way that it works according to the description contained in this manual, when it is installed, used, serviced, and repaired in accordance with the provided instruction. A defective product may not be used. Parts that are damaged, obviously worn, incomplete, or contaminated have to be replaced immediately. When a repair or replacement becomes necessary, it is recommended that all work be done by the manufacturer of the device. The user of the product carries the sole responsibility for any malfunction resulting from the improper use, deficient service, faulty repair, damage or modification by anyone other than Dr. Schwab Gesellschaft für Technologieberatung mbH, or the authorized service personnel of this company.

Indications and Contraindications of the System

Indications:

- Preventive Healthcare
- Pain Therapy
- Wound Healing
- Sports
- Beauty

General contraindications:

- Pacemaker
- Small children under the age of 6
- Pregnancy
- Malignant tumors
- Malignant blood diseases
- Epilepsy
- Auto-immune diseases
- Arrythmia
- Morbus Paget
- Brittle bone disease
- Muscular dystrophy

Adverse Side Effects

Adverse side effects in connection with the **BCR Premium** can be:

- Increased secretion of wounds in the early postoperative phase
- A feeling of pins and needles on the skin under the pad electrodes (in case of high sensitivity to electricity)
- Redness and itching of skin under the pad electrodes (in case of high sensitivity to electricity)
- Increased urge to urinate
- Temporary worsening of symptoms
- Flashes of light in the eyes when treating the head.
- Use of the electrodes close to the chest can increase the risk of ventricular fibrillation
- Microcurrent treatment may not be performed through the head, directly on the eyes, under covering of the mouth, on the front of the neck (especially common carotid artery), or with electrodes placed on the chest and the upper back, or crossing the heart.
- The material of the gel pads and of the light hand piece was tested for biocompatibility according to EN 10993-1, however an allergic reaction to these materials can't be excluded under all circumstances. In case of symptoms, abort the treatment immediately and remove the gel pads, respectively the light hand piece from your body.



Please refer to the section 'Further Information on Treatment' of this manual for more detailed information.

Mode of Operation of the Treatment

In the BCR treatment through microcurrent, currents between 10 and 999 microamps [μ A], with frequencies between 0.4 and 1000 Hertz [Hz] are applied to the affected region using electrodes. With this low current, a stimulation of physical activity takes place, which is the basis of the healing process.

Verifiably, microcurrent is effective in the painless treatment of acute and chronic pain, especially of the joints. Studies show a reduction in pain through microcurrent e.g. in cases of Rheumatoid and Osteo Arthritis, arthralgia, epicondylitis (tennis elbow), fibromyalgia, etc.

A blood circulation promoting effect has also been proven, which is beneficial for wound healing.

The *BCR Premium* is controlled by a central microprocessor. All user in and outputs are performed via a capacitive touch display. The hardware for the generation of the microcurrents allows for the independent generation of current pulses with frequencies of up to 1 kHz for two channels, with currents up to 999 μ A.

Additionally, a constant measurement of the skin resistance takes place. The generation of an initial voltage of 60V for each channel is galvanically isolated from all other electric potential, and allows for both the simultaneous treatment of one area or region with different currents, or the independent treatment of different regions.

Through the use of a flash-processor, the installation of firmware updates by the user is possible at any time.

The following parameters can be set for the channels:

- Currents from 10 to 999 μA in 1 μA steps
- Pulse frequencies of 0,1 Hz to 1 kHz in 0,1 Hz steps
- Rise time of the preset current from 0,1 to 1,0 sec (Amplitude modulation of the current output from 10 to 100% within the selected time in 10% steps)

The above parameters are preset in the programs installed in the device.

The programs are based on public accessible data and the experience from the use of former devices and are defined by BCR Singapore. Manual programs can be factory set.

From the output of current-controlled impulses, the maximum strength of which can be selected, the amplitude of the voltage output is derived, depending on the connected load, the

body through which the current flows. The maximum Amplitude of the voltage is limited to 60 Volts, so that the following relationship is valid for maximum current output (Ohm's law):

R = U/I

 $Rx = 60V / 990\mu A$

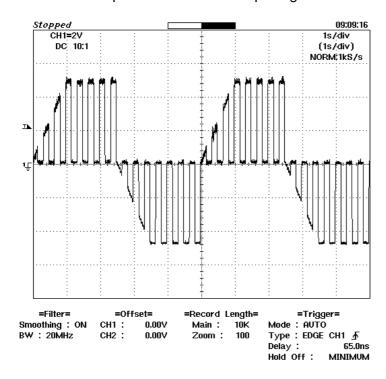
 $Rx = 60.6 k\Omega$

This means that in cases where the resistance of the connected body is lower than 60 k Ω , linearly lower voltages can be expected. Current regulation provides for an absolute short circuit resistance, and thereby the safety of the system.

The period of a master unit for current output is 2.5 seconds, so that the channels are restarted after 2.5 seconds while a program is running. The purpose of this sequence is as follows:

- A change, respectively restart every 2.5 seconds
- Channel A and/or B can output current impulses unidirectional (+ or -) or bidirectional, meaning that the polarity changes from + to and vice versa after 2.5 seconds.
 Simultaneously with the start of a cycle, the rise of the current is reactivated, so that an amplitude-modulated current flow follows.

Here is an example of a measured output signal:



The voltage was measured on a load of 10 k Ω with the following parameters:

Polarity: +/-, Current: 500µA , Rise time: 1 sec, Frequency: 3 Hz

At the beginning of a period, the amplitude of the pulses is zero, then it rises to its maximum value of 5 Volts within 1 second. It maintains this amplitude until the end of the period.

 $(U=R \times I, so 10k\Omega \times 500\mu A = 5V)$

The device contains an automatic diagnosis mode. At the start of each program segment, the conductivity of the connected body is measured on channel A, and the value is scaled on a logarithmic scale from 0 to 100. A value of 50 on this scale corresponds to a resistance of 95 $k\Omega$.



Please refer to the section 'Further Information on Treatment' of this manual for more detailed information.

Warnings!



Read the following warnings before using the device.

Important advices

Adequate Environment

• The device is designed for the use in professional institutions and for home use.

Inadequate Environment

• In close proximity to high frequency surgical devices, close to short wave or microwave therapeutic devices, within the shielded cages of MRI equipment.

Ambient conditions

- The device may not be used in a humid environment, or in places where it may come in contact with liquids.
- Don't expose the device to direct or indirect sources of heat. The device has to be used and stored in a safe environment.
- The device can be used in temperatures from +5℃ to +40℃, and up to an altitude of 2000m above sea level.
- Don't use the device in presence of free oxygen, anesthetics, or flammable substances.
 The device has to be used and stored in a safe environment.
- The device may cause radio frequency interference or interfere with the use of other devices in the area. If this happens, the interference should be eliminated by changing the orientation of the device or by shielding the immediate vicinity. The electromagnetic emissions emitted by the *BCR Premium* are below the limits set forth in the currently valid regulations (IEC 60601-1-2:2014, EN 60601-1-2:2015).
- The use of the device in the vicinity of, or on top of other devices should be avoided, as this might interfere with proper operation. If use in this manner is necessary, both devices should be monitored for proper operation.
- The device requires special precautions with respect to electromagnetic compatibility (EMC) and has to be installed and used in strict accordance with EMC guidelines. Don't use the device in close proximity to fluorescent lighting, radio transmitters, remote controls, or portable HF communication devices, even if these fulfill the requirements of CISPR-11.
- The use of accessories, converters or cables other than the ones indicated or delivered
 by the manufacturer of this device can lead to increased electromagnetic emissions or
 reduced interference immunity of the product, and affect its usability (See chapter
 "Scope of delivery" -> "Conforming cables and accessories).
- Portable HF communication devices (including peripheral devices like antenna cables and external antennas) should be kept at least 30cm from all parts of the *BCR Premium*, including the cables and accessories indicated by the manufacturer. Otherwise, the usability of the device may be affected.
- In order to avoid damage through electrostatic discharge, avoid charges by e.g. inadequate clothing, carpets, insufficient humidity, etc.
- The device may not be used on the patient in connection with other (medical) devices (e.g. high frequency surgical devices, ECG, defibrillator, etc.).
- It can't be ruled out that the *BCR Premium* may affect the operation of implantable devices. Patients with implantable devices should not use the *BCR Premium*.
- Don't insert any objects into openings of the device.
- Clean the device regularly and disinfect the accessories, should this become necessary. Disinfectant wipes are available as accessories.
- The integrated USB port may under no circumstances be used to connect the device to another device. This port is intended solely for the insertion of a USB drive.

- Set up the device so it is in a stable position and place the cables so they will not be damaged or may cause danger.
- When not in use, the device is to be placed in its transport case, to protect it from lint, dust, and sunlight.
- The device may only be stored in a dry place at temperatures ranging from -20°C to +70°C.
- The device is to be stored in its case out of reach of pets, pests and children.

During Treatment

- In case irregularities of the device occur during treatment, turn it off and contact the manufacturer or authorized service provider.
- The power of the light emitted by the hand piece was determined according to the rules of IEC 62471 and DIN EN 60601-2-57. The hand piece falls into the 'free group', which precludes a photobiological danger to the eyes. However, it is recommended not to look directly into the source of light, as this may trigger epileptic seizures in vulnerable patients. Should this not be possible in certain treatments, the eyes should be covered accordingly.

Accessories

- Only use components/accessories that are designed for the use with the BCR Premium.
- Only connect the patient cables and the cable for the light hand piece to the corresponding socket on the device don't insert the connectors into any other devices.
- Place the cables so no one can step on, or trip over them.
- Don't place any objects on the cables, as this may damage them.
- Don't exert excessive force on the connectors, e.g. from the side. This may lead to damages.
- Don't use excessive force when plugging in connectors and make sure of the correct orientation.
- Avoid short circuits of breaking of cables by not pinching or flexing excessively.

Power Supply

- Only use the supplied power converter ATM036T-A050 and the supplied power cord to connect the device to the mains.
- Please observe the power ratings (see Technical Data)

- The power converter can be used with a supply voltage of 100 240V. If you want to
 use the device abroad, inform yourself about the local mains voltage and which type of
 power cord will be needed.
- A damaged power cord may not be used under any circumstances. Please contact the manufacturer or an authorized service partner if you need a new power cord or a power cord with a country-specific plug.
- The power adapter should always be connected directly to an easily accessible wall outlet, do not use extension cords.
- In order to disconnect the device from the mains, pull the power plug from the wall outlet.

Repairs and Damages (also see section "Troubleshooting)

- Do not use the device if you suspect damages or a defect.
- Should liquid have entered the device or its accessories by accident, further use is prohibited. Please send the device and accessories to the manufacturer for inspection/repair.
- Repairs, alterations and modifications of the device without prior consent of the manufacturer are prohibited. Dr. Schwab GfT cannot be held accountable if the device has been altered or modified. If a defect appears, contact Dr. Schwab GfT or your authorized service provider.
- The device is designed in a way that it can only be opened with the use of tools. It may only be opened by the manufacturer. There is a risk of death, if you open the device or the power converter while connected to mains!
- The device contains an internal Li-Ion battery. Should the battery become weak or defective, it can be replaced by the manufacturer.

Transport

 Always use the supplied carrying case and transport packaging when transporting the device.

Information about Treatment

General Information

The skin of the patient/client should be free from oils and without wounds before the treatment. Potentially applied make up or similar must be removed.

It is very important to make sure that a good adhesive effect is found on the entire surface of the pad electrodes. The pad electrodes have to be in contact with the skin with their entire surface during the treatment and should not fall off.

Should the pad electrodes not fulfill the requirements mentioned above, they have to be replaced with new electrodes.

- the patient should be in a safe and relaxed position throughout the entire treatment
- except for cases where it is desired, the body of the patient should not be wet
- please abort the treatment in case something unusual happens
- don't place the electrodes over fresh surgery scars or open wounds
- avoid contact of the electrodes with metals like necklaces or belt buckles
- don't use knotted or defective cables
- the device may not be opened, don't drop it or expose it to heavy impacts or vibrations
- if you have doubts about the treatment, you should seek medical/professional help

Additional Information

For the treatment with an *BCR Premium*, a calm and relaxing atmosphere should be created. The patient should be treated sitting down or lying down, according to his ailment. Corresponding to the anamnesis, diagnosis or diagnostic findings, the progression of treatments should be planned and coordinated with the patient.



If you have questions or are unsure about the safety precautions, contact the manufacturer - he will be happy to provide information and help you ensure a safe and effective use of the device.

Standard Accessories

Overview

Pos.		Description:	Article No.:	Quantity:
1		HARD CARRYING CASE	9205	1
2		PATIENT CABLE	9029	2
3	The state of the s	GEL ELECTRODE PADS Small 40 X 40 mm (Size may vary)	4416	4

4

GEL ELECTRODE
PADS
Big
45 X 80 mm
(Size may
vary)

HAND 1
ELECTRODES
(Pair)

Cell Light hand piece with cable

Power supply ATM036Z-A050

Power supply 8366

1

8



Power cable with EURO connector, 1.50 m 8002

1

ATTENTION Important Safety Information!





Connecting or inserting the patient leads into other devices or to a patient who is connected to another medical device, when connected to the body, poses a risk of death for the user.

Only connect the patient leads of the *BCR Premium* to the respective sockets on the *BCR Premium* and never insert the connectors into any other devices/sockets or create a connection to another patient.

Only USB drives may be connected to the device's USB port!

Under no circumstances may the USB port be used to create a connection with another device, e.g. a PC or laptop, as this may lead to dangerously high touch currents/leakage currents on the *BCR Premium*!



Don't use any knotted, twisted or damaged patient leads.



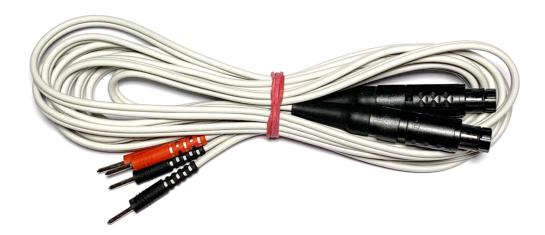
The electrode pad adapters of the patient cables are small parts that can be swallowed by children and might cause suffocation. The wrapping of patient cables around one's neck may also lead to strangulation. Therefore, always store the device and its accessories out of the reach of children. Only use the device on children in the presence of adults.

Hard-Carrying Case



The *BCR Premium* can be operated while still inside the Hard-carrying case. The Hard-carrying case is break-proof, water-proof and dust-proof with a built-in pressure gauge. The device can be operated while inside the hard casing.

Patient Cables



The patient cables provide an electrical connection between the *BCR Premium* device and the patient.

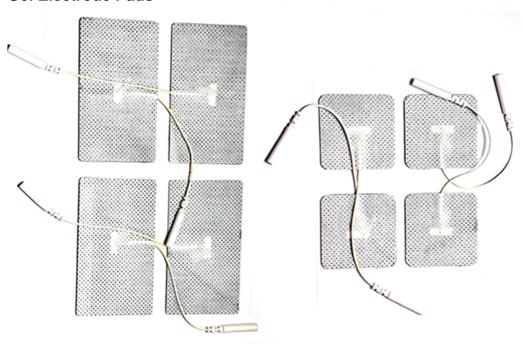
2 patient cables are provided as accessories with the device.

These cables are to be connected to sockets 'A' and 'B' on the device.

The other end of the patient cable is connected to the pad electrodes, which provide a conductive connection to the patient. Depending on the pad electrodes, the red and black pad electrode adapters are to be used.

The patient cables do not need to be serviced; they should only be gently cleaned with a damp rag when necessary. Please do not pull or stretch the cables.

Gel Electrode Pads



General Description

For Gel Electrode Pads these pads were used during testing with this device. For an optimal success of the treatment, only these types of pad electrodes may be used.



Please observe the following information when using pad electrodes.

The skin of the patient/client should be free from oils and without wounds before the treatment. Potentially applied make up or similar must be removed.

It is very important to make sure that a good adhesive effect is found on the entire surface of the pad electrodes.

The pad electrodes have to be in contact with the skin with their entire surface during the treatment and can't fall off.

Should the pad electrodes not fulfill the requirements mentioned above, they have to be replaced with new electrodes.

When using the device on different patients, the pad electrodes have to be replaced after each use.

Hand Electrodes



The usage of Hand Electrodes supplements the treatment with electrode pads. It works only when both balls are in contact with the skin. When in contact with the skin it can be painful in a stationary position, so it is recommended to keep moving. Water or conductive gels can be used for smooth gliding if necessary.



Further information can be found in the chapter 'Initial Operation' of this manual.

Light Hand Piece - Cell Light



The *CELL LIGHT* is a non-invasive and non-burdensome accessory for the *BCR Premium*. The electronics of the *BCR Premium* allow for the modulation of the Red and Blue LEDs, integrated into the *CELL LIGHT*. The light source is modulated according to the frequency that is output by channel A. The brightness of the light source is also dependent on the amplitude of the current from channel A. When the current polarity is positive the light source generates **RED** light at a wavelength of 625nm, and when the polarity is negative it generates **BLUE** light at a wavelength of 465 nm.

The power of the light emitted by the *CELL LIGHT* was determined according to the rules of IEC 62471 and DIN EN 60601-2-57. It falls into the 'free group', which precludes a photobiological danger to the eyes. However, it is recommended not to look directly into the source of light.

The light hand piece is to be connected to socket "L" of the **BCR Premium**.

NOTE: The light output only works when the device is connected via the power supply.

INFORMATION about Treatment with Light

The selective treatment with light is used to support the treatment with microcurrent. From practical experience, a positive effect of the light treatment can be derived. However, there are currently no clinical studies available that prove the effectiveness of light treatment.

Scope of Delivery

Standard items included in a purchase delivery.

- 1 x BCR Premium device
- 2 x Patient cables channel A and B
- 1 x Power adapter ATM036T-A050
- 1 x Power cable with EURO plug
- 1 x Hard-Carrying Case
- 4 x Gel Electrode Pads (big) 45 x80 mm
- 4 x Gel Electrode Pads (small) 40 x 40 mm
- 1 x Pair of Hand Electrodes (red and black)
- 1 x Cell Light with cable
- 1 x Instruction manual

Optional Accessories:

In addition to the standard accessories mentioned above these are optional additional items that can be purchased.

Gel Electrode Pads in packets of 40 pads (Optional).



Two-balls Hand Electrodes - Face lift Pen (Optional)



Two balls Hand Electrodes (Face Lift Pen) is convenient to apply with single hand instead of both hands in the case of the normal hand electrodes. Having two sets of Face Lift Pens makes it convenient to apply Face Therapy symmetrically on both sides of face.

Alligator clips for Acupuncture needles (in pairs of red and black) (Optional)





Storage/Transport

Always store the device in the Hard-Carrying Case provided in a dry location out of the reach of children, and don't use it in an environment, where it is exposed to the following influences:

- Magnetic fields and / or electromagnetic radiation
- Very high or very low temperatures (above 70℃ or below -20℃ storage / transport temperature). After the device has been exposed to very low temperatures and is supposed to be used in a warm room, please wait one tot wo hours before turning the device on, so condensation can evaporate.
- High humidity
- Direct sunlight
- Impact and vibrations
- Fully charge the internal battery if you intend to store the device for an extended period of time (more than 1 month)
- Don't place any containers with liquids on the device!
- Place the device on an even surface for use and storage!



Always use the Hard-Carrying Case and transport packaging when transporting the device in order to avoid damaging it.

Cleaning and Care

Before cleaning the device, please disconnect the device from the power converter. The cleaning/disinfection of the device, the light hand piece and the cables should be performed using the disinfectant wipes "acryl-des" by Schülke, available as accessories. If disinfection is not necessary, the device can also be cleaned using a mild detergent and a **no more than damp**, soft cloth. Please make sure that no liquid enters the openings of the device and don't use any sprays. Especially when cleaning the display and the light opening of the light hand piece, make sure you are not using any harsh chemicals or abrasive cleaning agents.

The pad electrodes are single use products that have to be replaced after each use.

Check the power cord and its plug for damage before each use. Damaged cables may no longer be used!



CAUTION!The device may only be opened by trained personnel.



ATTENTION!
There are no user serviceable parts inside the device.

ATTENTION Important Safety Information!





The housing of the power adapter may not be opened!

Touching parts inside the power adapter poses the risk of death

Conforming Cables and Accessories:

For the safety of the user, no accessories other than the ones provided by the manufacturer, or optionally available from the manufacturer, especially patient cables, power adapters and cables may be used.

Warranty and Maintenance

The manufacturer provides a one-year warranty for the technical and mechanical functions of the device. Additionally, the manufacturer offers assurance of after sales parts and repair support for 7 years or more. The device is designed as maintenance-free to last 10 years under normal careful handling

For warranty claim and repair assistance in the Asia-Pacific and Middle East countries please contact the regional distributor in Singapore www.bcrtherapie.com.

Initial Operation

Please read the instruction manual carefully and observe the safety precautions before using the *BCR Premium* for the first time.

In order to obtain a maximum lifetime for the integrated battery, it is recommended to fully charge the battery before the first use of the device.

Make sure that the device is placed on a sturdy, even surface and connect the supplied power adapter (see "Connecting power supply").

Once the white charging control light goes off, the battery has been fully charged.

Now, press the On/Off button on the side of the device.

The starting screen appears, and after a few seconds, the device is ready for use.



Please thoroughly read this instruction manual before the initial operation of this device. If you are unsure, please contact the manufacturer - he will be happy to help you.



ATTENTION!

The device is to be put in use observing the 'Warnings and Precautions' and the 'Information about Treatment' in this instruction manual. Pay special attention to the safety precautions with respect to the power supply and environmental conditions.

Device Properties



Fig. 1 – **BCR Premium**



Fig. 2 – **BCR Premium**

Connections and Control Elements



Fig. 3 – Control Elements & Indicators

The device is turned on or off by shortly pressing the On / Off button. If you want to turn the device off while a treatment is in progress, you can force this by pressing and holding the On / Off button for 10 seconds.

On the side of the device, you can find the On / Off button, the USB port, as well as the indicator lights for mains operation and Bluetooth connection.

The indicator light for 'mains operation' is on when the power adapter is connected and the battery is being charged. Once the battery has been fully charged, the light turns off.

The indicator light for Bluetooth flashes blue when the device is actively looking for a Bluetooth connection. As soon as a device has been connected, the light is permanently on. If Bluetooth is deactivated (default setting), the light is off.

NOTICE: The device is technically equipped to establish a connection to other devices via Bluetooth. Currently, this feature is deactivated. An activation of this feature via software update at a later point in time is possible.

NOTICE: The USB port is solely to be used for the transfer of program updates or backups from, respectively to a USB drive. The USB port may NOT be used to establish a connection with a PC.

Microcurrent and Light Channels



Fig. 4 – Connections Microcurrent / Light

The connectors for the microcurrent and light output can be found below the display. The channels A and B are for the connection of the patient cables. Channel L is to be used for the connection of the light hand piece.

NOTICE about treatment with light:

The selective treatment with light is used to support the treatment with microcurrent. From practical experience, a positive effect of the light treatment can be derived. However, there are currently no clinical studies available that prove the effectiveness of light treatment.

The light channel runs synchronous to channel A, that means the current signal output by channel A is output on channel L as light pulses via the light hand piece.

Connection of Patient and Light Cables:



Fig. 5 – Connection of Patient and Light Cables

When connecting a patient cable or light hand piece, it is important to observe the correct orientation of the connector. The arrow printed on the connector has to face upward and be aligned with the white mark on the socket in the device. Under no circumstances may the connector be forced into the socket! The connector snaps into the socket. When removing the connector, hold it on its sides with two fingers and pull straight back out of the socket. Do not twist or use excessive force to remove the connector.

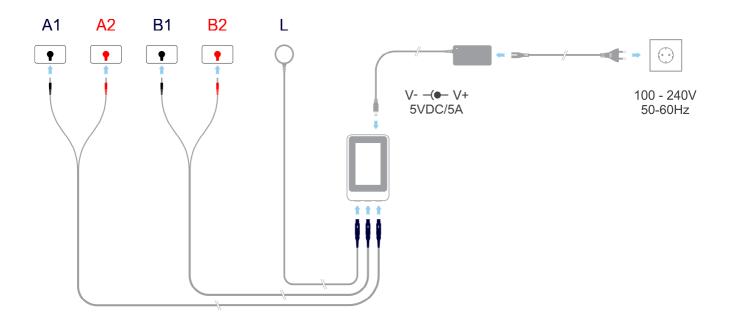
Connection of Power Adapter



Fig. 6 – Connection of Power Adapter

For the use of the device and for charging the internal battery, **only** the supplied, original and available as accessory, medical power adapter may be used!

Connectors - Overview



Navigation Menu Functions and operations

The device is equipped with state-of-the-art technology with highly integrated electronic components of the latest generation. The 5" TFT display with a resolution of 800 x 480 pixels and integrated touch functionality allows for an intuitive and unconventional operation.

The *BCR Premium* is equipped with a capacitive touch screen. This touchscreen works similar to a proximity sensor and detects the finger through the changes of the electrical field near the surface of the screen. For a reliable response, it is recommended to touch the buttons in their center, with light pressure. Not the amount of pressure, but the size of the area of contact between the finger and the touchscreen is the main criterion for the detection of a touch event.

After a function has been initiated by a touch event, it is important to remove the finger from the glass and establish a certain distance (> 1,0 cm), before a new touch event can be detected.

Navigation Menu

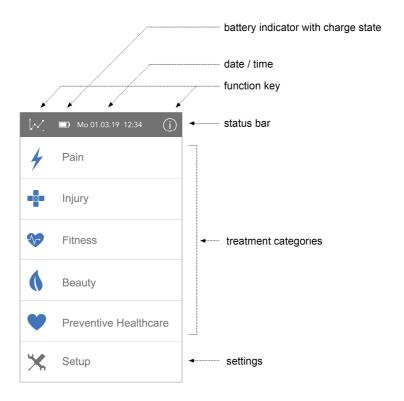


fig. 7 - User Interface Main Menu

User Interface Treatment – Page 1

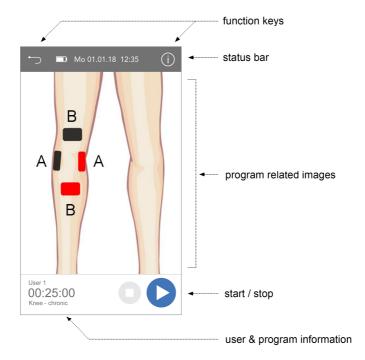


Fig. 8 - User Interface Treatment - Page 1

User Interface Treatment – Page 2

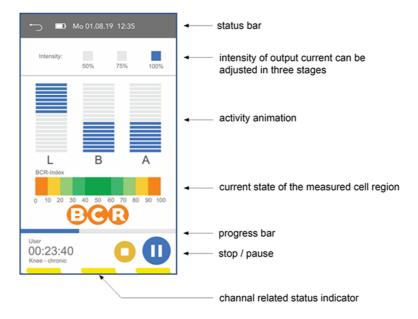


Fig. 9 – User Interface Treatment – Page 2

Explanation of Symbols, Buttons and User Interface

Symbols and Buttons of the Status Bar



Confirm

Confirm data entry with this button.



Next Page

When the content of a list can't be displayed on a single page, press this button to get to the next page of the list.



Information

By pressing the INFORMATION button, context sensitive information and hints are displayed.



Previous Page

When the content of a list can't be displayed on a single page, press this button to get to the previous page of the list.



Back

Pressing BACK moves you up to the next higher menu level.



Edit

Press this button to edit the user names.



Delete

Users can be deleted by pressing this button.



Statistics

This button takes you to the user statistics.



Charge State

Green: Battery is being charged



Charge State

White: Device is in a usable state



Charge State

Red: charge state < 20% Battery should be recharged



Charging Symbol

The device is connected to the power adapter.

Categories

For a simplified navigation, symbols can be associated to the program categories, using the PC software. The following symbols are available:











Function- and Menu Buttons

X

Settings

This button takes you to the device settings



User

This menu item takes you to the user management.



Edit User

This icon symbolizes that a user can be edited.



Statistics

With this button in the settings menu, you can display the user statistics, in the system menu, you can reset it.



Time / Date

Time and date can be changed in this menu.



Language

In this menu, you can select the menu language.



Device Information

With this button, information about the device can be accessed.



System

This button takes you to the menu for all system settings and for saving and loading software and updates.



Activation (optional)

In this menu, a time quota for treatments can be unlocked by entering a code.



Program Update

Under this menu item, you can load software updates and new treatment programs.



Backup > USB

This function allows you to create a backup of all device settings on a USB drive



Restore

This function allows you to restore the device from a backup on a USB drive.

Program specific Buttons and Notifications



channel

is active and no fault is

present

Menu Navigation and Settings

Startup Screen



Fig. 10 - Startup Screen

The BCR Premium is started by pressing the button on the left side of the device. After turning it on, the startup screen appears and the device boots.

At the lower edge of the screen, the name of the current user is displayed.

After a few seconds, the main menu is displayed. The device is now ready for use.

Main Menu

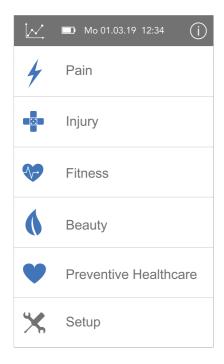


Fig. 11 - Main Menu

In the main menu, the 5 program categories are displayed. Pressing on a category takes you to a list of treatment programs of this category.

Pressing the 'Settings' button takes you to the device settings menu.

The 'statistics' button at the upper edge of the screen takes you to the user statistics.

By pressing the information button, information and hints about the current screen can be displayed.

Program Selection

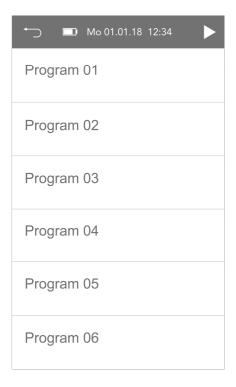


Fig. 12 - Program Selection

After selecting a category, a list of corresponding treatment programs is displayed. A maximum of 6 programs is displayed on one screen.

If a category contains more than six programs, you can switch to the next screen by pressing the arrow button in the upper right corner of the screen.

Below the name of each program, the time and date of the last use of the program is displayed.

The 'back' button in the upper left corner of the screen takes you back to the main menu.

Program Selected

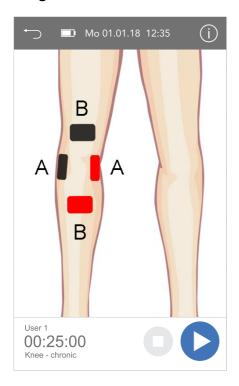


Fig. 13 - Program Selected

Once a program has been selected, the treatment screen is displayed. An image with information on where to place the electrodes is shown.

Below this image, the current user, program duration and the program name are displayed.

Pressing the 'Start' button starts the program. The 'Stop' button is not activated and grayed out.

Pressing the 'Information' button takes you to the second page of the treatment screen.

The 'back' button in the upper left corner takes you back to the main menu.

Depending on the type of treatment program, a screen with the option to enter your current pain level is shown after pressing the 'Start' button. In case of non-pain specific programs, this screen is not shown, the program starts immediately.

Pain before Treatment

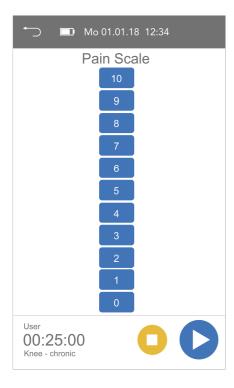


Fig. 14 - Pain before Treatment

When starting a program from the 'Pain' category, the currently felt pain can be recorded according to the 10-point pain scale.

This is done by pressing on the corresponding value in the diagram. 0 corresponds to no pain, 10 to the maximum pain.

This query is the basis of the statistics function of the *BCR Premium*. The pain before and after each treatment can be recorded. From the derived data, it can be seen how the pain develops over the course of the treatments.

Pressing the 'Start' button without selecting a pain scale allows you to skip this step. No pain value is recorded, and the display changes to the second treatment screen and the treatment starts.

The 'back' button in the upper left corner of the screen takes you back to the main menu.

Treatment - Page 1

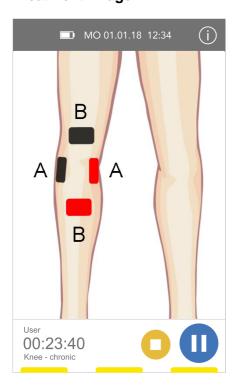


Fig. 15 - Treatment - Page 1

If a treatment is running, this is shown by the status indicators at the lower edge of the screen, as well as the counting down of the program duration. The status indicators correspond to the channels below.

If the indicator is yellow, this channel is active and no fault is present.

If the indicator is red, a fault is present. (see section 'Faults ')

Pressing 'pause' causes the treatment to pause.

Pressing 'stop' aborts the treatment.

Pressing the 'information' button takes you to the second page of the treatment screen.

Treatment – Page 2

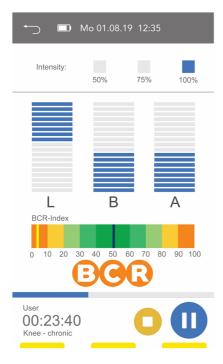


Fig. 16 - Treatment - Page 2

On the second page of the treatment screen, the intensity of the current output can be changed in three steps by pressing on the corresponding value.

Below, the current and light output is shown symbolically.

The indicator below shows the state of the affected cell region, as captured by the device. The measurement is inspired by Dr. R. Voll's method.

Pressing the 'back' button takes you back to the first page of the treatment screen.

If a program has finished, this is indicated by a sound signal. Unless the screen is touched while the signal is active, it will last up to 30 seconds.

Pressing 'stop' confirms the end of the treatment, and the screen changes to the entry of pain after treatment.

Fault

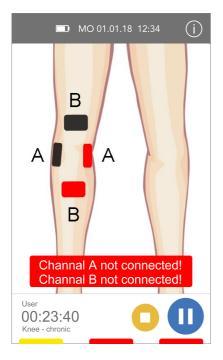


Fig. 17 - Fault

If a fault is present on one of the channels, this is shown by a red status indicator. Additionally, faults are indicated by a text field on the screen.

Possible causes for faults are:

- Insufficient or no contact between the pad electrode and the skin.
- Insufficient of no contact between the pad electrode and the BCR Premium
- Short circuit between the pad electrodes.
 (Electrode pads touching)
- Broken cable

Pressing on the error message causes it to disappear.

ATTENTION:

This does not solve the cause of the fault. The message is simply hidden.

Pain after Treatment



Fig. 18 - Pain after Treatment

Entry of the pain after treatment is similar to the entry of pain before treatment (see above).

Pressing the 'back' button in the upper left corner of the screen lets you skip the entry and takes you back to the main menu. No value will be saved.

Settings



Fig. 19 - Settings

Pressing 'settings' in the main menu takes you to the device settings menu of the *BCR Premium*.

Here, the following settings can be performed:

- User (select and manage user)
- Statistics (show treatment statistics)
- Time (set time and date)
- Language (select language)
- Device information (Software, service, etc.)
- System (Updates, Backups, Restore)

Pressing the 'back' button in the upper left corner takes you back to the main menu.

User

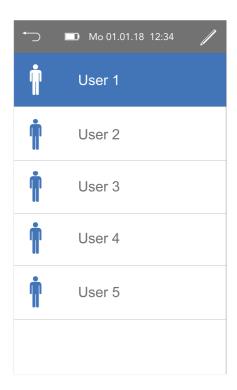


Fig. 20 - User

The **BCR Premium** contains a user management. Up to 5 different users can be created and managed.

The currently selected user is displayed inverted. Pressing on another user in the list causes this user to be selected.

In order to rename or delete a user, press on the 'edit' button in the upper right corner of the screen.

Pressing the 'back' button in the upper left corner aborts any entry and takes you back to the settings menu.

Statistics

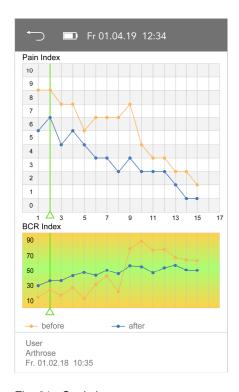


Fig. 21 - Statistics

In the upper area of the screen, the statistics for the development of the pain felt is shown over the course of treatment.

This function optionally saves the values of pain felt before and after a treatment. From the derived data, it can be seen how the pain develops over the course of the treatments.

0 corresponds to no pain, 10 to the maximum pain.

The orange curve represents the values before, the blue curve the values after the treatment.

Up to 250 treatments can be recorded for each user.

The lower diagram shows the development of the skin resistance measurement over the course of the treatment. One data point represents one treatment. The deviation of the measurement from the mean is shown before and after a treatment.

You can navigate between the treatments by pressing on the arrows in the upper right corner of the screen.

Below the diagrams, information about the user and the treatment program are displayed.

The 'back' button in the upper left corner of the screen takes you back to the main menu.

Time

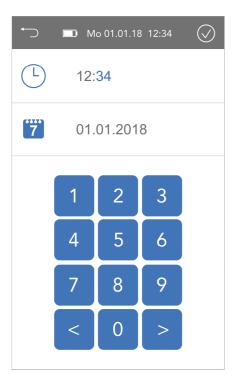


Fig. 22 - Time / Date

Under the menu item 'Time', time and date of the **BCR Premium** can be set.

To do so, select the number to be changed with your finger. The number changes to blue. The new value can now be entered through the displayed number pad. You can select the desired position with the arrows.

The new values are confirmed by pressing the 'confirm' button in the upper right corner of the screen. After confirmation, the screen changes back to the settings menu.

Pressing the 'back' button aborts data entry and takes you back to the settings menu without saving any changes.

Language



Fig. 23 - Language

Under menu item 'Language', the basic language of the device can be selected. The selection is indicated by an inverted representation of the current language.

The following languages can be selected:

- German
- English
- French
- Dutch

Device Information



Fig. 24 - Device Information

The following information is displayed under this item:

Device information:

- Serial number
- Software Version
- Information about the hardware
- User

Usage times:

- Total usage time
- Time since activation (in case of limited activation)
- Remaining time until next activation

MP Regulations:

 Number of hours remaining until next required check of the medical device.

Warnings:

If an activation or service is required, it will be indicated on this screen.

System

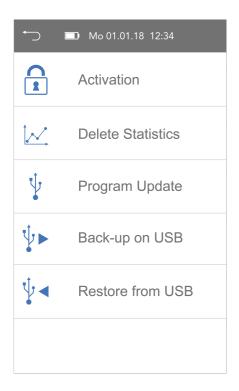


Fig. 25 - System

In the submenu 'system', the following settings can be performed:

Activation:

A time quota for treatments can be activated by entering a numerical code.

This function is optional!

Delete statistics:

The recorded treatment statistics can be deleted here.

Program update:

Software updates and new treatment programs can be loaded under this item.

Backup > USB:

With this function, a device backup can be created on a USB drive.

Restore:

This item allows you to restore the device from a previously created backup on a USB drive.

Activation



Fig. 26 - Activation

The **BCR Premium** has the option of activating a certain time quota for treatments.

Once this quota has been used, a new quota can be activated by entering a code.

Delete Statistics

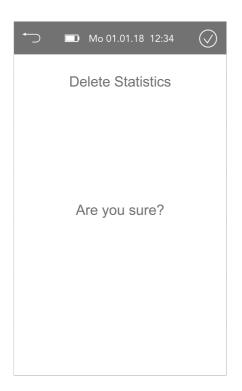


Fig. 27 - Delete Statistics

Under this menu item, the recorded treatment statistics can be deleted.

In order to permanently delete the data, the displayed message has to be confirmed by pressing the 'confirm' button in the upper right corner of the screen.

Pressing the 'back' button in the upper left corner of the screen aborts the operation and takes you back to the system menu.

Program Update

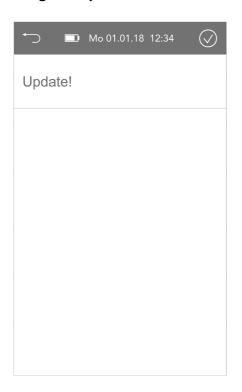


Fig. 28 - Program Update

The menu item 'Program Update' is used to load new treatment programs from a USB drive. In order to do this, you have to insert a USB drive with the appropriate programs into the USB port of the **BCR Premium** before selecting this menu item.

Program files have to be stored in the root directory of the USB drive. In order to load programs, the displayed message has to be confirmed by pressing the "confirm" button in the upper right corner of the screen. This operation may take serval minutes to complete.

Pressing the 'back' button in the upper left corner of the screen aborts the operation and takes you back to the system menu.

Error Message USB



Fig. 29 – Error Message USB

If no USB drive is found on the USB port of the **BCR Premium,** the message 'No USB drive' is displayed.

Make sure the USB drive is connected properly and repeat the procedure.

Pressing the 'back' button in the upper left corner of the screen aborts the operation and takes you back to the system menu.

Backup > USB

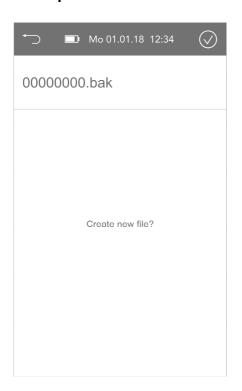


Fig. 30 – Backup > USB

This function allows the user to create a backup of the device on a USB drive.

Make sure that a USB drive is connected to the USB port of the **BCR Premium** before calling this function.

In order to create a backup, the message displayed has to be confirmed by pressing the 'confirm' button in the upper right corner of the screen. This operation may take several minutes to complete.

Pressing the 'back' button in the upper left corner of the screen aborts the operation and takes you back to the system menu.

Restore

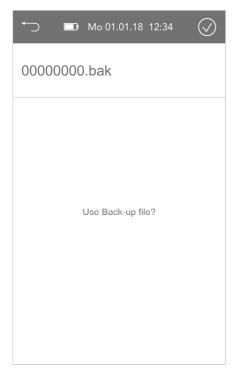


Fig. 31 - Restore

In order to restore the device setup from a file, the item "Restore" is used.

Make sure that a USB drive containing a valid backup file in the root directory is connected to the USB port of the *BCR Premium MSTU 100* before calling this function.

If several backup files are present on a USB drive, they are shown in a list. The desired file is selected by pressing on the corresponding entry.

In order to start the restore operation, the message displayed has to be confirmed by pressing the "confirm" button in the upper right corner of the screen. This operation may take several minutes to complete.

Pressing the "back" button in the upper left corner of the screen aborts the operation and takes you back to the system menu.

Treatment Programs

The factory built-in programs are based on public accessible data, private researches and the experience from use in former devices in Germany for 2 decades and are defined by BCR Singapore. Custom programs can be factory set.

Dr. Schwab Gesellschaft für Technologieberatung mbH assumes no responsibility for the effectiveness of the programs.



Troubleshooting

If your device is not working as desired, read the following check list. If you can't solve the problems with the help of this list, contact your authorized service partner.



Please observe the messages displayed on the screen!

Problem	Ursache / Lösung
Device can't be turned on – display dark – green LED in power adapter not lit	Battery empty Power supply to power adapter disrupted Make sure power cable is connected properly to wall outlet and power adapter Power cable or power adapter defective Have authorized service partner replace power cable or power adapter
Device can't be turned on – display dark – green LED in power adapter not lit	Battery empty Power supply to device disrupted Make sure low voltage connector of power adapter is connected properly to socket in device Device defective Have device repaired by authorized service partner
Battery is not being charged – white charge indicator is not lit while power adapter is connected	Check connection of power adapter Battery defective Have battery replaced by authorized service partner
No microcurrent output or light output after program was started	Patient cables or light cables defective Have cables replaced by authorized service partner
Shortened run time of battery	Battery weak Have battery replaced by authorized service partner

TECHNICAL HANDBOOK - BCR Premium

Device turns off on its	Device turned itself off because of e.g. ESD for safety reasons. Device
own	auto shuts down one minute after treatment is over.
	Turn device on by pressing ON/OFF switch
Loading of programs	USB drive not inserted correctly
from USB drive not possible	Properly insert USB drive into USB port
Error message:	USB drive not compatible or defective
No USB drive found!	Have USB drive replaced by authorized service partner
Loading of programs	File or folder structure on USB drive not correct or missing
from USB drive not possible	Check file and folder structure on USB drive
Error message:	
No file found!	
Cell Light not working	Check connection of power adapter. Cell Light works only when external
	power supply is connected and the device is charging.