LUXXAMED

HD 2000

Technical instructions for use

Version 1.04
As at February 2016

Contents

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The manufacturer reserves the right to make changes to the information in this handbook without prior notice

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Email: info@luxxamed.de

LU::::AMED C € 0044

Introduction

Notes on these instructions

*Warning symbols and signal words used
in these instructions*

**FOLLOW
INSTRUCTIONS**

Read these instructions carefully and follow all of the advice given in them. This will ensure reliable operation and a long life expectancy for your device.

CAUTION

CAUTION!
Warning with a direct risk to life! Note this information to avoid injuries and damage to property.
WARNING!
Warning of a potential risk to life and/or serious, irreversible injuries! Note this information to avoid damage to property.

NOTE

NOTE:
Further information on the use of the device.

Meaning of the symbols on the device/label

Manufacturer

EU mark fo conformity - notified body number
0044 = TÜV Nord, Germany

Ingress protection
Protection against solid particles with a caliber > 12,5 mm; no ingress protection against water

Date of manufacture YYYY-MM

Temperature limit - do not use the device below 0°C or above 40°C.

Store in a dry place and only use in dry places.

Level of protection against electric shock: BF-type

PE symbol (earth)

Do not dispose of in household waste

Follow instructions

equipotential bonding

Brief description

The HD2000 device is a diagnosis and treatment system which is part of the category of "electrotherapy devices" (biological cell regulation [BCR therapy ©] with micro current and LED light therapy [nanophoton therapy]) and is used in a medical environment to treat pain. The device is used in clinics, private doctors' practices, physiotherapy practices and natural medicine practices as a diagnosis and treatment device. The creation of patient chip cards for the mobile micro current device "Vital-Master©" by the doctor/therapist enables the patient to continue the therapy at home.

Intended use

The HD2000 is a diagnosis and treatment device. The correct use is the treatment of acute and chronic pain. Luxxamed is also used to treat neurological diseases.

User community

The user community for the HD2000 primarily consists of clinics, doctors, physiotherapists and non-medical practitioners. The device may only be used by people who are permitted to carry out therapeutic and/or medical treatments as a result of their training or study.

User responsibility

This product is designed to work in accordance with the descriptions contained in these instructions for use if it is installed, operated, maintained and repaired in accordance with the instructions provided. A defective product may not be used! Parts which are damaged, obviously worn, incomplete or contaminated or missing entirely should be replaced immediately. If a repair or exchange is necessary, we recommend that the service be carried out by the manufacturer. The user of the product bears sole responsibility for any malfunction which is caused by the improper use, incorrect maintenance, improper repair, damage or changes made by a person other that Luxxamed GmbH or the authorised customer services staff of this company.

Indications and contraindications of the system

Indications:

- Pain and restricted mobility of the entire musculoskeletal system
- Postoperative and post-traumatic pain
- Acute and chronic pain
- Neurological problems

CAUTION

Contraindications:

the conditions which present an increased risk of failure and therefore harm to the patient include:

- Pregnancy
- Epilepsy
- Cardiac pacemakers and implanted defibrillators
- Acute tumours (cancer)

If other active implanted medical devices are found in the body, the electromagnetic tolerance of the implants of one another and the potential interaction must be clarified with the manufacturers of these implants.

You should not use the HD2000 under any circumstances:

- In children under the age of three
- In patients with acute cardiac arrhythmia
- In patients who complain of dizziness, nausea or disorientation immediately before treatment

You should only use the HD2000 under medical supervision and following advice from a doctor in patients with

- a high fever
- abnormally high blood pressure

Undesirable side effects

The undesirable effects which may be directly linked to the HD2000 are:

- Increased wound secretion in the early postoperative phase
- A tingling of the skin underneath the adhesive electrodes (in the case of high sensitivity of the patient to currents)
- Reddening and itching of the skin underneath the adhesive electrodes (in the case of high sensitivity of the patient to currents)
- Increased desire to urinate
- Temporary worsening of symptoms
- In the case of treatment in the head region, flashes of light in the eyes

Mode of action of the treatment

The HD2000 is based on embedded PC hardware and software. All inputs and information for the user are via a touch screen. Completely redeveloped, modular additional hardware for the generation of micro currents and the emission of light enables the independent generation of current pulses with frequencies of up to 5 kHz for 4 channels and the generation of signals for 2 light channels in the same frequency range with currents of up to 200 mA. This means that the frequencies of the light channels can be set at any of the frequencies of the current channels. A permanent back measurement of the skin resistance on all of the current channels enables the precise recording of the progression of the treatment and automatic optimisation of the treatment.

In addition to the software on the specific hardware which controls the precise frequency and current generation and the back measurement of the skin resistance, the device has extensive user and therapy software which offers, among other things, the following options:

- Creation of new therapy programs with 4 current and 2 light channels with up to 200 treatment steps
- Limitation of the treatment duration to 24 hours without the intervention of the therapist
- Frequency-dependant measurement of the skin resistance with a graphic representation of all channels
- Graphic representation of the skin resistance during treatment on all channels
- Use of the back measurement for the automatic optimisation of the treatment
- Display of contact points for the electrodes
- Patient management with a recording of treatments
- User management for the device to be used in turns by several therapists

The generation of an initial voltage of 60V for each channel galvanically separated from each other potential ensures the best possible interference treatment (two different currents crossing at the location of the pain). This is not achieved by cheaper devices. The galvanic separation of the channels with voltages up to 60V and the measurement of the currents

emitted requires a very high use of electronic resources and a high degree of programming effort, which is why the price for a device of this type is what it is. On the other hand, you can be sure that with this micro current device you can cover all of your requirements.

The use between embedded PC hardware and software means that updates can easily be installed. Contact your dealer or the manufacturer about this.

You can find further information in the therapy handbook provided by the manufacturer.

Warnings and Precautions

- The device may only be installed and used by staff who have been appropriately trained
- The device may only be stored and used in dry rooms
- Only operate the device in the temperature range from 0-50°C
- Do not expose the device to humidity of below 40% or above 80%
- Please use the mains cable provided to connect the device to the mains supply
- Observe the mains connection values (see technical data)
- Never use damaged mains cables or patient wires
- Do not cover the ventilation slit in the device during operation
- Only use accessories which have been approved for the device
- Do not continue to use a device which is obviously not functioning correctly. Contact your Luxxamed supplier for a repair
- Do not place any items into the openings in the device
- Avoid any liquids or dust getting into the device
- The device is not intended for use in areas which are at risk of explosion and may not be used in areas of this type
- Even if the device has been switched off using the ON/OFF button (illuminated in orange), it is still connected to the mains power – to disconnect it from the mains power completely pull the plug out
- Only use the adhesive electrodes available as accessories approved for the device – these electrodes should be replaced after every use
- Never attempt to repair damaged accessories yourself – contact the manufacturer for this
- Clean the device regularly and disinfect the accessories if necessary
- The power adapter may not be operated directly adjacent to other devices or stacked with other devices. If this type of operation is unavoidable, the power adapter must be monitored to check that it is operating as intended in this arrangement.
- Note the recommendations on electromagnetic tolerance at the end of these instructions

WARNING

- In order to rule out damage to the device caused by electrostatic discharge, avoid discharge caused for example by unsuitable clothing, unsuitable carpets, too low humidity etc. and touch the metal housing before operating the device.

- Set the device up in a secure position and place the connection cable such that it is not damaged and does not present a risk.

- Avoid direct allowing direct sunlight to hit the device (increased heating up and poor legibility of the display).

- The device id designed so that it can only be opened using tools – the device may only be opened by the manufacturer – there is a risk to life if the housing is opened and the device is connected to the mains power!

- Only plug the device into sockets with protective contacts. Do not use extension cables or multiple sockets. If necessary, have the sockets checked by a specialist.

- Never try to connect an earthed plus to an unearthed socket.

- The device may not be used on the patient in combination with other medical devices (e.g. ECG).

- Only one HD2000 may be used on the patient.

- Never attach accessories from other devices to the HD2000 – this can lead to disorders of function and present a risk to the patient.

- Only connect the patient wires on the HD2000 to the sockets on the device intended for this purpose – do not insert the plug connections of the patient wires into another device or use them to create a connection to other patients.

- Only use the program memory cards with the HD2000. Using the card with, for example, PC card readers or similar can lead to the therapy program stored on the card being deleted or damaged.

- Place the cable in such a position that nobody can tread on it or stumble over it.

- Do not place any items on the cable as they may be damaged.

- Do not allow large amounts of force to be placed on plug connections, for example from the side. This can cause damage on and in your device.

- Do not exert any force when connecting cables or plus and ensure that the plug is oriented correctly.

- Avoid short circuits and breakages to the cable by not squeezing it or bending it too sharply.

- After stopping therapy, the power plug have to be disconnected.

CAUTION

WARNING: Any modifications of the device are not allowed!

WARNING: Without any permission it is not allowed to change or open the device.

WARNING: For securing a safe use of the device, the device must be reviewed after any change!

CAUTION

WARNUNG: If the device will be used with a multi-outlet power strip (multiple socket) causes this a ME-System (medical device system) and decreases the risk class.

In those cases the requirements according IEC 60601-1 must be applied through the particular organisation

CAUTION

WARNING: To avoid an electrical stroke for the patients, any patient cables and LED light cables must be disconnected if they are not in use.

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Final:

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Advice about treatment

TREATMENT

A calm, pleasant environment should be created for the patient for treatment with the Luxxamed HD2000. The patient should be treated sitting or lying depending on the problem they have. The course of treatment is to be planned by the doctor, non-medical practitioner or physiotherapist on the basis of the patient history, diagnosis and/or results and agreed with the patient.

When treating acute pain, daily treatment is recommended. A rhythm of 2 to 3 times weekly is recommended for the treatment of chronic clinical pictures. The patient's skin should be free from oil and unbroken before treatment in the area in which the adhesive electrodes are to be used. Any make-up or similar which has been applied must be removed. It is very important to ensure that the electrodes are fully adhered across their entire application surface. During treatment, the entire area of the adhesive electrodes must lie on the skin and may not fall off.

If the adhesive electrodes do not meet the above mentioned requirements, they are to be replaced with new adhesive electrodes. The patient should be given sufficient water (ideally low-mineral still water) for each treatment. A glass of water should be provided before and after the treatment for elderly patients.

- The device should only be used by therapists who have been instructed on its use
- The patient should be in a secure, relaxed position during treatment
- The patient's body should not be wet, except where this use is desired
- The device should be out of the patient's reach
- Please note the hygiene regulations set out by the Professional Association of the Healthcare Profession and Welfare Work and Medical Devices Regulation
- Please stop using the device if anything unusual happens
- Do not place the electrodes over fresh operation scars or over open wounds
- Avoid contact between the electrodes and metals such as chains or belt buckles
- Do not use knotted or defective cables
- The device may not be opened, do not let it fall and do not expose it to hard knocks or vibration
- If you have any doubts about the use, seek medical and/or specialist advice

⊞ccessories

NOTE

Alle accessories are applied parts simultaneously!

Light handpiece | light pen | LX9210

Essay for light pen | LX9210

General description

The MSTH-01 light handpiece is a non-invasive, non-aggravating accessory for the Luxxamed HD2000.
Its function is based on the stimulation of diseased cells using micro current and light. Stimulation using light is carried out in parallel to the current and supports the current in its effect.

Light handpiece | "medium" light head | MSTH-02

General description

The "medium" light head is a non-invasive, non-aggravating accessory for the Luxxamed HD2000.
Its function is based on the stimulation of diseased cells using micro current and light. Stimulation using light is carried out in parallel to the current and supports the current in its effect.

Light handpiece | "large" light head | LX9230

General description

The "large" light head is a non-invasive, non-aggravating accessory for the Luxxamed HD2000.
Its function is based on the stimulation of diseased cells using micro current and light. Stimulation using light is carried out in parallel to the current and supports the current in its effect.

Patient wire LED | LX9200

General description

The LED light wires are the electrical connection between the HD2000 micro current device and the patient.
Two light wires are supplied with the device.
On the device, these wires are to be connected to the sockets **"L1" and "L2",** The patient wires do not require maintenance and should only be cleaned with a damp cloth as needed.

LX9200 - Patientenleitungen Licht

NOTE
Disconnect all wires during therapy if they are not in use!

Mode of action of nanophotons in light therapy

The electronics in the Luxxamed HD2000 micro current device enable the modulation and regulation of the brightness of the red/blue LEDs using the handpiece. The transfer of the light to the patient is carried out by means of a plastic fibre optic cable in the handpiece.
The modulated currents emitted from the HD2000 micro current device are simultaneously emitted to the patient via the light cable.
When the current polarity is positive, the light source, which is made up of a duo-LED for each channel, generates red light at a wavelength of 625nm, and when the polarity is negative it generates blue light at a wavelength of 465nm.
The light source is modulated depending on the frequency of the micro current emitted by

the Luxxamed HD2000 and regulated depending on the level of the micro current in the intensity. This parallel stimulation using currents and light increases the effect of treatment.

The light handpieces are to be connected to one of the two interface sockets "L1" or "L2" of the Luxxamed, depending on the treatment to be administered. The effect of the nanophoton light therapy provided by the Luxxamed HD2000 on an activation of cell metabolism and inflammation in the tissue has been confirmed by a study carried out by the Fraunhofer Institute.
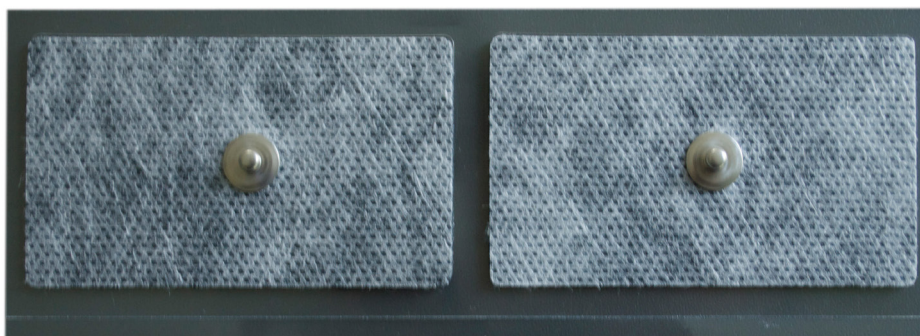
Please ensure that the light head does not come into direct contact with the patient's skin. Always keep it at a few centimetres above the patient's skin.

Adhesive electrodes

LX9020

LX9030

General description

The two types "Gel-Pad PG470" and "Gel-Pad-473" are available from Luxxamed GmbH as adhesive electrodes. In order to ensure optimal treatment success, only these adhesive electrodes should be used.

Dimensions
LX9020:   35 x 45mm
LX9030:   45 x 80mm

When using the adhesive electrodes, please note the following tips.

- The patient's skin should be free from oil and unbroken before treatment in the area in which the adhesive electrodes are to be used. Any make-up or similar which has been applied must be removed.
- It is very important to ensure that the electrodes are fully adhered across their entire application surface.
- During treatment, the entire area of the adhesive electrodes must lie on the skin and may not fall off.
- If the adhesive electrodes do not meet the above mentioned requirements, they are to be replaced with new adhesive electrodes.
- The adhesive electrodes are a single-use product and must be replaced for each treatment.
- The adhesive electrodes only have a limited shelf life. The expiry date for the electrodes can be found on the electrode packaging. Do not use any electrodes which are past their expiry date.

Patient wires | LX9100

General description

The patient wires are the electrical connection between the HD2000 micro current device and the patient.

Four patient wires are supplied with the device.

On the device, these wires are to be connected to the sockets **"A", "B", "C" and "D"**.

The other end of the patient wires is attached to the adhesive electrodes, which provide a conductive connection to the patient.

The patient wires do not require maintenance and should only be cleaned with a damp cloth as needed.

NOTE

Disconnect all wires during therapy which are not in use for the current therapy!

Do not use knotted, twisted or damaged patient wires.

Only connect the patient wires on the HD2000 to the sockets on the device intended for this purpose – do not insert the plug connections of the patient wires into another device or use them to create a connection to other patients.
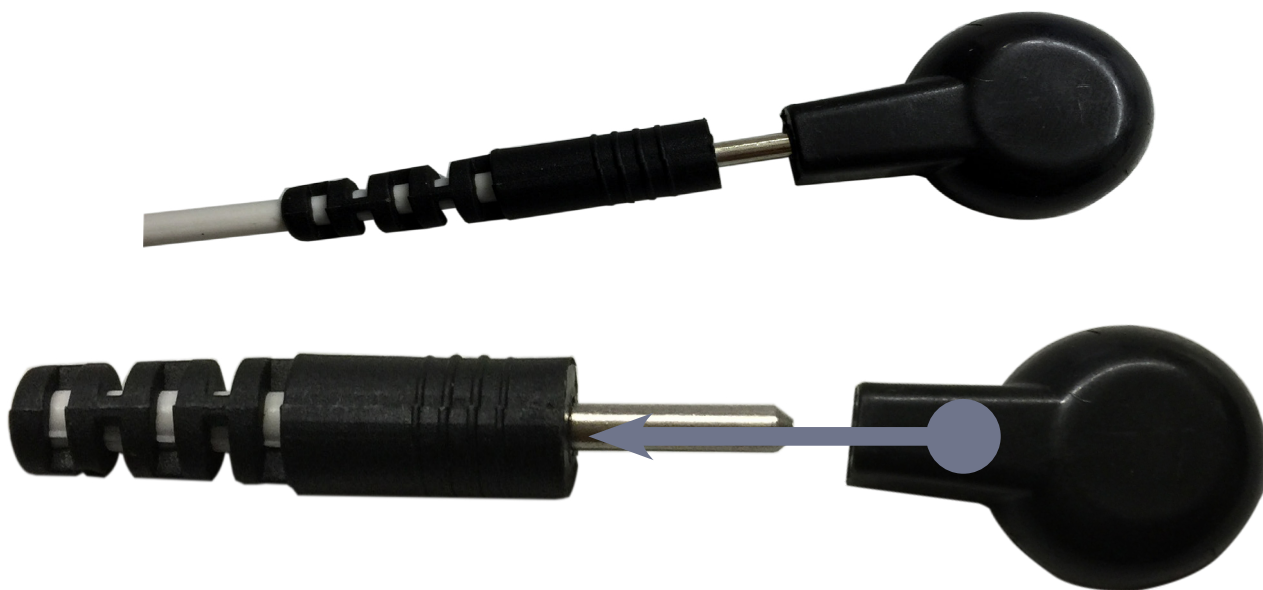

NOTE

You can find further information in the treatment handbook provided by the manufacturer.

NOTE

Pay attention that the patient wire is fully connected to the clip!

CAUTION

Be aware that the patient wires and light wires are pluged in correctly. To pull of the wires, use the corrugated part of the plug to pull it out with your fingers.
DO NOT pull on the wire itself or the bend protection!

Guarantee, maintenance and replacement parts, repairs

The manufacturer provides a two-year guarantee for the technical and mechanical functions of the device. For accessories that are used with the product, the statutory guarantee applies from the date of purchase. Damage caused by incorrect handling, excessive use of force or force majeure is not covered by the guarantee.

All repairs to products which come under the guarantee must be carried out or approved by Luxxamed GmbH. Unauthorised repairs result in the forfeit of all claims under the guarantee. In addition to this, the repair of any products, regardless of whether they are covered by the guarantee or not, may only be carried out by qualified Luxxamed GmbH maintenance staff.

Maintenance and replacement parts

If the product is not functioning correctly or support, maintenance or replacement parts are needed, please contact Luxxamed GmbH's technical customer service.

You can contact the technical customer service by telephone on

+ 49 [0] 561 - 50395528

or by email on

info@luxxamed.de

Before contacting Luxxamed GmbH, you should try to generate the problem again and check all of the accessories to rule these out as the cause of the problem.

Please have the following information available when you make the phone call:

- product name, model number and a full description of the problem
- the series number of the product
- the names and full address and telephone number of your facility

Repairs

If repairs under the guarantee, extensive repairs under the guarantee or repairs which are unrelated to the guarantee need to be carried out on your product, please contact Luxxamed's technical customer service. A customer service employee will help you to identify the problem and try to resolve the issue over the phone to avoid you unnecessarily returning the device.

If returning the device is unavoidable, the customer service employee will take all of the necessary information and give you a correct return address.

Information about the packaging

If you need to return products for maintenance or repair, follow the following guidelines on packaging:

Remove all cables and accessories if you don't think they are part of the "problem" before packaging the device. (Send us the device without accessories unless they are the problem.)
Where possible, use the original box and the
original packaging materials to avoid external damage.
Include a list of what is included and as precise a description of the error as possible.

We recommend that you insure all products which are returned. Claims for loss or damage to the product must be made by the sender.

Information on the limited guarantee

Luxxamed GmbH guarantees that the product you have purchased meets the technical data mentioned for the product and that it is free from technical material and manufacturing errors which occur within two years of the date of purchase. For accessories that are used with the product, there is an additional guarantee of two years from the date of purchase.
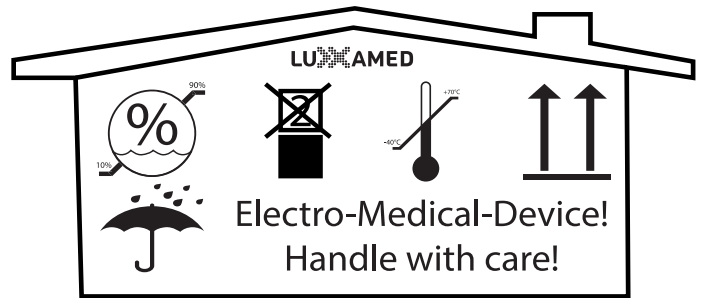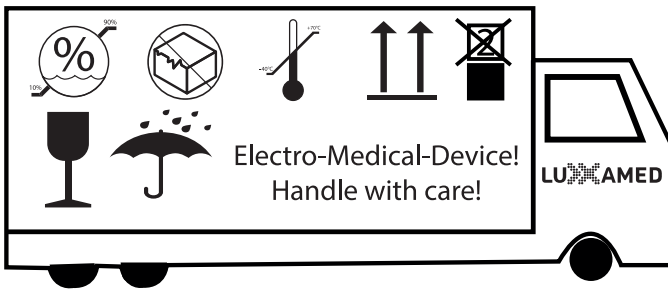
The date of purchase is defined as follows: 1.) The date indicated in our records for when you bought the product directly from us; 2.) The date indicated to us by an intermediary for when you bought the product not directly from us.

This guarantee does not cover any damage which has been caused by the following: 1.) Handling during transport; 2.) Use or maintenance which does not correspond to the instructions; 3.) Changes or repairs carried out by a technician who has not been authorised by Luxxamed GmbH; and 4.) Accidents.
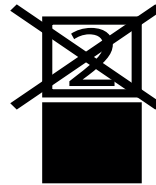
If a product covered or accessory covered by this guarantee is damaged due to defective materials or components or due to poor processing and a claim is made under the guarantee within the above mentioned guarantee period, the damaged product or accessory will be repaired or replaced free of charge. The decision on this lies with Luxxamed GmbH.

THIS GUARANTEE EXCLUDES ALL OTHER GUARANTEES, REGARDLESS OF WHETHER THIS IS EXPRESSLY NOTED OR IMPLICIT, INCLUDING BUT NOT LIMITED TO IMPLICIT GUARANTEES FOR THE MARKETABILITY OR SUITABILITY FOR A CERTAIN PURPOSE. LUXXAMED GMBH'S OBLIGATION IN ACCORDANCE WITH THIS GUARANTEE IS LIMITED TO THE REPAIR OR REPLACEMENT OF THE DAMAGED PRODUCT. LUXXAMED GMBH IS NOT RESPONSIBLE FOR INDIRECT OR CONSEQUENTIAL DAMAGES CAUSED BY A PRODUCT ERROR WHICH IS COVERED BY THIS GUARANTEE.

Storage and transportation

Electro-Medical-Device!
Handle with care!

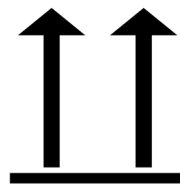Electro-Medical-Device!
Handle with care!

Do not use the device in case of broken packing.

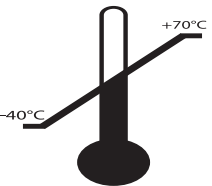Do not stacking

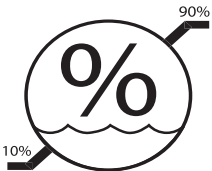Caution! Content is highly sensitive and fragile

This side up!
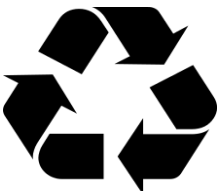

Temperature range
Tranport / Storage
-40°C bis +70°C

Avoid of wetness

Humidity range
Transport / Storage
10% - 90%

Disposal considerations

Packaging

Your device is in packaging to prevent is from damage during transport. The packaging is made of raw materials so can be reused or put back into the raw materials cycle.

Device

Do not throw your device into the normal household waste at the end of its life span under any circumstances. Ask your municipal administration office how to dispose of the device in a proper, environmentally friendly manner.

Operating instructions for the treatment unit

Scope of delivery

The scope of delivery includes the following devices/accessories:

- Luxxamed HD2000
- 4 patient wires
- 1 light handpiece with connection cable
- 1 light applicator middle
- 1 light applicator big
- 2 light wires
- 1 set (4 PG470 adhesive electrodes)
- 1 set (4 PG473 adhesive electrodes)
- These instructions for use

Starting up

Each device is delivered along with these technical instructions for use and an introduction by the manufacturer and started up. The introduction is carried out in accordance with the provisions of the Medicinal Products Act and is documented by the manufacturer in a traceable manner. Only those who have achieved authorisation to be medicinal product consultants after having completed the relevant training sessions with the manufacture are permitted to provide the introduction. On request, the medicinal product consultant must provide identification in the form of an appropriate certificate from the manufacturer.

Please read the instructions for use through carefully and only start using the device after you have read them. If you have any questions, please contact the manufacturer who will be happy to help.

CAUTION!
It is explicitly noted that the device may only be installed and used by trained personnel.

CAUTION
WARNING!

The device is to be started up taking into account the "warnings and precautions" and "information on handling" found in these instructions. Pay particular attention to the safety precautions relating to electricity supply and environmental conditions.
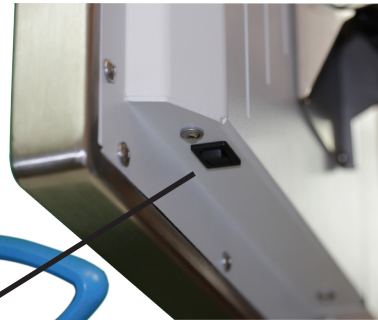

CAUTION!

After finished the therapy the power plug have to be disconnected from electricity, because the device is under voltage.

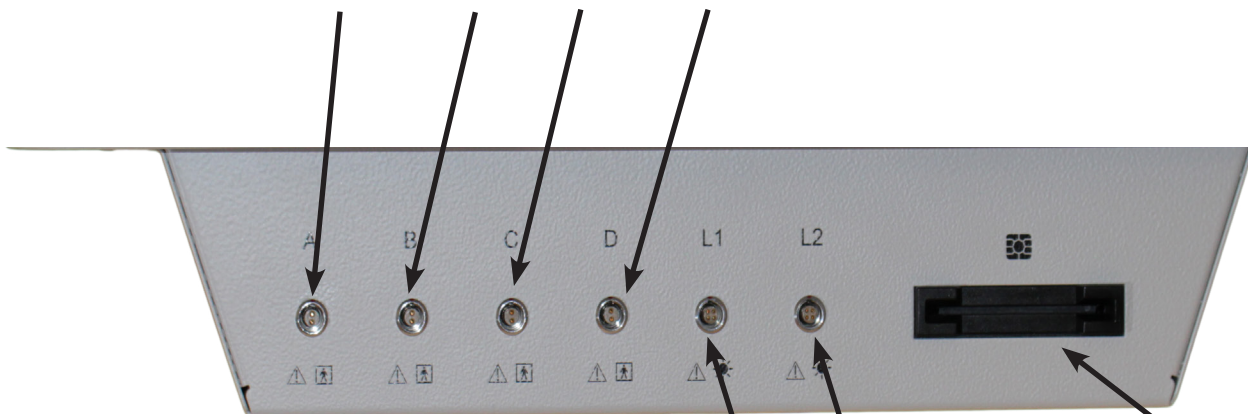# Operating elements, displays and connections

ON/OFF switch

USB connection

Patient connections

Power connection

Patient connection – wires for channel A, B, C, D

Light cable connection L1, L2

Chip card slot

Power connention

USB connection

⁙afety indications

CAUTION!

Load
The following load should not be exceed!

15 KG

10 KG

65 KG

Push of the trolley

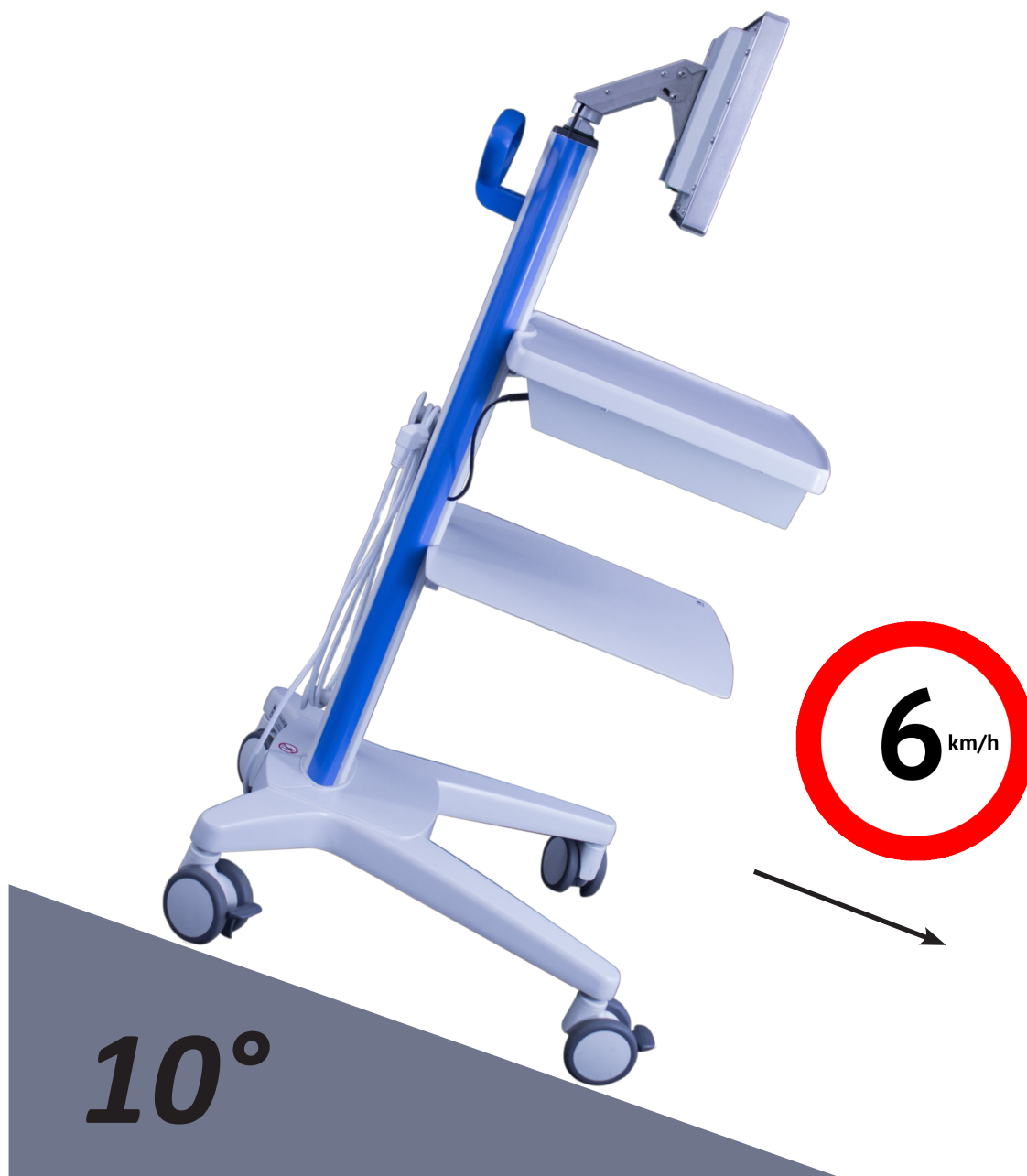**Be aware of the following situations before move the trolley:**

- **all parts on the rack needs to be secured.**
- **disconnect the main power supply from the grid.**
- **release the breaks of the trolley**

The maximum speed while moving the trolley is 6 km/h. In case of crossing edges, cables or steps, reduce the speed.

In case of grades or slopes be aware to not exceed the maximum bracket of 10°.

While you be aware of all dangerous circumstances take care during moving the trolley.

Basically obtain the requirements of the IEC 60601-1

Electrical power supply

The Luxxamed HD2000 is designed to operate at a voltage range of 100-240V (alternating current) at a frequency of 47-63Hz. For operation in foreign countries use the right connection lines. Contact a dealer for this purpose. The device may only be operated in dry rooms. A damaged power cord must not be used for safety reasons.

CAUTION!

CAUTION important safety instruction

The device is equipped with a power supply that is designed and manufactured for use in medical devices. This power supply contains special requirements for the protection of patients.

In any case the power supply should not be replaced by a not approved one.

A replacement of an non-approved power supply for this device may result in case of failure a serious injury or death to the patient!

A device with a faulty power supply, may no longer be used. Please contact you dealer

The power supply must be replaced only be the manufacture or an authorized person.

CAUTION!
WARNING: To avoid the risk of an electric shock, the device must be only connected to a grid with a protective conductor.
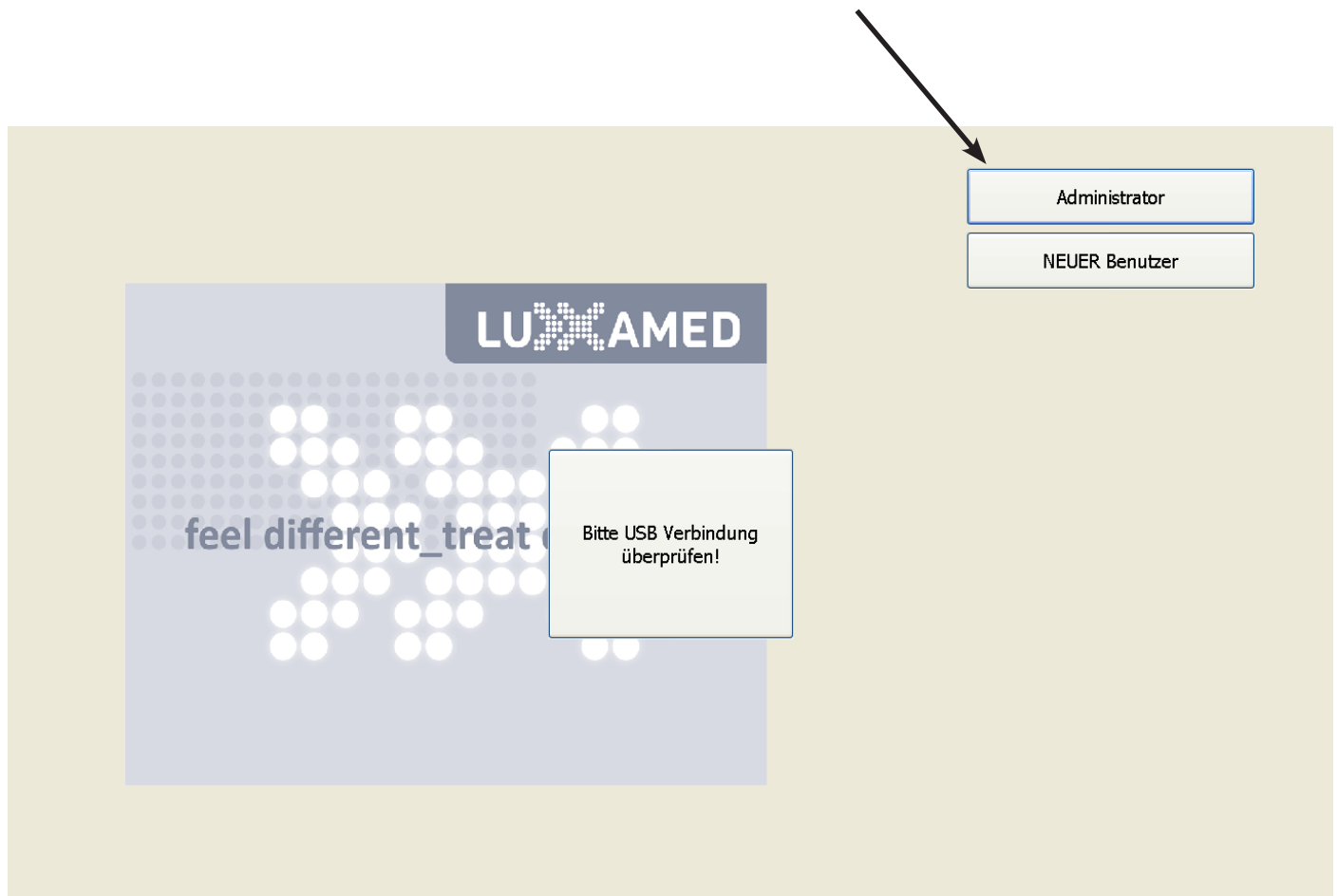
░peration

Switching on and off

When the device is switched off, the electricity supply to it is interrupted. When the button is briefly pushed, the operating system loads. Once the start process is complete, the home image with the Luxxamed logo and the open users appears. To switch the device off, push the on/off button briefly again. The operating system then shuts down. It is not necessary to click on log off before you switch off the device.

Logging in

In order to use Luxxamed, you need to log in using your **username** and **password** once the start process has completed. In order to do this, touch the start screen to enter the relevant username.

On the following screen, a keyboard now appears which can be used to enter the **password** for that username. You can either confirm by clicking **OK** or pushing the enter key. You can return to the home screen by pushing the **escape** key. When you are entering your password, ensure that caps lock is not activated.

TYPE IN PASSWORD

Passwort

Administrator

PASSWORT EINGEBEN

OK

Esc		^	1	2	3	4	5	6	7	8	9	0	ß	´	←
		q	w	e	r	t	z	u	i	o	p	ü	+	#	Entf
Feststell		a	s	d	f	g	h	j	k	l	ö	ä	←
⇧		<	y	x	c	v	b	n	m	,	.	-	⇧		↑	Fn
Strg	Alt								AltGr		Ctrl		←	↓	→

Function selection

In the Luxxamed, the basic functions can be selected using the tabs on the upper edge of the screen (shown here in green). The following functions are available depending on the type of user. Functions marked with an ***** are only accessible to administrators:

- Therapy
- Position images
- Therapy management*
- Therapist management*
- Patient management*
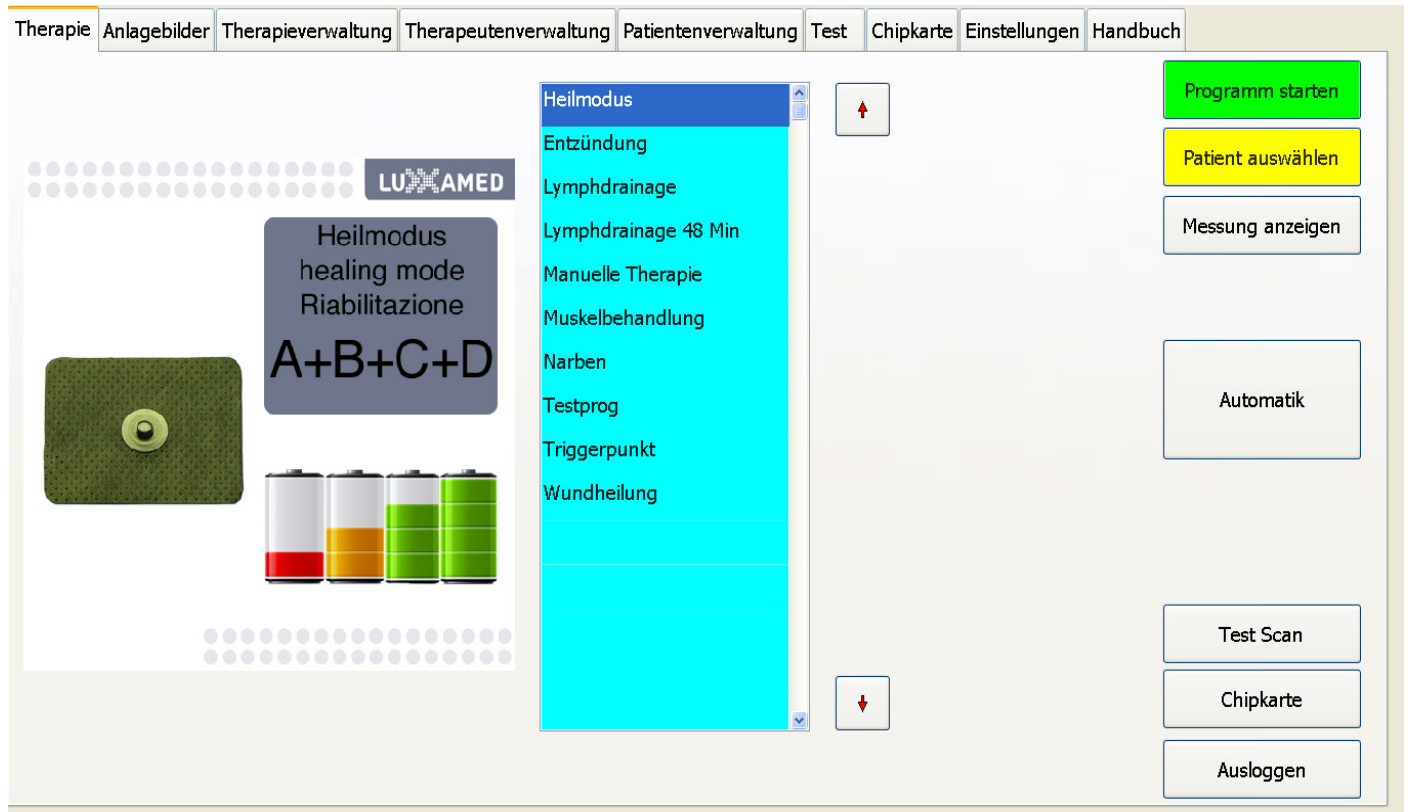- Test*
- Chip card
- Settings*
- Handbook

Therapy

Under the "therapy" tab, treatment programs (fixed programs, shown here in yellow) can be selected and the automatic program (shown here in blue) started. The test scan (shown here in orange) can also be started here.
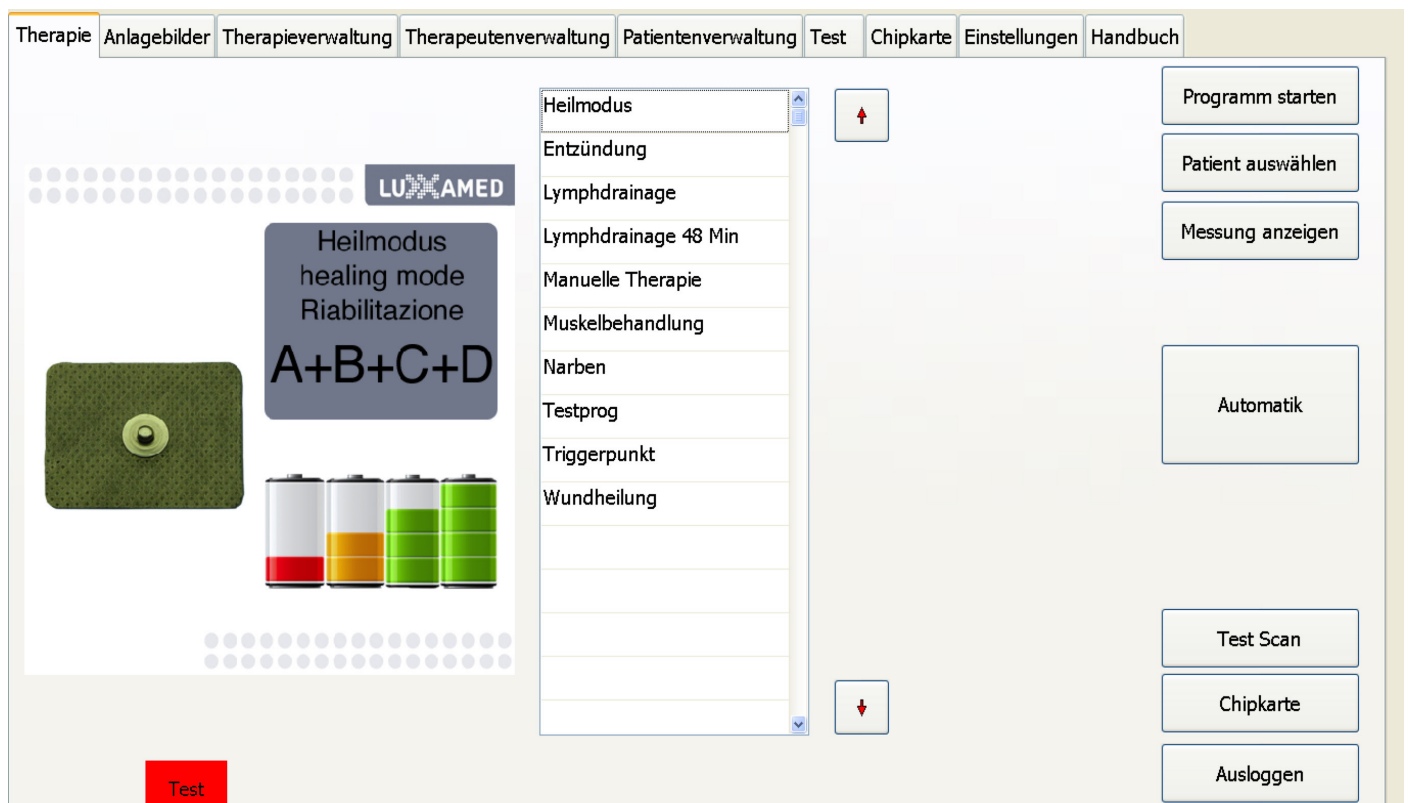
Therapy selection - fixed program

In order to select a pre-set fixed program (shown here in yellow), touch this program in the list. The list can be scrolled upwards or downwards using the arrows on the right next to the list of programs. No automatic measurement is carried out in the fixed programs.

In order to allocate the therapies carried out during the program sequence to a patient, the **"select patient"** button (shown here in yellow) can be used to display the list of patients. Touching an entry in the list (shown here in blue) selects the patient for the treatment to be carried out.

If no patient is selected, the measurement data is still recorded and can be allocated to a patient later. To start the programme, push **"start program"** in the list.
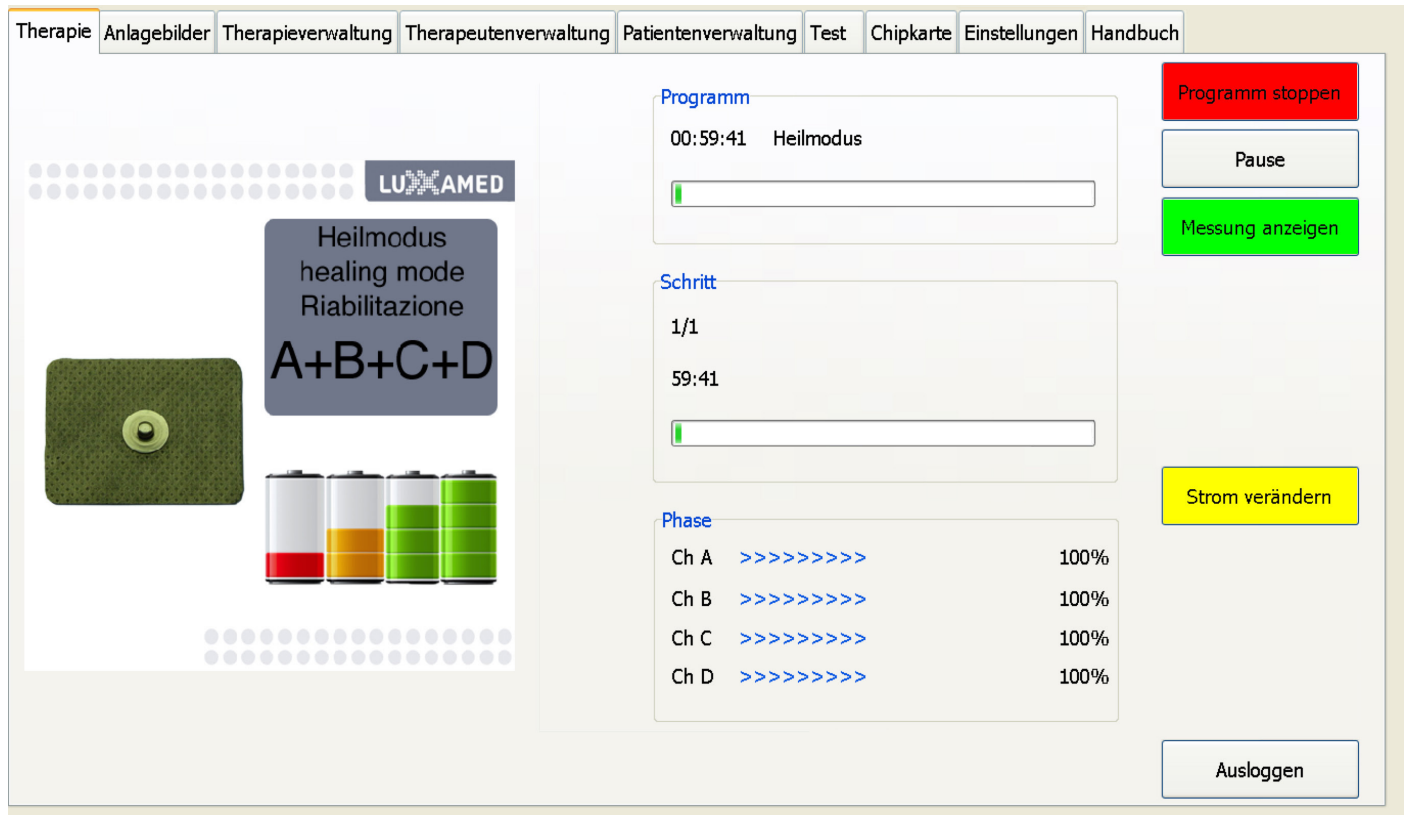
The selected patient is displayed in the bottom right of the screen. (shown here in red as a test)

To start the programme, push **"start program"** (shown here in red) in the list. The program name and the remaining time are shown both numerically and graphically under program. "Step" shows the current program step, the total number of steps in the selected program and the time remaining in the current step.

"Phase" is a graphic representation of which channels in the Luxxamed are currently active.

A program that has been started can be stopped by pushing **"stop program"** (shown here in green), or paused using the "pause" button.

The current in the individual channels can be regulated during treatment by pushing "change current". The range that can be set is between 0% and 150% of the value pre-set in the program. The value must then be accepted by pushing "confirm current".

The current in the individual channels can be regulated during treatment by pushing **"change current"**. The range that can be set is between 0% and 150% of the value pre-set in the program. The value must then be accepted by pushing "confirm current".

To display the progress of the measurements during treatment, push **"show measurement"**. This window shows the progression of the measurement values for the individual channels. The red lines in the diagram denote the start of a new therapy step.
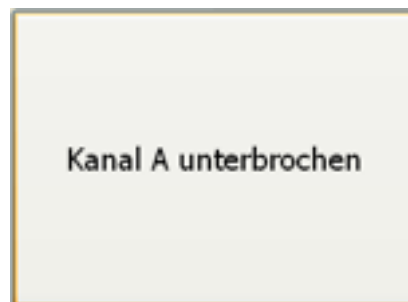

To display the program data again, push **"display program"** (shown here in blue).
The current strength can also be changed on this screen by pushing
"change current".

If no plausible measurement value can be measured for one of the channels which is in use (infinitely high resistance), a warning appears. If this happens, you need to check whether the adhesive electrodes are properly attached.

However, this is only a tip and can be closed again by clicking on the field where it is displayed. The interrupted channel is not switched off if this tip appears.

Test scan

You can carry out a 1-minute measurement analogue to the measurement in the "automatic mode" by pushing **"test scan"** (shown here in red. To do this, push **"test scan"** and the scan will start. Like with the fixed programmes, you can allocate the scan to a patient by pushing **"select patient"**.
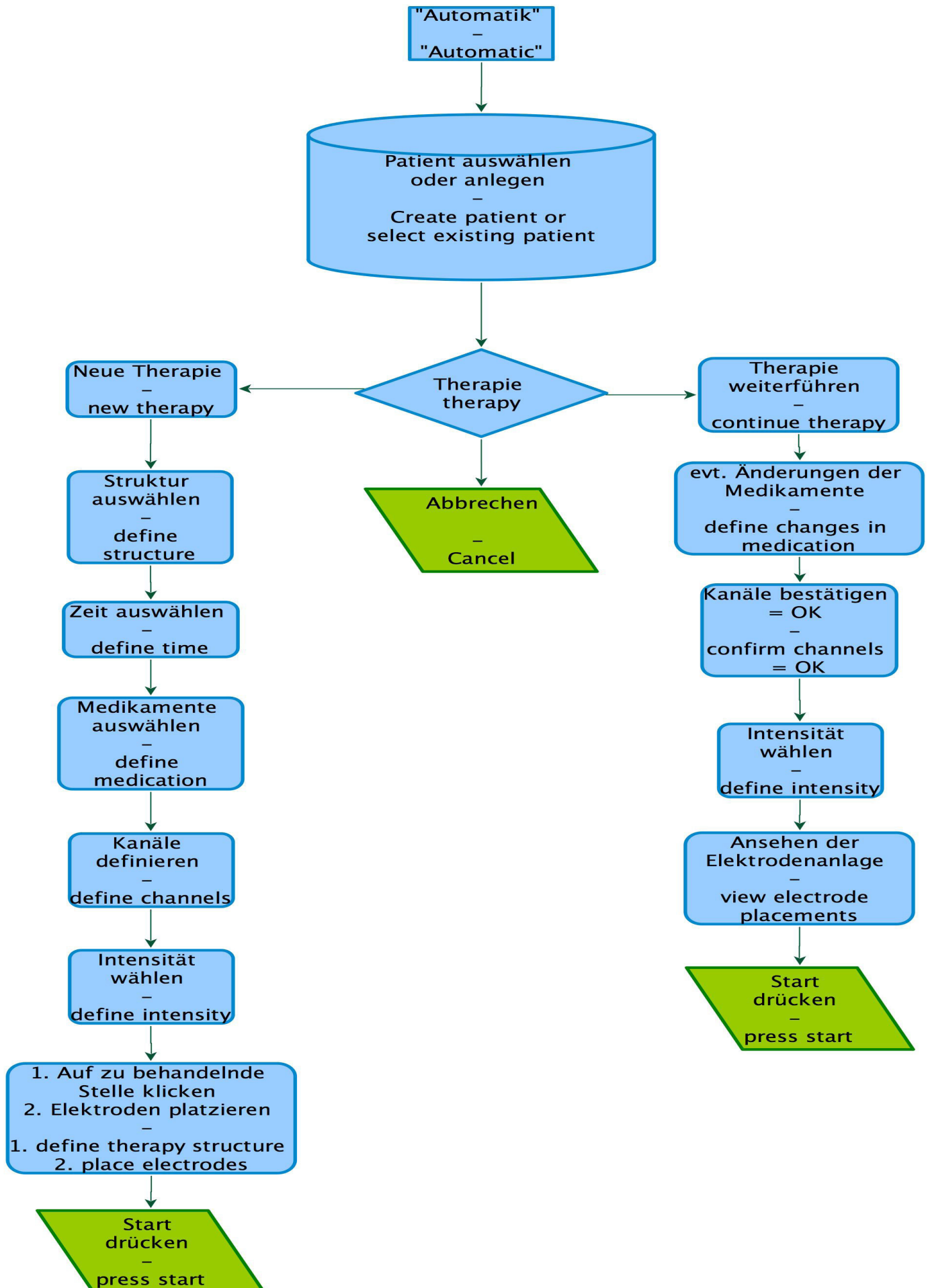

You can stop the test scan by pushing **"stop scan"** (shown here in yellow)**.** The scan will stop automatically after one minute of measurements.

Automatic mode

"Automatik"
–
"Automatic"

Patient auswählen
oder anlegen
–
Create patient or
select existing patient

Therapie
therapy

Neue Therapie
–
new therapy

Struktur
auswählen
–
define
structure

Zeit auswählen
–
define time

Medikamente
auswählen
–
define
medication

Kanäle
definieren
–
define channels

Intensität
wählen
–
define intensity

1. Auf zu behandelnde
Stelle klicken
2. Elektroden platzieren
–
1. define therapy structure
2. place electrodes

Start
drücken
–
press start

Abbrechen

–
Cancel

Therapie
weiterführen
–
continue therapy

evt. Änderungen der
Medikamente
–
define changes in
medication

Kanäle bestätigen
= OK
–
confirm channels
= OK

Intensität
wählen
–
define intensity

Ansehen der
Elektrodenanlage
–
view electrode
placements

Start
drücken
–
press start

In the automatic mode, patients can be treated largely automatically. The user simply enters the diagnosis and the device determines the course of treatment using this diagnosis and the measurement value.

The automatic mode is started by pushing **"automatic"** (shown here in blue). The patient to be treated is then selected from the patient management. The Luxxamed goes directly to the patient management once "automatic" has been selected.

Please note!
To start automatic treatment, just push "automatic". Do not push "select patient" first. In the automatic mode, you will be automatically guided through the Luxxamed menu.

Select/create patient

After pushing **"automatic"**, you will automatically be taken to patient management. Here you can use **"new patient"** (shown here in blue) to create a new patient or select an existing patient from the left-hand list (shown here in green). Ensure that you push **"confirm"** (shown here in red) after entering a new patient. The button appears on the right-hand side of the display after **"new patient" has been pushed.**

When you are creating a new patient, clicking in the "name" field (shown here in orange) will cause your digital keyboard to appear.

New therapy/continue therapy

You can then move on to the next step by pushing **"new therapy"** (shown here in green).
If you have already carried out therapy with the patient, you can continue with therapy by
pushing "continue therapy" **(shown here in blue)**.

| Therapie | Anlagebilder | Therapieverwaltung | Therapeutenverwaltung | Patientenverwaltung | Test | Chipkarte | Einstellungen | Handbuch |

Neue Therapie

Therapie weiterführen

Zurück

Abbrechen

ACHTEN SIE AUF DIE AUSWAHL DES RICHTIGEN PATIENTEN

TAKE CARE THAT THE CORRECT PATIENT IS SELECTED

AUTOMATIC STEP 3

Test

Ausloggen

Select treatment structure

If you are carrying out a new therapy, you can now select the structure for treatment from the
list on the left-hand side of your display (shown here in green). Then please enter chronicity
of the disease your patient has (shown here in blue).

| Therapie | Anlagebilder | Therapieverwaltung | Therapeutenverwaltung | Patientenverwaltung | Test | Chipkarte | Einstellungen | Handbuch |

Therapy

Gelenk
Gelenk + Muskel
Wirbelsäule
Wirbelsäule + Extremitä
Muskelsystem
Sehnen
Knochen
Vegetativum
Nervensystem peripher
Nervensystem zentral

Chronisch
○ akut
○ > 3 Mo.
○ > 6 Mo.

AUTOMATIC STEP 4

Zurück

Test

Ausloggen

Medications

Once you have set the settings described above, the "medication" window will appear in the display. Here you can select the medication your patient is taking from the list on the right-hand side (shown here in blue). The selected medications then appear in the list on the left-hand side (shown here in yellow). You can delete the medication by pushing it again in the list on the left-hand side. Confirm your entry by pushing **"OK"** (shown here in green), and you will be taken to the next page.

Define channels

On this page, you can set the channel configuration A-D. The following options are available: therapy, lymph and off (shown here in blue). When configuring the channels, please not that only a channel defined as a therapy channel is an autoregulating channel. If you set the setting "lymph", Luxxamed does not automatically make any adjustments. Confirm your entry by pushing **"OK"** (shown here in green), and you will be taken to the next page.

Select intensity

You can now choose the intensity (shown here in green) at which the Luxxamed should start the therapy. The standard is 100%. For very sensitive people you can also choose a lower amount. The intensity can be adjusted at any time during the program.

Therapie	Anlagebilder	Therapieverwaltung	Therapeutenverwaltung	Patientenverwaltung	Test	Chipkarte	Einstellungen	Handbuch

Intensität

10 %
20 %
30 %
40 %
50 %
60 %
70 %
80 %
90 %
100 %

AUTOMATIC STEP 7

Zurück

Test

Ausloggen

Saving electrode positions

In this entry step, you can save the arrangement of your adhesive electrodes. This is then displayed each time at this entry step when you continue therapy. For a "new therapy", the previously saved electrode position for that patient will be deleted.

First of all, you define the region to be treated by touching the figure. Green, expanding rings briefly appear. Now click on the firs electrode (shown here in yellow) and place this in the relevant position on the person. Repeat this process for all further electrodes and channels. Ensure that after you place the electrodes on the person you select the next electrode properly when you are entering it using the touch screen, otherwise you will remove the electrode you added previously. To place electrodes on the back of the person, push **"back"** (shown here in blue). When you have finished entering and placing the adhesive electrodes, push **"start"** (shown here in green) to start the therapy.

| Therapie | Anlagebilder | Therapieverwaltung | Therapeutenverwaltung | Patientenverwaltung | Test | Chipkarte | Einstellungen | Handbuch |

Behandlung

AUTOMATIC STEP 8

Zurück

A
A
B
B
C
C
D
D

Rücken

Start

Ausloggen

Test

While the automatic therapy runs, you can use the **"100%"** button (shown here in yellow) to adjust the current strength/intensity for all four channels A-D. You can stop the program early at any time by pushing **"stop"** (shown here in red).

Some information will now be shown on the display:

- *Information*: Patient name, remaining time in the session
- *Status*: Here the current strengths of the respective channels are displayed using graphs. The bars fill up in green. The current strength is automatically adjusted over the entire duration of therapy using the measurement data recorded by Luxxamed in the scan.
- *Progress*: Here you can identify the responsiveness of the tissue to be treated. The battery fills up in accordance with the result of therapy. However, the battery is not designed for a single treatment session but rather for a therapy series. It is therefore possible that the battery is only assembled after a subsequent session.
- *Conductive value:* Here you can see the current conductive value of the tissue for each channel individually. These data are later summarised in a diagram in the patient management.

AUTOMATIC MODE

Once the therapy has ended, "therapy ended" appears in the display. Clicking on this infor-mation ends the automatic session and takes you back to the home screen. You can view the recording of the automatic treatment in the menu item "patient management". It will remain saved there.

Continue therapy

To continue therapy on an existing patient as part of a therapy series, initially proceed with "automatic treatment" as described on page 34 et seq. Select the patient to be treated from the list of patients (shown here in green).

Now click on **"continue therapy"** (shown here in blue).

In the following steps, you will be guided through the Luxxamed menu as normal. You will be asked about any changes to the medication the patient is taking.

All of the subsequent steps are saved from the first treatment, you just have to confirm them. If you want to make any changes, for example to the definition of the channels, you should do this as a new therapy. When continuing therapy, all of the settings should be kept the same except for the medication. Use the image of the saved electrode positions to attach the electrodes to the patient in the same positions as they were in the first treatment. If you want to change the position of the electrodes, we recommend you start a new therapy using the "new therapy" button (shown here in blue).

Position images

Through the menu item position images you are presented with a selection of positioning recommendations/examples of how you can attach adhesive electrodes. In the categories (shown here in blue), you can select various different treatment areas. By clicking on the arrows (shown here in green), you can choose between various different options and are given examples of treatment using nanophoton therapy in the muscles and trigger points.

Therapy management

New programs can be created in therapy management. The desired program name can be entered in the input field.

In the input field step duration the duration of the program step can be entered in minutes and seconds. By pushing the + button next to the program step display you can move on to the next step, and by pushing the – button you can go back to the previous step. To add an additional step at the end of a program, push the + button until you have reached the final program step. If a value greater than zero is entered for the duration of the step, both the current number of steps and the total number of steps can be increased by repeatedly pushing the + button.

The desired values for the four channels can be entered under current, frequency and increase. The values entered will each be rounded up to the closest permissible value. The polarity of the channels is selected using the buttons which appear when you touch the polarity field for the respective channel.

Under channel L1 and channel L2 you can select the current channels to which the two light channels L1 and L2 are allocated. The current values are ignored for this, and the intensity of the light is to be entered in the two input fields on the right-hand side adjacent to the selection fields.

Pushing "insert step" inserts an empty program step before the program step which is currently selected.

Pushing "delete step" deletes the currently selected program step from the program.

Pushing "confirm" accepts the changes to the program; pushing "cancel" discards all of the changes.

Chip card

Pushing "chip card" takes you to a mode in which chip cards (known as master cards) can be read and written. After pushing the button, insert the card into the device's card reader. Then push "read card". After a short pause, the programs on the card will be displayed in the program list. Selecting a program displays the program details. Entering a program is carried out as described above, but only two channels are available, the number of steps is limited to 4 and no changes can be made to the light channel settings.

Once the changes to the card program are complete, the data can be saved on the card by pushing "write card".

To switch from the chip card program back to the programs available in the device, push "internal".

Chip cards are created to be compatible with the predecessor devices Clinic Master and Vital Master. The creation of chip cards is intended exclusively for this field.

Therapist management

Under the "therapist management" tab, the administrator can create new therapists who can use the device, change the data for existing therapists and delete existing therapists. In addition to the administrator, a maximum of ten therapists can be created.

However, the additionally created therapists have limited rights to operate the Luxxamed.

Create therapist

A new therapist is created by pushing "new therapist". The desired username can be entered in the input field "name" and the password to be attached to this username can be entered in the input field "password". The entries can be accepted by pushing "confirm" or discarded by pushing "cancel".

Change therapist

The data for a therapist can be changed by pushing "change". The entries can be accepted by pushing "confirm" or discarded by pushing "cancel".

Delete therapist

Pushing "delete therapist" permanently deletes the selected therapist from the list of therapists.

Patient management

Under the "patient management" tab, the administrator can create new patients, change the data for existing patients and view recordings made for treatments which have already been carried out. In the left-hand column (shown here in green), you will find all of the patients who have already been created sorted alphabetically. You can scroll through the patients by clicking on the two arrow keys (shown here in orange).

Create patient

A new patient is created by pushing **"new patient"**. The desired username can be entered in the input field "name" and the patient's date of birth can be entered in the input field "date of birth". It is also possible to allocate a unique number to each patient under "patient number". General notes on the patient can also be entered in the field "notes". The entries can be accepted by pushing **"confirm"** or discarded by pushing "cancel". The "confirm" button is on the right-hand side of the screen. If your entries are not confirmed they will not be saved!

Change patient

The data for a patient can be changed by pushing "change". This also includes changing the treatment data. The entries can be accepted by pushing "confirm" or discarded by pushing "cancel".

Delete patient

Pushing "delete patient" permanently deletes the selected patient from the list of patients. This also deletes the treatment data stored.

Display treatment data

The treatment given to a patient to date is shown in the table on the right-hand side of the screen (shown here in yellow) with the name of the treatment carried out and the treatment date. Selecting one of these treatments displays the notes entered for this treatment, the pain values before and after treatment and the progression of the measurement curves during treatment.

Touching the measurement value diagram displays this in an enlarged view to enable the closer inspection of the progression of the measurement values. Clicking in an "empty" area of the screen shrinks the diagram again.

Change treatment data

It is possible to save certain data for each treatment session. Notes can also be made for each session and the pain subjectively experienced by a patient before and after treatment can also be saved to assess the success of treatment. To save data, select the relevant patient in the list (shown here in green). Then switch to editing mode by pushing **"change patient"**. The session to be edited can then be selected in the table on the right-hand side (shown here in yellow). Touching the "notices" field brings up a keyboard that can be used to enter the notes about the therapy session. The pain value can be entered by touching the arrow on the right-hand side next to the field "pain before" or "pain after". The relevant value can be selected by touch in the table which has now opened. The entries can be accepted by pushing **"confirm"** or discarded by pushing **"cancel"**.

Delete treatment data

If treatment data which is no longer needed is to be deleted, select the relevant patient and then switch to the editing mode by pushing "change". Once you have chosen the session which is no longer required from the list of therapy sessions, it can be permanently deleted by pushing "delete session".

Allocate treatment data

If no patient is selected before the start of treatment or the wrong patient is accidentally selected, the data can be allocated to another patient at a later point. To to this, select the treatment session which is to be allocated (from the unsorted or incorrectly selected patients), then push "allocate session" and then select the correct patient.

Unsorted treatment data

Treatment data which has not bee allocated to any patient can be displayed by pushing "display unsorted". These data can be allocated to a patient as described under treatment data. If the data are no longer required, they can be permanently deleted by pushing "delete unsorted".

Test

The measurement values for the skin resistance measurement on all four channels can be displayed in the "test" tab. Pushing **"start test"** (shown here in green) starts a continuous measurement which updates the measurement values once a second. The continuous measurement can be stopped by pushing **"stop"**. This function can also be used to test the functionality of the cable. Hold both ends of the cable for the channels together and start the test. The green bars in the display should be completely full. If this is not the case, touch the metal ends on one another to ensure contact. If the respective channel or green bar still does not fill up, there is a problem with the cable. Stop using this cable for treatment and contact the manufacturer.

⠿ettings

The "settings" tab can be used to change a number of basic settings on the device.

Language
The system language for Luxxamed can be set under "language". Please note that the device has to be restarted for the language to change.

"**Save settings**" accepts the changes.

Export data
The **"export data"** button enables the measurement curves saved in the device as comma-separated files to be exported to a USB stick.

Back-up
Pushing **"back-up"** saves the patient management data onto a USB stick. To do this, insert a standard USB stick into one of the USB slots on the device and push **"back-up"**. We recommend repeating this step at regular intervals.

Update
Pushing "update" will update your device with the latest software if the system has been updated. The manufacturer will provide the relevant version on a USB stick for this purpose. The procedure is the same as for a back-up. Insert the USB stick into the USB slot and push **"update"**. The program will automatically restart after completion of the update. Only use sticks provided by the manufacturer for the update, otherwise you may cause damage to the software. After an update, restart the device using the on/off switch on the device.

Software version
You can view the version of the software that you are currently using under "settings" in the bottom left. (Here: **SW Ver.: 2.0**)

Printing of patient data
To print the patient data and therapy curves there are two options available. You can print a single session or all therapeutic sessions and scans in the respective patient database:
- Single session: Select a patient in the database. Now plug in an USB-Stick in one of the free USB-ports on your HD2000. Now press the button „Printing Session". While pressing the button, the device creates a PDF file which will be stored on the USB-Stick.

Be aware the any USB-Stick must be plugged of in case of starting or restarting the device. If not, the device could not be started. In those cases just plug of the USB-Stick and restart the device again.

- Patient printing: To print all patient data's in one PDF file plug in the USB stick like before and press the button „Patient print". Now a PDF file will be stored on the USB stick which contains all sessions and scans of the selected patient.

Storage

Please store the device in a dry place out of reach of children and do not use it in an environment which is exposed to the following influences.

- magnetic fields and/or electromagnetic radiation
- very high or very low temperatures (above 40°C or below 0°C storage temperature). If the device has been exposed to very low temperatures and is to be used in a warm room, you should wait for 1 to 2 hours for it to acclimatise so the condensation can evaporate.
- high levels of humidity
- direct sunlight

Do not place any containers of liquid on the device!
The device must be placed on a flat surface for operation and storage and the brake must be applied to the wheels.

Cleaning and care

Unplug the device from the power supply before cleaning it. The housing and the cable can be cleaned with water and a mild detergent using a soft cloth which is no more than damp. Please ensure that no liquid gets into the openings on the Luxxamed and do not use a spray. When cleaning the screen in particular, ensure that it is not damaged by strong or abrasive detergents.

Ensure that no drops of water remain on the screen. Water can cause permanent discolouration.
Only use suitable cleaning agents such as glass cleaner or monitor cleaner to clean the screen.
The electrodes must be replaced after each use.
Check the device connection cable and the plug for damage before each use. Damaged wires may not be used any more.
Contact your dealer.

▦isinfection

Only use alcohol-based disinfectants to disinfect the Luxxamed HD2000. The manufacturer recommends the use of the following disinfectants:

- Kodan-Tiktur forte (Schülke & Mayr)
- Softasept N colourless (B. Braun)
- Sterillium (Bode Chemie)

▦aintenance

The Luxxamed HD2000 is fundamentally maintenance-free.

Safety/metrological control

Since this device is a medical device, the manufacturer stipulates that there must be an annual safety/metrological control. Contact the manufacturer to carry out this control.

Caution!
The device may only be opened by staff we have trained to do so.

Note:
There are no parts that require maintenance or cleaning inside the device.

Technical data

Product:	HD2000
Product type:	micro current device
Product form:	case
Material type:	aluminium, stainless steel, metal
Housing protection type:	IP20
CE marking:	CE0044
MPA classification:	Class IIa medicinal device with BF-type application part
UMDNS classification:	electrotherapy device (11-503)
Dimensions:	WxDxH 600mm x 220mm x 500mm
Weight:	36kg
Electricity supply;	90-264VAC – 47-63Hz
Max. power consumption:	300W
Temperature range during operation:	0° - 40°C
Relative humidity during operation:	40 - 90% (non-condensing)
Relative air pressure during operation:	70kPA - 106kPA
Storage/transportation temperature:	-40°C - +70°C
Storage/transport humidity:	10% - 100%
Patient outputs:	4
Patient output current:	1µA – 999µA in 1µA steps
Patient output voltage (max.):	60V
Patient output frequency:	0.1Hz – 10kHz in 0.1Hz steps

Light outputs:	2
Light output current:	50µA – 200mA in 200µA steps
Light output voltage (max.):	5V
Light output frequency:	0.1Hz – 10kHz in 0.1Hz steps
Diagnosis:	Logarithmic measurement (+/- 5% of Ω value)
Blue light wavelength:	465nm
Red light wavelength:	625nm

Wave form

Rise of the wave slop until max. voltage

DC signal of 40Hz, resistive load 95kΩ

single impulse

NOTE!

Relation between current and resistance

The Luxxamed is capable to produce a maximum voltage V (volts) of 60 V per channel. The maximum current is 990 micro ampere depending on the current resistance in kOhm. (See chart on the next page)

Mikroampere im Verhältnis zum Widerstand in kΩ

Wert (Y-Achse im Diagramm)	kΩ	µA max.
120	0	990
110	10	990
100	20	990
90	30	990
80	46,25	990
70	62,5	960
60	78,75	761
50	95	630
40	158,75	377
30	222,5	269
20	286,25	209
10	350	170
0	∞	0

⠿⠿arning!

Important warning about the Luxxamed HD2000

Warnings and manufacturer declarations on electromagnetic tolerance in accordance with DIN EN 60601-1-2:2007
The HD2000 may not be operated directly adjacent to other electromagnetic devices or stacked with other electromagnetic devices. If this type of operation is unavoidable, the HD2000 must be monitored to check that it is operating as intended in this arrangement.

The Luxxamed HD2000 is sensitive to ESD (electrostatic discharge)!

If there is electrostatic discharge from the Luxxamed HD2000 during its operation, it is possible that the device may switch to a planned safety mode and the ongoing therapy may switch off.
To continue the therapy with the patient, switch the device off and back on again using the mains switch. The HD2000 must be restarted if it is in "safety mode".

Electrostatics (ESD) [Information]

Electrostatics is the oldest field in electrical engineering. As far back as in Ancient Greece, Thales of Miletus discovered that if you rub amber it attracts small, light particles. So the Greek word electron, meaning amber, gave the modern-day study of electricity its name. "Rubbing electricity"

Electrostatic energy occurs everywhere that charge is transferred by rubbing (or more specifically by the contact and separation of surfaces). In order for this to occur, at least one of the two contact partners must be an insulator. In very think layers on the surface (Helmholtz boundary layers) charge carriers can migrate from one surface to another even in non-conducting materials.

Measures to prevent static discharge in the Luxxamed HD2000:

- Increase the relative humidity to 50%-60%
- Discharge yourself and the patient at an earthed point before operating the Luxxamed (e.g. radiator, metallic door frame etc.)
- Only use the Luxxamed in rooms with wooden or concrete floors. Use on ceramic tiles is also conceivable.

You can find more information on electromagnetic interference immunity in the Luxxamed HD2000 in the tables on pages 63 to 66 of these instructions.

Declaration of conformity

Technische Dokumentation - Technical documentation
Medizinprodukt - Medical product:
Luxxamed HD3000

Konformitätserklärung - Declaration of conformity

EG-Konformitätserklärung - European declaration of conformity

Entsprechend Anhang VII der Richtlinie 93/42/EWG über Medizinprodukte
According to addendum VII of the guid line 93/42/EG for medical products

Wir / We:

Luxxamed GmbH
Fiedlerstr. 20
34127 Kassel
Germany

erklären in alleiniger Verantworung, dass das Produkt
declare under our sole risponbility that the product

LUXXAMED
HD 2000

mit den Anforderungen der Richtlinie 93/42/EWG übereinstimmt.
conformity to the guide line 93/42/EG.

Durchgeführt wurde das Konformitätsbewertungsverfahren durchgeführt nach Anhang V von der Firma
Luxxamed GmbH
The conformity assessment procedures was realized by the Luxxamed GmbH according to annex V

C E 0044

Notified body:
TÜV Nord CERT GmbH - Langemarckstraße 20 - 45141 Essen Germany

Gültig bis: 2017-08-15
vaild until: 2017-08-15

Kassel, 2014-04-14

Geschäftsleitung DManagement

Manufacturer's declaration – EMC Guidelines

Guidelines on the manufacturer's declaration – electromagnetic emitted interference		
The Luxxamed HD2000 is intended for operation in an electromagnetic environment as indicated below. Users of the Luxxamed HD2000 should ensure that it is operated in an environment of this type.		
Emitted interference measurement	**Compliance**	**Electromagnetic environment – guideline**
1 HF emission in accordance with CISPR 11	Group 1	The Luxxamed HD2000 uses high frequency energy exclusively for its internal function. Its HF emission is therefore very low and it is unlikely that adjacent electronic devices will be disturbed.
2 HF emission in accordance with CISPR 11	Class B	The Luxxamed HD2000 is suitable for use in all establishments including domestic establishments and those that are directly connected to a public power grid that also serves buildings for residential use.
3 Emissions from fluctuations in voltage/flickers in accordance with IEC 61000-3-3	Not applicable	

Guidelines and manufacturer's declaration – electromagnetic emitted interference			
The Luxxamed HD2000 is intended for operation in an electromagnetic environment as indicated below. Users of the Luxxamed HD2000 should ensure that it is operated in an environment of this type.			
Interference immunity tests	**IEC 60601 testing level**	**Compliance level**	**Electromagnetic environment guideline**
Conducted HF interference according to IEC 61000-4-6	10V *effective value* 150kHz to 80MHZ	10V	$d = [\frac{3,5}{10}]\sqrt{P}$
Radiated HF interference according to IEC 61000-4-3	10V/m 80 MHz to 2.5 GHz	10V/m	$d = [\frac{3,5}{10}]\sqrt{P}$ P* for 80MHz to 800 MHz $d = [\frac{7}{10}]\sqrt{P}$ P* for 800 MHz to 2.5 GHz
with *P as the nominal capacity of the transmitter in watts (W) according to information provided by the transmitter manufacturer and d as the recommended safety distance in metres (m). The field strength of stationary radio transmitters should be less than the compliance level (b) at all frequencies based on an examination on site (a). Interference is possible around devices which bear the following pictograms.			
Note 1: The higher frequency range applies at 80 MHz and 800 MHz			
Note 2: These guidelines may not be applicable in all cases. The propagation of electromagnetic parameters is affected by the absorptions and reflections of buildings, objects and persons.			
a) The field strength of stationary transmitters such as base stations for radio telephones and mobile land radio devices, amateur radio stations, AM and FM radio and television devices can theoretically not be accurately determined in advance. In order to determine the electromagnetic environment for the stationary transmitter, a study of the electromagnetic phenomena at the location should be considered. If the field strength measured at the location at which the Luxxamed HD2000 is used exceeds the above mentioned compliance level, the Luxxamed HD2000 should be monitored to prove that it is functioning correctly. If unusual features are observed, additional measures such as a change in alignment or a different location for the Luxxamed HD2000 may be necessary. b) Above the frequency range from 150 kHz to 80 MHz, the field strength should be less than 10V/m.			

Recommended safety distances between portable and mobile HF telecommunication devices and the Luxxamed HD2000			
The Luxxamed HD2000 is intended for operation in an electromagnetic environment in which the HF interference is controlled. The user of the Luxxamed HD 3000 can help avoid electromagnetic interference by maintaining a minimum distance between portable and mobile HF telecommunication equipment (transmitters) and the Luxxamed HD2000, depending on the output power of the communication device, as specified below.			
Nominal capacity of the transmitter in W	Safety distance, depending on the transmission frequency m		
	150 kHz to 80 MHz $d=[\frac{3,5}{10}]\sqrt{P}$	80 MHz to 800 MHz $d=[\frac{3,5}{10}]\sqrt{P}$	800 MHz to 2.5 GHz $d=[\frac{7}{10}]\sqrt{P}$
0.01	0.04	0.04	0.07
0.1	0.11	0.11	0.22
1	0.35	0.35	0.7
2	0.78	0.78	1.57
10	1.11	1.11	2.21
100	3.50	3.50	7.00

The recommended protective distance d in metres (m) can be determined for transmitters whose maximum nominal power is not provided in the table above by using the equation associated with the respective column, where P is the maximum nominal power of the transmitter in Watts (W) according to the specification of the manufacturer of the transmitter.

Note 1: The higher frequency range applies at 80 MHz and 800 MHz.

Note 2: These guidelines may not be applicable in all cases. The propagation of electromagnetic parameters is affected by the absorptions and reflections of buildings, objects and persons.

EMC GUIDELINES

Guidelines and manufacturer's declaration – electromagnetic emitted interference			
The Luxxamed HD2000 is intended for operation in the electromagnetic environment indicated below. Users of the Luxxamed HD2000 should ensure that it is used in an environment of this type.			
Interference immunity tests	IEC 60601 testing level	Compliance level	Electromagnetic environment guideline
Electrostatic discharge (ESD) in accordance with IEC 61000-4-2	+/- 6 kV contact discharge +/- 8kV air discharge	< ± 1 kV < ± 1 kV	Floors should be made of wood or concrete or be covered with ceramic tiles. If the floors are made of a synthetic material, the relative humidity must be at least 40%.
Rapid transient electrical interference/Burts in accordance with IEC 61000-4-4	+/- 2kV for grid supply +/- 1kV for input and output supply	± 2kV ± 1kV	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Surge voltages in accordance with IEC 61000-4-5	+/- 1kV voltage Outer cable-outer cable +/- 2 kV voltage Outer cable-earth	± 1kV ± 2 kV	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Voltage drops, temporary interruptions and fluctuations in the supply voltage in accordance with IEC 61000-4-11	< 5% U_T (> 95% drop in the U_T) for 1/2 of the period 40% U_T (60% drop in the U_T) for 5 periods 70% U_T (30% drop in the U_T) for 5 periods <5 % U_T (> 95% drop in the U_T) for 5 s	< 5% U_T (> 95% drop in the U_T) for 1/2 of the period 40% U_T (60% drop in the U_T) for 5 periods 70% U_T (30% drop in the U_T) for 5 periods <5 % U_T (> 95% drop in the U_T) for 5 s	The quality of the supply voltage should correspond to that of a typical business or hospital environment. It is recommended to power the Luxxamed HD2000 from an uninterruptible power supply or a battery if the user requires continued functioning of the Luxxamed HD2000 even during power outages.
Magnetic field at the supply frequency (50/60 Hz) in accordance with IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields at the mains frequency should correspond to the typical value as found in a business or hospital environment
Note: U_T is the mains AC voltage before the use of the testing level			

Consumables and accessories

You can order consumables and accessories easily via our partner online shop:
www.klebeelektrode.de

Artikel-Nr.	Bezeichnung
LX9100	patient wires
LX9210	patient wires LED light
LX9210	light pen LED
LX9220	light applicator middle
LX9230	light applicator big
LX9020	adhesive electrodes (45x30 mm)
LX9030	adhesive electrodes (80x45 mm)
LX9235	wrap for light applicators

Manufacturer information

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Quality management in accordance with
DIN EN ISO 13485,
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