GME
German Medical Engineering

GME LinScan

User Manual

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Like for any technical device, the medical devices of GME German Medical Engineering GmbH are subject to ongoing developments. Even though the publisher has taken all possible care that the information contained in this manual is correct and corresponds to the knowledge at the release of the manual, it is nevertheless subject to changes and errors.

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1. General Information

This manual is directed exclusively to users who possess the necessary medical knowledge to operate the device in accordance with the legal requirements and have received training in device handling. All other persons are not permitted to use the equipment.

The instructions have to be observed in all dealings with the device. This includes transportation, unpacking, installation, medical application, maintenance, decommissioning and scrapping.

In the instructions you will find two types of advice for potential hazards:

1. Fields with the heading "Caution!" indicate hazards, which can damage the device (or possibly other connected medical devices). Such damage can also be the loss of patient or system data. Precautions are proposed to avoid this damage.
2. Fields with the heading "Warning!" indicate hazards by which the patient, the user or third persons may be injured. Measures are proposed to minimize the risk of injury.

Example:

	**Caution! (Or Warning!)** **Hazard: There is the hazard that ...** **Action: Avoid ...**

2. General Hazards and Safety Measures

When using this medical device, the user has to take into account the general hazards described in this chapter and observe the prescribed safety measures.

In addition to these general hazards there are additional risks that occur at various stages of use. These are described in the chapters on these stages.

2.1 Main Hazards and Measures

	**Warning!** **Hazard:** The use of controls or settings or performance of procedures other than those specified herein may result in the emission of dangerous electromagnetic radiation. **Action:** Follow the instructions in this manual exactly and do not use any other controls.

	**Warning!** **Hazard:** Wireless communication devices, such as for example mobile phones, portable phones or headsets can interfere with the unit. **Action:** Wireless communication devices have to be switched off before starting treatment.

	**Warning!** **Hazard:** The device emits electromagnetic radiation. The effect on cardiac pacemaker is not known. It cannot be excluded that this radiation affects the proper functioning of the pacemaker. **Measure:** Persons with pacemakers should not be present in the treatment room during device operation.

	**Warning!** **Hazard:** The device emits electromagnetic radiation. The effect on pregnant women is not known. Damage cannot be excluded. **Action:** Pregnant women must not be present in the treatment room during device operation.

	**Warning!** **Hazard:** Improper use may result in hazardous laser radiation being emitted uncontrolledly. This can lead to irreparable eye or skin damage for persons present in the treatment room. **Action:** The user manual has to be read completely by the user before using the device. The instructions contained in this manual have to be complied with.

	**Warning!** **Hazard:** Improper use may damage the patient during treatment. **Action:** The user must have the necessary and, where legally required, medical expertise and be fully trained on the use of this device. Without medical expertise and instructions in the use of the device, the device may not be operated.

	**Warning!** **Hazard:** When the device is operated by unauthorized persons, the persons present in the treatment room may be irreparably damaged. **Action:** The device is secured entry against unauthorized use by a PIN. This PIN protection implements the function of a key switch. Therefore the user must not disclose the PIN to unauthorized persons, or note it on / near the device.

	**Warning!** **Hazard:** The high power density in the laser beam of the device may ignite inflammatory substances, such as gases or liquids and cause fire or explosions. Especially when working in the vicinity of tubes or cavities of the body that contain flammable substances, there is a fire and explosion hazard. **Action:** The user must take precautions to avoid fire or explosion hazard.

	**Warning!** **Hazard:** The technological and medical advances may mean that the technology used and / or medical application may be outdated and the benefit from the device might no longer outweigh the risks after 10 years. **Action:** The life time of the unit is limited to 10 years from the date of first use. After this time, the intended use of the device has to be re-evaluated by the manufacturer. Further use is permitted only with a positive assessment.

	**Warning!** **Hazard:** The smoke or vapor generated by the laser light may contain viable biological material such as viruses or bacteria. Therefore there is a risk of transmission of diseases or infection. **Action:** Use a mask and / or smoke evacuation during treatment.

	**Warning!** **Hazard:** The unit is connected to the mains. The mains voltages can cause an electric shock upon touching the device if the device does not work properly or is damaged. This can lead to injury or even death. **Action:** Check that the device and especially the cables are in an undamaged condition before switching on.

	**Warning!** **Hazard:** The unit is connected to the mains. The mains voltages can cause an electric shock upon touching the device if the device does not work properly or is damaged. This can lead to injury or even death. **Action:** Check that you have purchased the product from GME or an approved GME distributor before switching on. Do not switch the unit on if you cannot exclude that an unauthorized manipulation to the device has been done or that it has been opened by an unauthorized person. This device may not be modified without the permission of the manufacturer. If the unit has been modified, appropriate examinations and tests have to be are carried out in order to ensure safe use.

	**Warning!** **Hazard:** The unit is connected to the mains. The mains voltages can cause an electric shock upon touching the device if the device does not work properly or is damaged. This can lead to injury or even death. **Action:** Maintenance and repair works on the device may only be performed by GME or an authorized GME distributor.

	**Warning!** **Hazard:** The unit is a Class I electrical medical device. It must therefore be connected with protective earth conductor to a utility grid. The voltages applied here can otherwise cause injuries or death due to an electrical shock upon touching if the device is damaged or not working properly. **Action:** Warning! To avoid the risk of electric shock, this unit must be connected to a power supply line using a protective earth conductor.

	**Warning!** **Hazard:** The device is an electrical product with integrated liquid-cooling circuit. In the case of a liquid leakage with liquid covering electronic components of the device, there is the risk of device malfunctions and electric shock. This electric shock could cause injuries and even death. **Action:** Attention! Before switching on the device check if there is cooling liquid close to, under, or at the device. In order to avoid the risk of an electric shock the device may only be switched on if the test showed no visible liquid. In case of a leakage during device operation, switch off the device immediately by using the main switch on the left side of the housing.

2.2 Device Description and Security Concept

The device LinScan consists of a base unit and an applicator. Both are connected by a hose.

The base unit contains most of the controls, such as the touch-screen, the on / off switch or the emergency stop button. In addition the power cord, foot switch, the door plug and USB devices are connected there. The touch-screen serves as the main control panel.

	**Warning!** **Hazard:** If the touch-screen is defective, damaged, poorly legible or filthy this may lead to incorrect treatment settings. In this way the patient may be injured. **Action:** Do not use the unit with a defective, damaged, poorly legible or filthy touch-screen. If necessary, clean the touch-screen or call service to have a repair / maintenance performed.

The applicator directs the laser light along an optical path to a scanning device for deflecting the laser beam. The applicator is hand-held by the user and placed onto the skin. It has a hand switch on the front of the handle.

During development and manufacturing applicable directives, legal requirements and standards for medical devices were considered. Your product complies to them.

If you turn on the device, then the unit performs several tests automatically. Thereby the proper functioning of the device - according to the specifications - is ensured. As soon as these tests have been completed successfully, the device is ready for parameter selection and patient treatment. In addition to the initial tests a number of device functions and parameters are monitored continuously.

If the unit detects abnormalities or defects, then it reacts depending on the nature and importance by a notice, a warning or error message. This message needs to be confirmed by the user. Depending on the message one of the following cases is possible:

- the user needs to perform an action to eliminate the cause of the message (Example: The user has to take his foot off the foot switch or order a device service)
- the user must wait for a change of parameters (Example: the temperature of the device is too low, the user must wait until the unit has warmed up sufficiently.)
- the device attempts to resolve the cause of the error and performs a re-test (Example: a too high / low laser power was measured. The device performs an adjustment of power.)
- A reboot of the device is required. The device switches off automatically.

	**Caution!** **Hazard:** Not observing device messages may result in damage or malfunction of the device. **Action:** Make sure you follow the instructions that are displayed by your device.

	**Warning!** **Hazard:** Not observing device messages may result in device malfunction and injury to patients, users or other persons present in the treatment room. **Action:** Make sure you follow the instructions that are displayed by your device.

2.3 Eye Protection

The device LinScan emits laser radiation in both the visible (target beam) and invisible regime. This radiation can damage the eyes of all persons present in the treatment room. Therefore, all people in the room have to wear eye protection. The user and any other people in the room except the patient must wear protective eyewear that meets the specifications below. For patients, there is a choice between protective goggles or ocular shield.

The LinScan is a class 4 laser, i.e., it may cause damage eyes and skin. At the laser wavelength of 808nm or 980nm the laser radiation has the following characteristic values:

- The maximum permissible exposure (MPE) is 16 W / m ²
- The safety distance for damage to the eyes (NOHD) is 4.36 km.
- The minimum optical density (OD) of the eye protection goggles for all persons within the safety distance is 6

The standard EN 207 defines the classification of protective eyewear. The protective eyewear used for the LinScan 808 must carry at least the following markings:

D 808 LB 6

The protective eyewear used for the LinScan 980 must carry at least the following markings:

D 980 LB 6

This means:

- Operating Mode D (= CW emission) and I (=pulsed emission)
- Wavelength 808nm or 980nm (it is also possible that a wavelength interval is specified which includes 808nm or 980nm, such as e.g. 800-1000)
- Protective Level LB 6 (a higher level of protection may also be selected)

	**Warning!** **Hazard:** The laser light may damage the eyes of all people in the room even by only indirect irradiation or diffuse reflection beyond repair and result in blindness. **Action:** All people in the room must wear eye protection that meets the requirements defined above. Make sure of eye protection that is undamaged and in perfect condition before each use. Never look directly into the laser beam even with eye protection.

2.4 Patient Protection

Due to the treatment the patient is subject to hazards which are described below and can be minimized by the measures described.

- To protect the patients against allergic or toxic reactions and irritation from contact with parts, only accessory parts authorized by GME may be used. Only for these parts biocompatibility is ensured.
- Infectious biological material can be transmitted by not properly disinfected parts which contact the patient. Disinfect any parts that touch the patient after each patient!
- To protect the eyes, protective measures in accordance with Section 2.3 have to be taken.
- Substances applied to the skin of the patient, such as creams, ointments, perfumes, or ingested photosensitizing drugs can alter the interaction of the incident light with the skin. This might cause injury to the skin of the patient. Therefore, the ingestion of such drugs should be asked for by the practitioner before the treatment. If the patient has taken such drugs he/she should not be treated. Similarly, the treatment zones have to be cleaned of all applied substances before treatment.
- The use of accessories not authorized by the manufacturer can lead both to a change in the clinical effect as well as to a change in the actual treatment parameters. Therefore, only accessories authorized by GME may be used. This stays valid even if the manufacturer of the accessory issued a release document or a test laboratory states the innocuousness.

3. Intended Use

The device LinScan is a diode laser (808nm or 980nm) with scanner for dermatological treatments. Upon impingement of the laser radiation on the skin, the infrared light is mainly absorbed by the melanin and hemoglobin in the skin. Skin structures containing melanin and hemoglobin, like e.g. hair, pigmented lesions, blood vessels are thus heated more strongly than the surrounding tissue. These structures are thus damaged irreversibly or are coagulated.

3.1 Intended Use

The intended use of the device LinScan is:

- Permanent hair removal
- Vascular lesions including angiomas, hemangiomas, telangiectasia, leg veins
- Pigmented lesions
- Pseudofolliculitis barbae
- Onychomycosis

3.2 Side effects and Complications

The following side effects and complications have been reported in treatments with the same or similar intended use in the literature and can therefore occur also in treatments with the LinScan:

a) For all indications

- Erythema
- Blister formation
- Edema
- Pigmented lesions (lentigines) and freckles may bleach or disappear
- Light Pain
- Postinflammatory hyperpigmentation
- Hypopigmentation
- Scarring
- Herpes simplex
- Purpura
- Hyperhidrosis (increased sweating)
- Bromhidrosis (strong smell and excessive sweating)
- Leukotrichia (White hair)

b) In addition to a) for the indication onychomycosis

- Hematomas
- Nail deformities
- Nail discoloration
- Onycholysis

3.3 Contraindications

For treatment with the LinScan the following contraindications exist:

a) For all indications:

- Long healing periods after preceding treatments
- Tanned skin
- Known keloid formation or anormal scar formation
- Predisposition for hypo- or hyperpigmentation
- Isotretinoin medication
- Photosensitizing medication like tetracylines or retinoids
- Hydroquinone or other bleaching agents

- Known herpes infection in treatment area
- Tattoo in treatment area
- Pregnancy

b) In addition to a) for the indication hair removal:
- Use of other hair removal devices or other hair removal methods like e.g., waxing, hair plucking, or hair removal by electrolysis during the preceding 6 weeks

c) In addition to a) for the indication vascular:
- Blood coagulation disorders
- Anti-coagulation medication
- Presence of varices that are feeding telangiectasias

d) In addition to a) for the indication pigments:
- Blood coagulation disorders
- Personal or family history of melanoma
- Dysplastic nevi
- Lack of ability or will to obey physician's orders

e) In addition to a) for the indication onychomycosis
- polyneuropathy
- scleroderma
- psoriasis of the skin and / or nails
- circulatory disorders

These contraindications must be asked for by the user during anamneses in order to avoid later complications.

The user should take steps to herpes prophylaxis prior to treatment if a relevant medical history exists.

4. Installation

4.1 Scope of delivery and Unpacking

The unit is supplied in a special carrying case, which in turn is put into an outer package for transportation by mail or parcel service. Upon delivery, please remove the carrying case and any accessories from the outer packaging. Please open the carrying case carefully so that no parts can fall out.

Please check that all parts – according to the delivery note - are actually included and undamaged. A complete delivery - ordered without any additional optional accessories - includes the following components:

- Base unit with an attached applicator
- User manual (this document)
- Quick Treatment Guide
- Packaging Instruction
- Power cord
- Foot switch with connecting cable
- One pair of laser protective goggles
- Applicator holder
- Refill kit

Upon damaged or missing parts, please immediately contact the manufacturer or distributor. Do not use the device under any circumstances!
If all parts are contained place the base unit with the applicator on a stable surface. Follow the installation requirements specified in the following chapter.

Keep the outer packaging and packing materials. The carrying case and outer packaging may be required for the transport or shipping of the device. Do not ship or transport the device without the appropriate box!

	**Caution!** **Hazard:** The transport or shipping of the device without appropriate packaging may damage the device and thus lead to a malfunction of the device. **Action:** Transport or ship the device only in transport cases and packaging cleared by the manufacturer. If you do not have such case or such packaging, please contact the manufacturer or your dealer. He will provide you with suitable means of transport.

4.2 Installation Requirements

Before installing this equipment, users must make sure that the following requirements are fulfilled at the intended treatment room. In addition, the user has to comply with all legal requirements, which are valid at the location of use.

- Required installation location: The device should be placed on a table. It must not be placed directly against a wall, neither on the left nor right side, otherwise the ventilation is blocked. On both sides, a distance of 50 cm to the next surface is required.
- Separation from other electrical devices: The equipment must not be placed directly above, below or next to other electrical devices. Excluded are devices or accessories that are specifically provided by GME for such an assembly or have been released for this purpose by GME.
- Electrical connection: The appliance should be plugged into an outlet with its own fuse protection. It must not be connected to multi-outlet power strips or other distribution outlets. An appropriate power cord with a protective earth is provided by the manufacturer.

- Electric power supply: The electric power supply must be within the specification of the technical data, see Chapter 7.1. The quality of the supply voltage should correspond to the quality of a typical commercial or hospital environment.
- In order to prevent damage by electrostatic discharge, the floor in the treatment room should be made of concrete, wood or tiles. When using synthetic materials, the relative humidity has to be above 30%.
- The treatment room must meet the requirements for laser safety according to EN 60825-1. Especially, it must be equipped with laser warning signs, as shown below, which have to be placed at all entrances to the treatment room at eye level. In addition, a laser warning light must be available at all entrances. The room itself must not contain reflecting surfaces, such as mirrors.

- Room temperature and humidity: The device may only be operated within the acceptable temperature and humidity range in accordance with the technical data, see chapter 7.1.
- Heat dissipation: The unit produces heat due to technical reasons. This can lead to a significant warming of the treatment room and to a rise of temperature above the maximum permissible ambient temperature for device operation. To ensure continuous operation and to keep the room temperature for users and patients as comfortable as possible, we recommend air-condition of the treatment room. An air-conditioner with a maximum cooling power> 1000W should be used.
- Renovations: Renovation work in the treatment room must be completed at least 1 week prior to installation of the device. Otherwise, dust or paint fumes may deposit on optical elements cause damage to them.

4.3 Installing and Connecting

Lift the base unit with an attached applicator from the carrying case and put it in a suitable place (according to the installation requirements in the previous section).

Figure 1: LinScan base unit, applicator and applicator holder

Make sure that the applicator is not detached from the holder and does not fall to the ground!

Connect the foot switch on the left side of the base unit. Make sure that the connector locks into place completely. Then connect the base unit to the power socket using the supplied power cord. The device-side connector is also located on the left side of the base unit. The power connector and the socket must meet the "Installation Requirements" described above.

If you want to use a remote door interlock remove the protective cap of the jack on the left side of the device. Connect the two cables of the remote interlock to the plug of the device terminals. While connected to the plug, the device only allows the emission of laser light when the door is closed and thus the remote door interlock contact is closed. If the door is opened, laser emission is stopped.

Double check that all parts are connected correctly and securely and that they are not damaged. Use the device only if this is the case.

	**Warning!** **Hazard:** The device is an electrical product with integrated liquid-cooling circuit. In the case of a liquid leakage with liquid covering electronic components of the device, there is the risk of device malfunctions and electric shock. This electric shock could cause injuries and even death. **Action:** Attention! Before switching on the device check if there is cooling liquid close to, under, or at the device. In order to avoid the risk of an electric shock the device may only be switched on if the test showed no visible liquid. In case of a leakage during device operation, switch off the device immediately by using the main switch on the left side of the housing.

4.4 Initial start-up

Put on laser protective eyewear that meets the requirements of the chapter "Eye protection".

Unlock the red emergency stop button on the top of the base unit by turning the button. Otherwise the device cannot be switched on. Then use the power switch on the left side of the device to turn on the device. On the front panel you now see the blue/red (depending on the device version) light of a LED below the Power-on symbol in the middle. Press this symbol and hold it pressed for one second. The LED turns green and the boot process of the device starts.

Figure 2: Left side of base unit with power switch and connectors for foot switch, mains cable, door interlock, and USB memory stick

After a short time, an input screen is displayed, which prompts you to enter a PIN. This PIN can be obtained from the person doing the initial training on the use of the device.

After entering the PIN the device displays the main menu. Proceed as described in the following chapter "Function Test" to check that the device is functioning properly in accordance with the intended use.

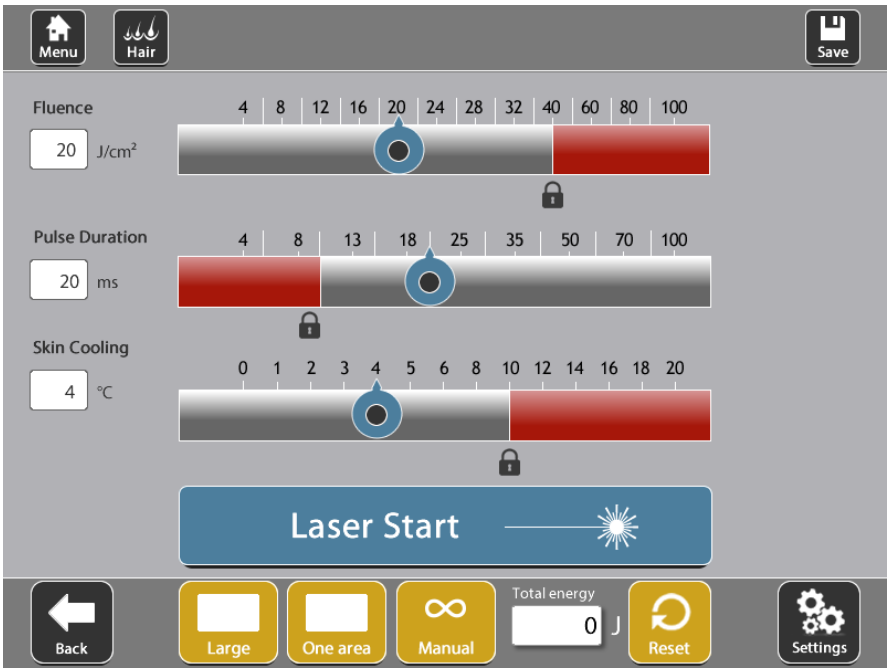
4.5 Functional Test

The function test has to be performed during the initial installation and after every change of location to ensure proper function.

	**Warning!** **Hazard:** The functional test verifies that the device works as intended. If it is not performed during initial start-up or after change of location, the proper working according to the intended use is not guaranteed. Injury of patients or users cannot be excluded in this case. **Action:** Perform the functional test at initial start-up at a site and after each change of location.

For functional testing, you will need the device, a microscope slide, and a grey or grey-printed piece of paper or, alternatively, a cardboard.

Press the left button "Hair removal" located on the top left. The screen now changes to the screen for selecting the treatment parameters, called the treatment menu. The screen should look like the following:



If you see other parameter settings as given in the above image, change the settings, please see the section "Treatment menu" to set the values.

Place the microscope slide on the cardboard or grey paper. Then press the "Laser Start" button and set the sapphire crystal vertically onto the slide.

After a short time, the red aiming beam should be visible, showing the outer contours of the treatment area. The aiming beam moves through the same optical system as the working beam. Therefore, the aiming beam offers a suitable means of verifying the integrity of the optical system. If the target beam is not present at the distal end of the optical system, its intensity is reduced, it can be seen only diffusely or the shape is distorted, it is a sign of damaged or faulty optical system. Stop the function test in this case and contact the manufacturer or distributor.

If the aiming beam shows the defined rectangle, press the foot switch with your foot and hold it down until the device has covered the full rectangle. Then take your foot off the foot switch.

Make sure that the burned area is uniform and the outer limits of the square coincide with the rectangle shown by the aiming beam. Do not use the device if the pattern is uneven, if no 50mm x 15mm rectangle was scanned or if the individual areas are darker than others. Stop the function test in this case and contact the manufacturer or distributor.

	**Warning!** **Hazard:** The occurrence of errors during the functional test indicates damage to the device. A proper function is no longer guaranteed. Patients or users could be injured by using the damaged unit. **Action:** Stop use of the device immediately if errors occur during the functional test. Turn the unit off and contact the manufacturer or your dealer.

5. Device Operation

This chapter describes the operation during normal use, as it was valid at the time of printing this manual. Due to technical changes and software updates the handling may change. If you find discrepancies, please contact the manufacturer or distributor. He will send you the latest version of this manual.

5.1 Starting the device

Put on laser protective eyewear that meets the requirements of the chapter "Eye Protection".

Then use the power switch on the left side of the device to turn on the device. On the front panel you now see the blue/red (depending on the device version) light of a LED below the Power-on symbol in the middle. Press this symbol and hold it pressed for one second. The LED turns green and the boot process of the device starts.

After a short time, an input screen is displayed, which prompts you to enter a PIN. This PIN can be obtained from the person doing the initial training on the use of the device or you can define your own PIN. In chapter “Setup menu” this is described.

After entering the correct PIN the device displays the main menu. If you entered the PIN incorrectly three times in a row, the device will be blocked for one hour. Renewed attempts to enter PIN are only possible after this time again.

If errors occur during self-test a message will be displayed. The device might also ask you to perform an appropriate action. Follow the instructions!

5.2 Main Menu: Choice of treatment

The main menu shows several buttons arranged in rows and columns. The middle display zone – highlighted by the light gray background - contains all the keys you need for performing a treatment. The bottom row contains the “Settings” button, which provides access to device-specific settings, see the chapter "Setup Menu".

Press one of the slightly larger buttons of the first column to enter the treatment menu (see "Treatment Menu"). No indication-specific parameter recommendations are provided in this case. This option is therefore suitable for experienced users and experts who have already gained clinical experience with this or similar systems and who know the appropriate treatment parameters.

By selecting one of the slightly smaller buttons of the following columns you can also access to the treatment menu (see "Treatment Menu"). However, in this case the device recommends appropriate treatment parameters for a specific indication. This wizard system is particularly suitable for beginners and other users who are not experienced in treating with the device. It is possible to change the proposed parameters in the treatment menu itself also in this case.

If you select one of the buttons in the last column, you enter the menu "Custom Parameters". Here, you can save or load your preferred individual treatment parameters.

5.3 Setup Menu: Setting the System Parameters

In this menu you can change the following system settings to suit your needs:

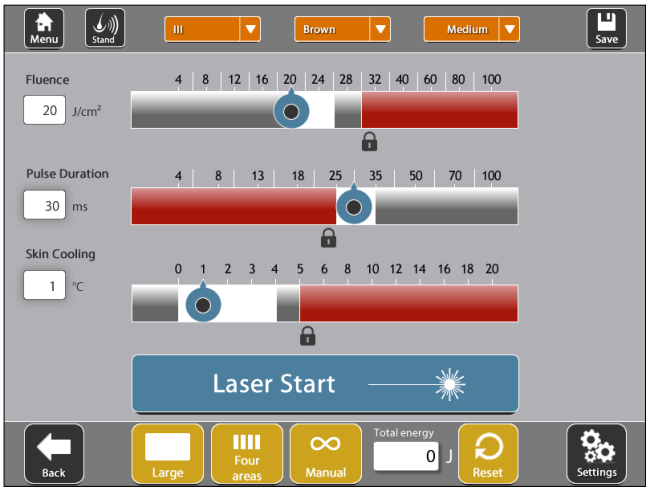
- The date and time can be set. Press the labeled button and perform the changes in the resulting window.
- You can select the language. Once you press the arrow button on the right side of the language box, you get a list of available languages. Select the desired language.
- You can choose to start laser emission using the foot or hand switch by pressing the appropriate button.
- Pressing the button "System Data" opens a window in which you receive basic information about the device status. These include the serial number of your device, information about the last service, operating hours, temperature information and the software version information.
- Pressing the button "Applicator Settings" opens a window where you can see applicator-specific data and set applicator-specific parameters.
- The section "Volume" allows you to specify how loud notification beeps such as the confirmation of a pressed button are heard. However, this setting does not change the volume of warning signals because of legal reasons.
- The button "Service" is only relevant for service technicians. It leads to a PIN-protected menu. Never try to guess the service PIN of the device or do changes in the service menu settings. This could either damage the device or lead to hazards for users and / or patients.
- Pressing the "Software Update" button allows you to update the software on your device by yourself. If you want to perform a software update, then plug the storage device (e.g. an USB memory stick or USB hard drive) into the USB port of the device. Press the "Software Update" button. The unit will now recognize the storage medium automatically and display the software versions thereon. Likewise, the currently installed software versions are displayed on the device. Select the software version that you want to install and start the installation. The unit will guide you through the installation process and gives you instructions. Follow the instructions in any case and do not turn the power off during the update process! In general, a device reboot is necessary when the installation is complete.
- Under "Error List" you will find information about the error and warning messages that the device has generated in recent times. This information is usually required by a technician to determine the cause of equipment failure. The error list can be transferred to a USB storage device and then be transmitted by email to the manufacturer or distributor.
- Under “Master License” and “User License” you are able to check the license status of the device. Here you are able to create a new key for receiving a new license if necessary.
- Under “User PIN” you are able to define your own PIN. The PIN has to consist of 5 numbers.

	**Caution!** **Hazard:** Turning off the device during a software update or canceling the software update may cause the device to remain in an inoperative state so that it cannot be used further. **Action:** Never interrupt a software update. Always obey the instructions given by the device during the update process.

	**Caution!** **Hazard:** Storage media may contain malicious software such as computer viruses, Trojan horses or computer worms that can affect the operation of this unit. **Action:** Check the storage medium that you want to use for the software installation, with an up-to-date virus scanner for malicious software before you connect it to the device. Never use the media, if malicious software has been found.

5.4 Treatment menu: Setting the treatment parameters

The treatment menu shows a tripartite division. The top row contains information about your selected clinical indications and relevant clinical parameters. In the middle you see the most important treatment parameters of the laser and can change them. In the bottom line, technical parameters such as selected scan field can be viewed and modified.

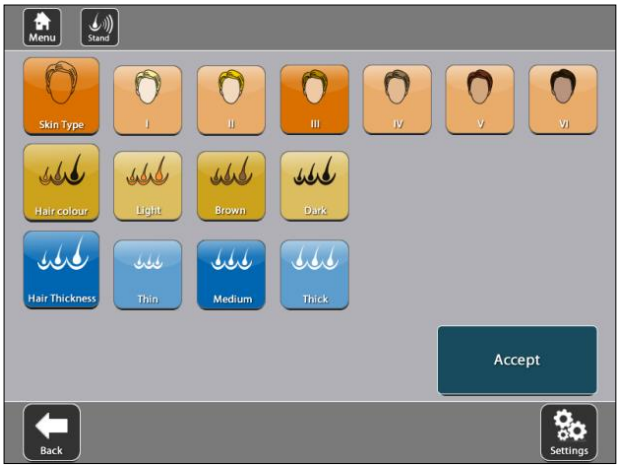


5.4.1 Setting the Clinical Parameters

In the top row of the treatment menu you see an icon of the indication that you selected on the main menu. In addition, depending on the indications, more buttons appear. In the shown example, these are the skin type, the hair thickness, and the hair color. Press the "Accept" button to confirm the selection.

According to your selection the device recommends an appropriate set of treatment parameters.

The treatment parameters proposed by the device are merely a non-binding recommendation. Because of the complexity and numerous factors that can influence these recommendations not all clinical relevant facts can be included. Specifically consider contraindications, susceptibility to side effects, medical history, current health situation, etc. The user must not rely on the correctness of the recommendations, otherwise the patient may be harmed. The user must take into account all clinically relevant facts that are known via the medical history or clinical case in the selection of treatment parameters before any treatment. With these treatment parameters the user must perform a test treatment on one location. Wait for the patient's response to this test treatment before performing further treatment.



5.4.2 Adjusting the treatment parameters

The middle area of the treatment menu allows adjustment of the relevant treatment parameters. Use the slider to adjust - depending on the application - the fluence or energy density, pulse duration, and skin cooling temperature.

If you have entered the treatment menu via an indication-based button, the pointer of each slider represents a recommended value. In addition, a light-background zone denotes a recommended parameter regime for the selected indication.

For some sliders, there might be a red parameter zone that is secured with a lock. Parameters in the red zone are potentially dangerous and might harm the patient. They should be used only for carefully selected, specific treatments. The use of this parameter regime is not recommended by the manufacturer. If you still want to use these parameters, you must first unlock the red zone by touching the lock. Only after that you can move the slider into the red zone.

	**Warning!** **Hazard:** The unit allows you to treat even with aggressive treatment parameters that are appropriate only in special cases. If these parameters are used for other indications, the patient may be injured permanently or temporarily. **Action:** Only use aggressive treatment parameters with adequate experience and for indications that do not allow more conservative parameters. Do a test treatment on a small area to ensure that no adverse side effects or unacceptable damage will be caused by the treatment. Wait for the patient's response to the test treatment. Stop treatment immediately if unwanted side effects occur.

Please note that the device generates the recommended parameter sets as a result of your entered data and without knowledge of the actual patient history. It is your responsibility as a physician to take into account all other patient data according to medical history, contraindications, clinical findings or other knowledge.

	**Warning!** **Hazard:** The treatment parameters proposed by the device are merely a non-binding recommendation. Because of the complexity and numerous factors that can influence these recommendations not all clinical relevant facts can be included. Specifically consider contraindications, susceptibility to side effects, medical history, current health situation, etc. The user must not rely on the correctness of the recommendations, otherwise the patient may be harmed. **Action:** The user must take into account all clinically relevant facts that are known via the medical history or clinical case in the selection of treatment parameters before any treatment. With these treatment parameters the user must perform a test treatment on one location. Wait for the patient's response to this test treatment before performing further treatment.

On the left side of the slide you see the selected treatment parameters as a number value in SI units.

As soon as you have set all the parameters, confirm your selection by pressing the "Laser Start" button. The device enters the “Laser Ready Menu”, which is described in the relevant section.

5.4.3 Setting the Technical Parameters

The bottom row on the treatment menu includes navigation buttons as well as information and settings for technical parameters.

The navigation elements are arranged in the outer left and right buttons. Pressing the "Back" button allows you to access the main menu. The "Settings" button leads to the "Setup Menu" and pressing the "Save" allows you to save individual parameters.

In the field "Total energy", the emitted laser energy since the last reset is displayed. Pressing the "Reset" button sets this counter to zero.

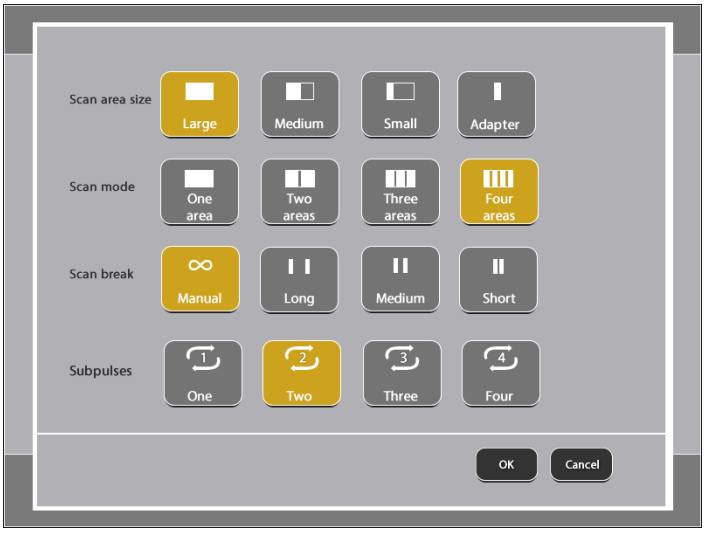
The remaining 3 buttons indicate the selected parameters for the scan pattern, namely its size, the scan mode, and the repositioning break. Press one of the 3 buttons, to enter the "Scan menu", which is described in the following chapter.

5.5 Scan Menu: Set the Scan Parameters

In the Scan menu, you can set the following parameters of the scan pattern on the skin:

- Scan Area Size: In the uppermost line you will find the possible choices of scan area size. Select your preferred size by pressing the corresponding button. By pressing the button “Adapter” you can activate or deactivate the settings for using the small spot adapter.
- Scan mode: In the second line you can choose in how many parts the scan area should be divided in order to reduce pain. Choosing the first setting “One area” causes the whole treatment area to be scanned in one go, i.e., without any pause. Choosing the “Four area” setting will cause the treatment area to be divided into four areas which are treated temporarily separated. This leads to a significantly reduced patient pain level. The desired mode is selected by pressing the corresponding button.
- Scan break: In the third line the buttons to select the duration of the repositioning scan break, i.e., the pause between two laser pulses in case the user keeps the selected switch pressed. During this break the user has to move the applicator to the next treatment position. If “Manual” has been selected the device will not emit a second laser pulse. In this case the user has to release the switch and press it again in order to treat the next location. The desired mode is selected by pressing the corresponding button.
- Subpulses: In the last line the number of subpulses is selected. This line is only visible in MCT hair removal mode. In this mode each area is treated more than once. The desired number (1-

4) can be selected by the user. Be aware that the treatment menu always displays the total fluence, i.e. the fluence of each pass is only a uniform fraction of the total fluence.



5.6 Laser Ready menu: Treatment

To start a treatment and trigger laser pulses press the "Laser Start" button on the treatment menu screen, as described in chapter "Treatment menu". When changing from/to adapter mode the device is asking you if you have removed/attached the adapter.

Place the applicator on the skin.

The screen changes and the aiming beam moves along the external boundaries of the area to be treated on the skin. The screen shows your selected treatment parameters. These cannot be changed in the laser ready menu.

The treatment, i.e., emission of laser pulses, starts when you press the hand or foot switch. It stops as soon as

- the selected skin area was treated completely
- the hand or foot switch is released
- the door contact is open
- the "STOP" button on the screen is pressed
- the selected skin cooling temperature cannot be maintained any longer
- an error occurs

During the emission of laser pulses, an acoustic warning signal is heard. In addition, an indicator LED on the applicator signals the emission optically.

When you release the hand or foot switch or the door contact is opened, while the selected skin area has not been fully treated, the treatment is continued at the next treatment position, when you press the hand or foot switch again. This, however, is not the case, if you press the "STOP" button.

As long as you are in the laser ready menu, you cannot change treatment parameters on the screen. Press the "STOP" button on the screen to stop the laser emission and / or return to the treatment menu. No laser pulses can be triggered any more.

5.7 Applicator handling

5.7.1 General operating instructions

On the front side of the applicator there is a hand switch. Laser pulses can be triggered by pressing this switch if the hand switch has been activated in the setup menu. Please note that the operator has to hold the handle of the applicator tightly in order to start laser emission. The applicator is equipped with a heel-of-hand detection to avoid unintended laser emission!

Figure 3: LinScan applicator with hand switch and sapphire crystal

When not in use place the applicator on the applicator holder to prevent it from falling down or being damaged by other sharp items.

	**Caution!** **Hazard:** The applicator may fall down or be damaged by sharp items/ edges when not placed on the appropriate applicator holder while not in use. **Action:** Always place the applicator on the applicator holder when not using it.

5.7.2 Usage of the small spot adapter

To use the small spot adapter you have to fix it to the sapphire crystal. Put the applicator into the applicator holder as shown in figure 4.

Figure 4: Position of the applicator for installing the small spot adapter

Mount the small spot adapter on the sapphire crystal so that the screw points in the direction of the applicator handle (Figure 5). Please ensure that the adapter flatly touches the colored elastomer.

Figure 5: Small spot adapter mounted on the sapphire crystal

Use two fingers to press down the small spot adapter while tightening the screw (Figure 6).

Figure 6: Fixing the small spot adapter

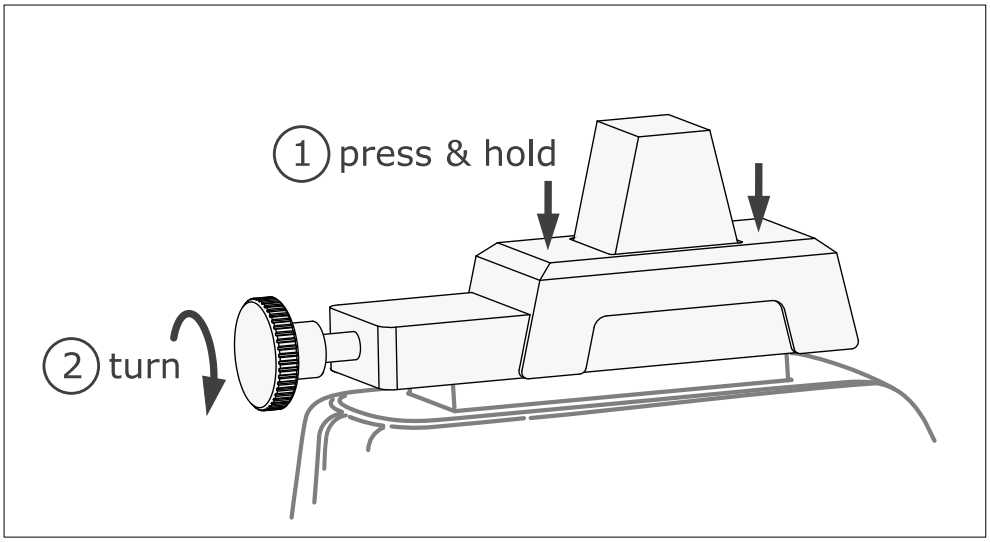


Figure 7: Schematic drawing –fixing the small spot adapter

Remove the adapter from the sapphire crystal after you finished treatment and deactivate the adapter mode in the scan menu by choosing another scan area size.

	**Caution!** **Hazard:** If the adaptor is not attached and the software is in the adaptor mode, a higher fluency will be delivered. **Action:** Attach adaptor then select adaptor mode in software. De-select adaptor mode when adaptor is removed.

	**Caution!** **Hazard:** There will be no laser emission if the adapter is fixed in the wrong direction to the sapphire crystal. **Action:** Please check whether the screw of the adapter points in the direction of the applicator handle before using the small spot adapter.

5.8 Menu Individual Parameters: Storage of Treatment Parameters

To save the last set of your treatment parameters, press the "Save" button on the treatment screen. Pressing this button takes you to the "Individual Parameters" menu. Here you can save the data using a name of your own choice or load already stored parameters.

To enter the menu “Individual Parameters” directly press the button “Stored settings” in main menu.

By pressing the button of a previously stored parameter set you enter the treatment menu. The stored parameters are now already set. By confirming with the "Laser Start" button you can directly start the treatment with this set of parameters.

5.9 Switching off

To switch the device off, press the On /Off button in the middle of the front panel of the device. Wait until the LED color changes from green to blue/red (depending on the device version). Then you can turn off the power completely at the main switch on the left side of the device.

In an emergency, the unit can be switched off be pressing the red emergency stop button on the top of the base unit. Any laser emission is stopped immediately. The LED on the front panel turns to white/red (depending on the device version). If the button has been pressed, it must first be unlocked by turning the button. Otherwise the device cannot be switched on again.

Always switch off the power using the main switch before performing cleaning or maintenance work or before moving the unit.

6. Maintenance

6.1 Cleaning of the base unit and the applicator

Before cleaning, always unplug the device completely from the mains. For this purpose unplug the power supply cord from the outlet. The surfaces of the device should be cleaned at regular intervals using a cleaning agent suited for PMMA (acrylic glass), e.g., dish liquid mixed with water. For severe, fat-containing stains you can also use pure benzene-free gasoline (benzine, light benzine). Never use cleaning agents that contain abrasive materials.

If disinfection is required, please use a spray or wipe disinfectant that is suited for acrylic glass (or PMMA) and displays. Examples are “Hexawol” produced by the company Dreiturm or Kohrsolin extra produced by the company Hartmann. When using other disinfectants, the front of the device or the display may be damaged.

The applicator and its sapphire crystal should be disinfected using the above mentioned disinfectants. Applicator cleaning can be done using the cleaning agents defined above.

Please check whether the sapphire crystal is free from contamination before turning on the device. If you find dirt on the sapphire crystal, then clean it using the disinfectants defined above. Never perform this crystal cleaning action when the unit is switched on.

	**Warning!** **Hazard:** In case of an accidental triggering of laser pulses during the cleaning process of the sapphire crystal, the eyes or skin of the cleaning person could be harmed. **Action:** Do not perform sapphire crystal cleaning with the unit switched on. Turn off the power before any equipment cleaning and always unplug the power cord from the wall outlet.

	**Caution!** **Hazard:** The penetration of larger quantities of liquid into the device can damage the unit. This is also true for water. **Action:** Only perform any cleaning actions with wipes lightly dampened with cleaning agents. Do not use wet wipes. Do not pour any liquids on the device. Avoid penetration of liquids into the unit.

6.2 Cleaning of the small spot adapter

The adapter should be cleaned after each usage. Please use a suited cleaning or disinfectant agent, as the ones mentioned in chapter 6.1.

6.3 Storage and Transport

The device is a high quality electric device with optical elements. When not in use, the device should be stored in the included carrying case, but in any case protected against dust and moisture.

The transport of the equipment should be performed only in the supplied carrying case. Should the unit be shipped, then the carrying case has to be put in the outer packaging specified by the manufacturer.

You should therefore keep the case and on the outer packaging. Case and packaging are always required for the transport or shipment of the unit. Never ship or transport the device without the appropriate packaging!

	**Caution!** **Hazard:** The transport or shipping of the device without appropriate packaging may damage the device and thus lead to a malfunction of the device. **Action:** Transport or ship the unit in packaging specified by the manufacturer. If there is no such packaging, please contact the manufacturer or your distributor. He will provide you with suitable means of transport.

6.4 Maintenance and Warranty

The device comes with various sensors and wear counters. Should they detect the need for maintenance, you will receive a user a notification by the device. After confirmation of the notice you can continue working. Please immediately contact the manufacturer or his authorized distributor.

Should the device detect critical wear which does not guarantee safe working any more or could lead to more damage to the device, you will also get a notification by the device. However, it is no longer possible to continue work in this case. Please immediately contact the manufacturer or his authorized distributor.

Regardless of the actual use at least once per year an inspection and service of the equipment is compulsory. Please contact the manufacturer or his authorized distributor in time.

	**Caution!** **Hazard:** The maintenance and repair of the equipment requires a detailed knowledge of the device. Without this knowledge, the device may be damaged during maintenance or repair. Moreover, a proper function is no longer guaranteed in this case. **Action:** Any maintenance or repair work may only be done by the manufacturer or an authorized person. Never let any unauthorized persons perform such work.

Warranty is granted in accordance with the conditions set out in purchase contract and the respective national laws. Single-use parts, wear parts, and consumables are excluded from this warranty. In addition, it voids the warranty, if

- maintenance or repair was conducted by unauthorized persons.
- the device was opened by unauthorized persons.
- the installation requirements were not met.
- the device was not used in accordance with the instructions contained in this user manual.
- the device was used in combination with accessories or other equipment not authorized by the manufacturer.

For any warranty claim, please contact the manufacturer or your local distributor immediately.

6.5 Disposal

	**Warning!** **Hazard:** The technological and medical advances may mean that the technology used and / or medical application will be outdated and no longer the benefit from the device might outweigh the risks after 10 years. **Action:** The life time of the unit is limited to 10 years from the date of first use. After this time, the intended use of the device has to be re-evaluated by the manufacturer. Further use is permitted only with a positive assessment.

The device must not be disposed of as waste or household waste. It falls under the provisions of EU Directive 2002/96/EC (known as WEEE) on electrical and electronic equipment waste and must be disposed of properly. For disposal, contact your distributor or the manufacturer directly.

6.6 Refilling cooling liquid

If you note a noisy sound of the internal pump or the message „Liquid flow too low“ appears there is probably not enough cooling liquid in the device. Use the provided refill kit to increase the cooling liquid level.

Fill the bottle of the refill kit with cooling liquid. If available, use a mixture of 2 parts distilled water and one part propylene glycol (1,2-propanediol) in order to ensure frost protection till -10°C during storage and transport. If temperatures are always above 0°C pure distilled water can be used, too.

Screw the lid on the bottle and connect it to the coupling on the right side of the base unit.

Switch on the device, if you have not done so already. Hold the bottle up above device level. Squeeze the bottle so that the liquid is flowing into the device. Loosen the pressure afterwards to de-aerate the device.

Disconnect the hoses as soon as no more liquid is flowing into the device and no more air bubbles coming up into the refill bottle. The device is now filled-up and ready for use.

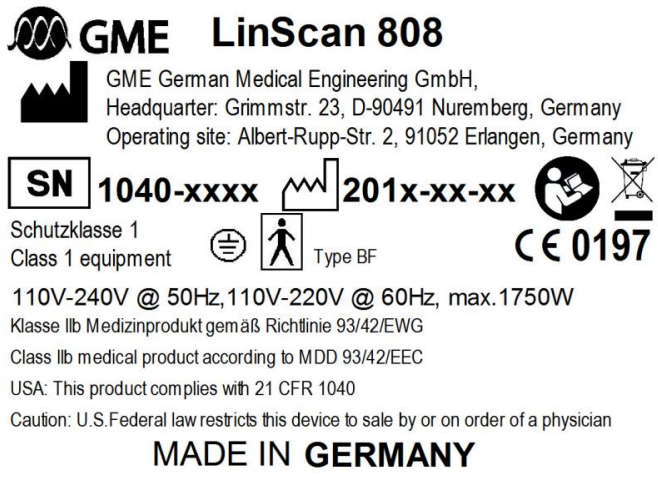
7. Specifications

7.1 Specifications and Certification

Designation	Value
Working beam wavelength	808 nm (LinScan 808) oder 980 nm (LinScan 980)
Aiming beam wavelength	635 nm
Maximum power working beam	300 W
Maximum power aiming beam	<1 mW
Working beam laser class	4
Aiming beam laser class	2
Pulse duration	4 – 100 ms
Nominal ocular hazard distance (NOHD)	4,36 km
Beam divergence	Fast Axis: <1 mrad Slow Axis: 0,42 rad
Dimensions	Base unit: 30 cm (W) x 30cm (D) x 25cm (H) Applicator: 15 cm (L) x 10 cm (W) x 20cm (H)
Weight	Base unit: 15 kg Applicator: 0.9 kg
Electrical safety class	Class I  , Type BF Applied Part 
Ambient temperature during use	18 ° C to 30 ° C
Humidity during use	<= 90% noncondensing
Ambient temperature during storage and transport	-10 ° C to 60 ° C
Humidity during storage and transport	<= 100%
Cooling	Integrated water cooling
Cooling liquid	• mixture of 2 parts distilled water and one part propylene glycol (1,2-propanediol) for frost protection down to -10°C • Pure distilled water in case of storage and transport at temperatures above 0°C
Electrical Connection	110V-240V at 50Hz, 110V-220V at 60Hz, max. 1750W
Fuses	3AB (6,3x32mm), 250V, 20A Fast acting
Maximum operating altitude above sea level	2000m
Allowable air pressure during use	795-1050 hPa
Interfaces	• USB 2.0 connector for USB memory sticks • Foot switch connector for foot switch Steute MKF 2S-MED SK12 • Door interlock connector for connector Würth Elektronik Art-No. 691 361 300 0xx

The medical device meets the requirements of EU Directive 93/42/EEC and the requirements from the national laws and mandatory standards derived from this directive.

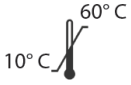
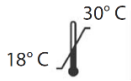
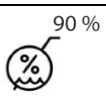
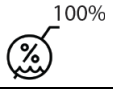
7.2 Device Labeling



Name plate

Laser warning label

Labeling Symbols

Description	Symbol
Caution/Warning: See Instructions for Use (User Manual)	
Catalog Number	
Serial Number	
Date of Manufacture	
Do Not Discard in Trash	
Refer to “Instructions For Use (User Manual)"	
Manufacturer Symbol	
Type BF Applied Part	
Protective earth (ground)	
European Conformity	CE 0197
TUV Rheinland logo	
Laser aperture label	
Ambient temperature during storage and transport: -10 °C to 60 °C	
Ambient temperature during use: 18 ° C to 30 ° C	
Humidity during use: <= 90% noncondensing	
Humidity during storage and transport: <= 100%	

Fragile, handle with care	
Consult Instructions for Use	
Do not stack	
Avoid moisture	
Made in Germany	MADE IN GERMANY

7.3 Electromagnetic compatibility (EMC)

The medical device was tested according to EN 60601-1-2 on electromagnetic compatibility. Nevertheless, it should be noted that RF communication devices can affect electrical medical devices. Therefore, the medical device must be installed and operated strictly according to the prescribed environmental and installation instructions. RF devices must be operated at a safe distance, which depends on the frequency and the power of the RF device.

In addition, the following precautions should be observed:

	**Caution!** **Hazard:** The EMC tests were performed with the device and the cables and connectors specified by the manufacturer and included in the delivery of your device. Using other cables or connectors can negatively affect the EMC of the device. When using such cables or connectors other devices placed in the surrounding could be disturbed or the other devices could disturb the medical device. **Action**: Only use the original cable and / or connectors supplied by the manufacturer.

	**Caution!** **Hazard:** When testing the device for compliance with EN 60601-1-2 standardized measuring distances are used. These distances may be greater than the distances to nearby electrical devices that occur when devices are placed directly next to, above or below the medical device. With a too tight set-up it cannot be excluded that the electrical devices interfere with each other and thus a proper functioning with respect to the intended use is no longer guaranteed. This does not apply to equipment that the manufacturer has specified and tested for such a placement. **Action:** Do not place electrical devices in the immediate vicinity of the medical device, except for accessories that were released for this purpose by the manufacturer.

The medical device may only be used in an electromagnetic environment specified below. The customer or user of the medical device must verify that the device is used only under these conditions.

Test	Test Level and Conformity	Electromagnetic environment
Irradiated / forwarded emissions CISPR 11	Group 1	This medical device uses RF energy only for its internal operation. That is why it has very low RF emissions that cause no interference in the vicinity of any electronic device.
Irradiated / forwarded emissions CISPR 11	Class B	
Harmonics IEC / EN 61000-3-2	Class A	The medical device is suitable for use in all environments, including domestic use and direct connection to household electricity.
Voltage fluctuations / flicker IEC / EN 61000-3-3	Complies	
Electrostatic discharge (ESD) IEC / EN 61000-4-2	+ / - 6 kV with contact + / - 8kV in the air	The floors shall be wood, concrete or ceramic. If the floor is covered with synthetic material, the relative humidity must be larger than 30%.
Fast transient / burst IEC / EN 61000-4-4	+ / - 2kV supply (mains), + / - 1 kV power supply input and output lines	The power supply must be the one common for a commercial or clinical setting.
Surge IEC / EN 61000-4-5	+ / - 1kV fed push-pull, + / - 2kV power supply common mode	
Voltage drops, short interruptions and voltage variations IEC / EN 61000-4-11	5% UT for 0.5 cycles 40% UT for 5 cycles 70% UT for 25 cycles <5% UT for 5 sec	The power supply must be the one common for a commercial or clinical setting. If the user requires that the medical device works continuously even in case of interruptions of the supply voltage, it is recommended to use it with an uninterruptible power supply.
Magnetic field IEC / EN 61000-4-8	3 A / m	The magnetic field should be the one common for a commercial or hospital environment.
Conducted Immunity IEC / EN 61000-4-6	3Vrms 150kHz to 80MHz	Recommended safety distance: 1.2 * sqrt (P)
Radiated immunity IEC / EN 61000-4-3	3 V / m 80MHz to 1GHz	Recommended safety distance: 1.2 * sqrt (P) below 800 MHz 2.3 * sqrt (P) above 800 MHz

7.4 System and Error Messages

No.	Message	Cause	User Action
101	Trace Server not ready	Software component not answering	Switch off and on device again. If error persists contact service.
102	Workflow Server not ready	Software component not answering	Switch off and on device again. If error persists contact service.
103	IO Device not ready	Software component not answering	Switch off and on device again. If error persists contact service.
104	Service.xml backup/restore failed	File cannot be loaded	Switch off and on device again. If error persists contact service.
105	IODeviceConfig.xml back-	File cannot be loaded	Switch off and on de-

No.	Message	Cause	User Action
	up/restore failed		vice again. If error persists contact service.
201	guarding timeout occurred	Software component not answering	Switch off and on device again. If error persists contact service.
202	Workflow not ready, please wait...	Software component needs more time for starting	No user action required
203	Workflow configuration not found	Software component missing or defective	Switch off and on device again. If error persists contact service.
204	Wrong PIN input. Please try again!	User has entered wrong PIN	Enter correct PIN. If you don't know the correct PIN contact service
205	Missing data from IO device	Software component missing or defective	Switch off and on device again. If error persists contact service.
206	Missing general configuration file	Software component missing or defective	Switch off and on device again. If error persists contact service.
207	General configuration data incomplete (see trace log)	Software component defective	Switch off and on device again. If error persists contact service.
208	Missing UI configuration file	Software component missing or defective	Switch off and on device again. If error persists contact service.
209	UI configuration data incomplete (see trace log)	Software component defective	Switch off and on device again. If error persists contact service.
210	Missing service configuration file	Software component missing or defective	Switch off and on device again. If error persists contact service.
211	Service configuration data incomplete (see trace log)	Software component defective	Switch off and on device again. If error persists contact service.
212	Applicator limits data incomplete	Software component missing or defective	Switch off and on device again. If error persists contact service.
213	Software update failed	Software update could not be completed, e.g. because USB stick has been removed	Switch off and on device again. Restart update. If error message occurs use another USB stick and retry.
214	Software update complete. Please remove your USB stick and reboot	Software update has been completed.	Remove USB stick and restart device.
215	Saving the operation time failed	Hardware or software component defective	Switch off and on device again. If error persists contact service.
216	Starting the operation timer failed	Hardware or software component defective	Switch off and on device again. If error persists contact service.
217	Setting the system time failed	Hardware or software component defective	Switch off and on device again. If error persists contact service.
218	Saving the error log to USB stick failed	USB stick not connected or damaged	Reconnect USB stick and wait 30 seconds.

No.	Message	Cause	User Action
			Then try saving again. If error persists use another USB stick.
219	Save errorlog complete	Error log has been saved to folder GME on USB stick	You may remove the USB stick now.
220	Creating the directory GME on the USB stick failed	USB stick not connected or damaged	Reconnect USB stick and wait 30 seconds. Then try saving again. If error persists use another USB stick.
221	Saving the settings failed	Hardware or software component defective	Switch off and on device again. If error persists contact service.
222	Setting the new PIN failed	Hardware or software component defective	Switch off and on device again. If error persists contact service.
223	Saving the production data failed	Hardware or software component defective	Switch off and on device again. If error persists contact service.
224	Service reset failed	Hardware or software component defective	Switch off and on device again. If error persists contact service.
225	Saving speaker volume failed	Hardware or software component defective	Switch off and on device again. If error persists contact service.
226	Setting speaker volume failed	Hardware or software component defective	Switch off and on device again. If error persists contact service.
227	Please fill in all fields	Input data is missing.	Please enter data.
228	Saving timeformat failed	Hardware or software component defective	Switch off and on device again. If error persists contact service.
229	Setting timeformat failed	Hardware or software component defective	Switch off and on device again. If error persists contact service.
230	Parametertable attribute check failed	Hardware or software component defective	Switch off and on device again. If error persists contact service.
231	Rowidentifier calculation failed	Hardware or software component defective	Switch off and on device again. If error persists contact service.
232	Saving switch selection failed	Hardware or software component defective	Switch off and on device again. If error persists contact service.
233	Device has to be serviced (days). Please call service	The admissible service interval is exceeded	Please contact GME or your local distributor and arrange service appointment
234	Device has to be serviced (emission time). Please call service	The admissible service interval is exceeded	Please contact GME or your local distributor and arrange service appointment
249	2. power has to be larger than the 1. power!	Hardware or software component defective	Switch off and on device again. If error persists contact service.
250	The configured power is not in the working range of the laser!	Hardware or software component defective	Switch off and on device again. If error persists contact service.

No.	Message	Cause	User Action
251	2. puls duration has to be lower than the 1. puls duration!	Hardware or software component defective	Switch off and on device again. If error persists contact service.
252	Decryption of the PIN failed!	Hardware or software component defective	Switch off and on device again. If error persists contact service.
253	Encryption of the PIN failed!	Hardware or software component defective	Switch off and on device again. If error persists contact service.
254	The design configuration is incomplete!	Hardware or software component defective	Switch off and on device again. If error persists contact service.
255	Failed to load design!	Hardware or software component defective	Switch off and on device again. If error persists contact service.
256	Factory default failed	Hardware or software component defective	Switch off and on device again. If error persists contact service.
301	guarding timeout occurred	Software component not answering	Switch off and on device again. If error persists contact service.
302	file open failed	Hardware or software component defective	Switch off and on device again. If error persists contact service.
303	Save the language failed	Hardware or software component defective	Switch off and on device again. If error persists contact service.
304	Read the language error file failed	File is missing or corrupted.	Switch off and on device again. If error persists contact service.
305	Reset of the pulse counter failed!	Hardware or software component defective	Switch off and on device again. If error persists contact service.
306	Set of the pulse counter failed!	Hardware or software component defective	Switch off and on device again. If error persists contact service.
401	guarding timeout occurred	Software component not answering	Switch off and on device again. If error persists contact service.
402	COM-port error	Defective hardware component	Switch off and on device again. If error persists contact service.
403	COM-Port property error	Hardware or software component defective	Switch off and on device again. If error persists contact service.
404	Rx-thread error	No answer from software component received	Switch off and on device again. If error persists contact service.
405	read port error	Hardware or software component defective	Switch off and on device again. If error persists contact service.
406	write port error	Hardware or software component defective	Switch off and on device again. If error persists contact service.
407	protocol timeout occurred	Software component not answering	Switch off and on device again. If error per-

No.	Message	Cause	User Action
			sists contact service.
408	checksum error	Software component defective	Switch off and on device again. If error persists contact service.
409	applicator communication error	Software component not answering	Switch off and on device again. If error persists contact service.
410	no applicator connected	Software component not answering	Switch off and on device again. If error persists contact service.
411	unknown response message	Wrong message from software components	Switch off and on device again. If error persists contact service.
412	applicator detects a checksum error	Message not transmitted correctly	Switch off and on device again. If error persists contact service
413	applicator detects a message format error	Message not transmitted correctly	Switch off and on device again. If error persists contact service
414	applicator receives unknown id	Message not transmitted correctly	Switch off and on device again. If error persists contact service
415	applicator receives no scan pattern	Message not transmitted correctly	Switch off and on device again. If error persists contact service
416	applicator detects scan pattern error	Message not transmitted correctly	Switch off and on device again. If error persists contact service
417	scanner data error	Scanner detects wrong/ missing data	Switch off and on device again. If error persists contact service
418	applicator detects an CRC- error	Software component defective	Switch off and on device again. If error persists contact service.
419	scanner 1 detects an flash CRC error	Software component defective	Switch off and on device again. If error persists contact service.
420	scanner 2 detects an flash CRC error	Software component defective	Switch off and on device again. If error persists contact service.
421	Scanner 1: reference scan failed	Scanner is not operating properly	Switch off and on device again. If error persists contact service.
422	Scanner 2: reference scan failed	Scanner is not operating properly	Switch off and on device again. If error persists contact service.
423	Applicator data error occurred	Message not transmitted correctly	Switch off and on device again. If error persists contact service
424	Save scanner data failed	Message not transmitted correctly	Switch off and on device again. If error persists contact service
425	No scanner connected	Hardware or software component defective	Switch off and on device again. If error persists contact service.
430	RF-Generator error occurred	Hardware or software component defective	Switch off and on device again. If error persists contact service.

No.	Message	Cause	User Action
431	RF-Generator standby error occurred	Hardware or software component defective	Switch off and on device again. If error persists contact service.
432	RF-Generator laser on error occurred	Hardware or software component defective	Switch off and on device again. If error persists contact service.
433	Door interlock open. Please close door or door interlock contact!	Door interlock contact is open	Close door or connect both contacts of the door interlock connector.
434	Applicator temperature error occurred	Temperature in applicator is too high or too low	Please wait till temperature reaches allowed range.
435	Foot switch active error occurred. Please release foot switch!	Foot switch has been pressed for a very long time	Release foot switch or check if anything blocks the foot switch.
436	Laser current high error occurred. Please restart treatment!	A too high current to the light source was measured	If error only occurs once then continue working. If error occurs frequently contact service.
437	Laser current low error occurred. Please restart treatment!	A too low current to the light source was measured	If error only occurs once then continue working. If error occurs frequently contact service.
438	Laser pulse long error occurred. Please restart treatment!	Hardware or software component defective	Switch off and on device again. If error persists contact service.
439	Calibration failed! Start calibration again	Hardware or software component defective	Only for service
440	Illegal scanner position	Scanner damaged or blocked	Switch off and on device again. If error persists contact service.
441	Foot switch is pressed. Please release foot switch!"	Foot switch has already been pressed before laser was put in ready mode.	Release foot switch or check if anything blocks the foot switch.
442	Power calibration failed	Hardware or software component defective	Only for service
443	Scanner move fine error occurred	Hardware or software component defective	Only for service
444	Get scanner position failed	Hardware or software component defective	Switch off and on device again. If error persists contact service.
445	Save of the power calibration failed	Hardware or software component defective	Only for service
446	Base unit cold side too cold! Please wait while warming up...	Temperature of the cold side of the built-in Peltier cooler is too low.	Please wait till temperature reaches allowed range. Minimal warm-up time is achieved if device is kept running.
447	Base unit cold side too warm! Please wait and do not switch off device!	Temperature of the cold side of the built-in Peltier cooler is too high.	Please wait till temperature reaches allowed range. Minimal cooling time is achieved if device is kept running.
448	Base unit hot side too warm! Please wait while cooling	Temperature of the hot side of the built-in Peltier cooler	Please wait till temperature reaches allowed

No.	Message	Cause	User Action
	down...	is too high.	range. Minimal cooling time is achieved if device is kept running.
449	Applicator is cooling to configured skin temperature. Please wait..	Skin cooling temperature is too high.	Please wait till temperature reaches allowed range.
450	Hand switch active error occurred. Please release hand switch!	Hand switch has already been pressed before laser was put in ready mode.	Release hand switch or check if anything blocks the hand switch.
451	Liquid flowrate low. Please refill cooling liquid or straighten cable!	Not enough cooling liquid is pumped through the device. Two causes are possible: - There is not enough cooling liquid in the device - The applicator cable is squeezed or twisted	Fill up cooling liquid. Check if cable to applicator is bent heavily or twisted. Straighten cable! Restart device. If error persists call service.
460	Creation of IO_READ_THREAD failed	Hardware or software component defective	Switch off and on device again. If error persists contact service.
461	Creation of IO_EMISSION_THREAD failed	Hardware or software component defective	Switch off and on device again. If error persists contact service.
462	Applicator error	Hardware or software component defective	Switch off and on device again. If error persists contact service.
463	bootloader in error state	Hardware or software component defective	Switch off and on device again. If error persists contact service.
464	erase flash failed	Hardware or software component defective	Switch off and on device again. If error persists contact service.
465	firmware upload failed	Hardware or software component defective	Only for service
466	firmware crc error	Hardware or software component defective	Switch off and on device again. If error persists contact service.
467	start application failed	Hardware or software component defective	Switch off and on device again. If error persists contact service.
468	File not found	Hardware or software component defective	Switch off and on device again. If error persists contact service.
469	Queue overflow	Hardware or software component defective	Switch off and on device again. If error persists contact service.
470	general purpose input/output error	Hardware or software component defective	Switch off and on device again. If error persists contact service.
471	Unallowed temperature difference at applicator	Hardware or software component defective	Switch off and on device again. If error persists contact service.
472	Thermoelement Base Unit: Open circuit	Hardware or software component defective	Switch off and on device again. If error persists contact service.
473	Thermoelement Base Unit: Short circuit	Hardware or software component defective	Switch off and on device again. If error per-

No.	Message	Cause	User Action
			sists contact service.
474	IODevice configuration not found	Hardware or software component defective	Switch off and on device again. If error persists contact service.
475	IODevice configuration data incomplete	Hardware or software component defective	Switch off and on device again. If error persists contact service.
476	Saving the settings failed	Hardware or software component defective	Switch off and on device again. If error persists contact service.
477	Open the registry failed	Hardware or software component defective	Switch off and on device again. If error persists contact service.
478	Read computer name from the registry failed	Hardware or software component defective	Switch off and on device again. If error persists contact service.
479	Write computer name into the registry failed	Hardware or software component defective	Switch off and on device again. If error persists contact service.
480	Initialize the WiFi module failed	Hardware or software component defective	Switch off and on device again. If error persists contact service.
481	Syntax failure in the applicator response.	Hardware or software component defective	Switch off and on device again. If error persists contact service.
482	Laser diode voltage error	Hardware component defective	Please contact service.
483	Laser diode current offset too low.	Hardware component defective	Please contact service.
484	Laser diode current offset too high	Hardware component defective	Please contact service.
501	Scanner ignored SSCAN Signal	Hardware or software component defective	Switch off and on device again. If error persists contact service.
502	Scanner X-Axis Drive Timeout occurred. Please restart treatment!	Hardware or software component defective	If error only occurs once then continue working. If error occurs frequently contact service.
503	Scanner Y-Axis Drive Timeout occurred. Please restart treatment!	Hardware or software component defective	If error only occurs once then continue working. If error occurs frequently contact service.
504	Scanner Error occurred prior Laser emission	Hardware or software component defective	Switch off and on device again. If error persists contact service.
505	Scanner Error occurred while Laser emission	Hardware or software component defective	Switch off and on device again. If error persists contact service.
506	Timeout occurred while Laser emission	Hardware or software component defective	Switch off and on device again. If error persists contact service.
507	Scanner detects Scanpattern CRC error	Hardware or software component defective	Switch off and on device again. If error persists contact service.
508	Laser Emission could not be	Hardware or software com-	Switch off and on de-

No.	Message	Cause	User Action
	started	ponent defective	vice again. If error persists contact service.
509	Error while transmitting Scanpattern to Scanner	Hardware or software component defective	Switch off and on device again. If error persists contact service.
510	Scanner ignored SetStandby command	Hardware or software component defective	Switch off and on device again. If error persists contact service.
511	Timeout while transmitting Scanpattern to Scanner	Hardware or software component defective	Switch off and on device again. If error persists contact service.
512	Scanner X-Axis Safety Error occurred	Hardware or software component defective	Switch off and on device again. If error persists contact service.
513	Scanner Y-Axis Safety Error occurred	Hardware or software component defective	Switch off and on device again. If error persists contact service.
514	Applicator received no Scandata	Hardware or software component defective	Switch off and on device again. If error persists contact service.
515	Scanner SSCAN Error occurred	Hardware or software component defective	Switch off and on device again. If error persists contact service.
516	Unknown Calibration received by Applicator	Hardware or software component defective	Switch off and on device again. If error persists contact service.
517	Applicator warmup error	Hardware or software component defective	Switch off and on device again. If error persists contact service.
518	Wrong Calibration received by Applicator	Hardware or software component defective	Switch off and on device again. If error persists contact service.
519	Wrong warmup position received by Scanner	Hardware or software component defective	Switch off and on device again. If error persists contact service.
520	Scanner synchronization failed	Hardware or software component defective	Switch off and on device again. If error persists contact service.
521	Scanner moves too slow. Please restart treatment!	Hardware or software component defective	If error only occurs once then continue working. If error occurs frequently contact service.
522	Scanner moves too fast. Please restart treatment!	Hardware or software component defective	If error only occurs once then continue working. If error occurs frequently contact service.
523	Handswitch Error occurred	Hardware or software component defective	Switch off and on device again. If error persists contact service.
524	Thermoelement Sensor 1: Open Circuit	Hardware or software component defective	Switch off and on device again. If error persists contact service.
525	Thermoelement Sensor 1: Short Circuit	Hardware or software component defective	Switch off and on device again. If error persists contact service.
526	Thermoelement Sensor 2: Open	Hardware or software com-	Switch off and on de-

No.	Message	Cause	User Action
	Circuit	ponent defective	vice again. If error persists contact service.
527	Thermoelement Sensor 2: Short Circuit	Hardware or software component defective	Switch off and on device again. If error persists contact service.
528	Laser pulse short error occurred. Please restart treatment!	Hardware or software component defective	If error only occurs once then continue working. If error occurs frequently contact service.
534	Synchronization timeout error occurred	Hardware or software component defective	Switch off and on device again. If error persists contact service.
598	Applicator System Tick Error	Hardware or software component defective	Switch off and on device again. If error persists contact service.
599	Applicator detects an Program CRC error	Hardware or software component defective	Switch off and on device again. If error persists contact service.

7.5 Accessories

The following accessories/ detachable parts are intended to be used with the medical product:

- Foot switch (Item-No. GME1020.2201)
- Protective goggles (Item-No. GME1042.2100)
- Applicator holder (Item-No. GME1040.2102)
- Small spot adapter (Item-No. GME1040.4000)
- Cover Door Interlock (Item-No. GME1020.0124)
- Power cable (Item-No. GME1040.2200)
- Transport box LinScan (Item-No. GME1040.3000)
- Refill kit (Item-No. GME1040.2002)