CareMin650™

Instruction for Use

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CareMin650™

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User Responsibility

These Instructions for Use describe the proper setup, use, and maintenance of the CareMin650™ phototherapy system[a] - the Device or the System. The Device is to be used exclusively by a properly trained user and should not be used if it is damaged, contaminated, or if parts are missing. In which case, kindly contact the supplier immediately. For questions about Device care and maintenance kindly contact the supplier or authorized staff member of your facility. The user is solely responsible for the risks to the patient, clinicians, third parties or properties. He is also responsible in case where a treatment with inadequate performances is delivered to a patient due to an abusive or improper use of the device, inadequate maintenance, reparation or modifications made by unauthorized individuals.Any serious incident which occurs in relation to the device should be reported to the manufacturer and the local competent authority of the state in which the user and/or patient is established. You can contact NeoMedLight at the following address: quality@neomedlight.com.

CE 0459

NeoMedLight declares that the Device complies with the European Directive 93/42/EEC and that the single-use sleeves comply with the European Regulation MDR 2017/745.
The CE mark was obtained, and the Device was launched in March 2020.

This product should be handled with care and should be processed separately from consumer waste. Waste of Electrical and Electronic Equipment (WEEE) can pollute the environment. Thereby, the product is to be disposed of according to its specific Directive 2012/19/EU and following the appropriate paths.
Contact the local authorities or the supplier to determine the proper method of disposal of potentially biohazardous parts and accessories.

Types of Safety Symbols

⚠	***Warning:*** informs of a danger or a hazard for the patient or the operator.
⚠	***Caution:*** indicates a risk of damage to the Device.

1 PRODUCT DESCRIPTION AND APPLICATION

1.A Description

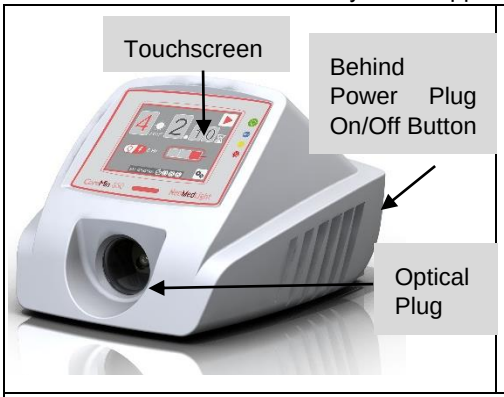
The CareMin650™ System is a phototherapy system designed to treat and/or to prevent mucositis and dermatitis. CareMin650™ consists of a Lightbox and a light applicator which delivers red light to skin or mucosa (cf. Figure 1). The Lightbox is made up of high-power red-light emitting LEDs. Several kinds of applicators can be connected to the Lightbox for applying light, depending on the tissue to be treated. Appropriate non-sterile plastic transparent single use disposables (called sleeves) are used to cover the part in contact with patient's skin or mucosa. CareMin650™ system can deliver from 1 up to 9 J/cm² at an irradiance range between 16 to 50 mW/cm².

[a] The term "System" is not used in this document with the meaning given by the standard EN 60601-1, definition 3.64. It stands for the group of interconnected parts which compose the medical device.

The Lightbox is an electronic box which role is to provide light via LEDs. This Lightbox can be controlled using its touchscreen, the user can set the energy dose (in Joules per square centimeters). The size of the Lightbox is 23x30x30 cm3, weights is 4.7 kg. The power cable connected to the Lightbox is a H05VVF 3G1.0 C13 type and is 2.5 m long.

Each applicator consists of a plastic connector, an optical cable composed of plastic optical fibres, a biocompatible polyurethane tube encapsulating the fibres, and a luminous textile element encapsulated in the same material as the tube. The textile element provides red light when the connector is plugged to the Lightbox. Applicators are cleanable.

To ensure the patient's comfort, as well as the cleanliness and biocompatibility of the device, sleeves must be added to cover the applicators. They are produced specifically for CareMin650™. The use of sleeves on CareMin650™ Photobiomodulation system's applicator is compulsory.



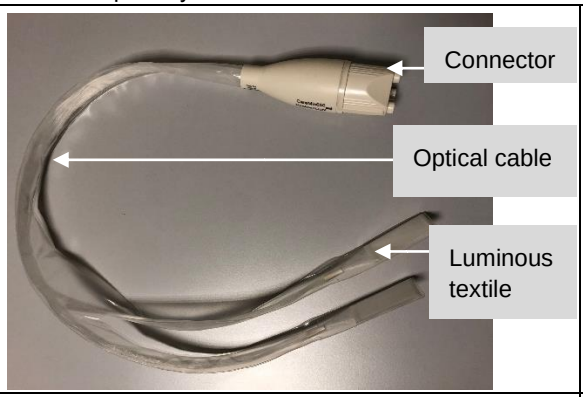
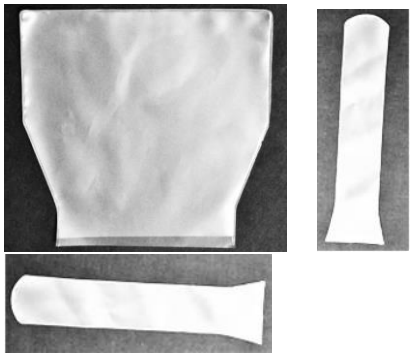


Figure 1 The Lightbox has a touchscreen to command the device, an electric cable to connect the electrical plug on the rear, an on/off button at the rear and at the front an optical plug from where the light is emitted. The applicators consist of a connector which is plugged to the optical plug, an optical cable and a luminous textile part



Derma-sleeve (at the upper left corner) and Oral-sleeves (at the right and below)

1.B List of the accessories and commercial references

Reference	Designation	Description
CM010	CareMin650™ Lightbox	Lightbox
CM201	CareMin650™ Oral Pad	Applicator for oral application
CM301	CareMin650™ Derma Pad	Applicator for cutaneous application
CM21150	CareMin650™ Oral Sleeve x50	Single use disposable sleeves for CM201 x50
CM31150	CareMin650™ Derma Sleeve x50	Single use disposable sleeves for CM301 x50

1.C Intended use of the Device

The CareMin650™ Phototherapy System is intended for the treatment and/or the prevention of mucositis and dermatitis.

1.D Contraindications

The use of the device is contraindicated for patients presenting allergy to polyurethane. Sleeves are made of fully biocompatible polyurethane, and had been tested according to the latest state of the art. However, please ensure that the patient is not allergic to polyurethane.

1.E Target patient

The target patient populations are adults and children aged above 5~~3~~ years old.

1.F Intended user

The CareMin650™ medical device is intended to be used in hospital or in oncological center, only by physicians and qualified technical staff (nurses, radiotherapy/radiology operator, etc). Phototherapy systems should only be used by trained medical staff.

1.G Performance of the Device

The light emitted has its wavelength peak at 650 nm. 95% of the light is delivered between 620 nm and 680 nm (cf.Figure 2). The irradiance of each applicator is ranged between 16 and 50 mW/cm². The mean value of the light is precise at +/- 20 %. **The light belongs to the SL continuous service classification group of risk 0 according to norm ISO60601-2-57**, meaning that it is safe. Lightbox is electrically supplied in between 100 V and 240 V. Its maximum power is 250 W. Any other input voltage might destroy the Lightbox and cause incidents. The device is not designed for continuous service but for sessions of maximum 9 J/cm² and have an automatic cooling cycle between each session.

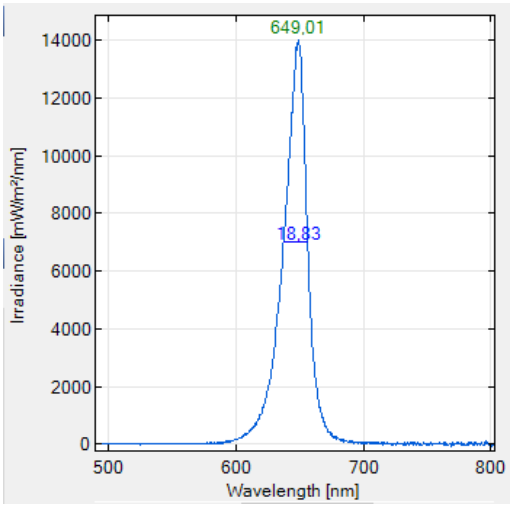


Figure 2 Light's spectrum of CareMin650™

1.H Clinical performance

The powerful red light of CareMin650™ has the appropriate power and the appropriate wavelength to reduce or prevent skin or mucosa ulcerations (i.e. Figure 2). CareMin650™ provides a controlled dose of light, through accurate calculation based on the output power and the time of irradiation. The applicator is flexible and is as close to the skin as possible. The right dose is between 1 J/cm² and 9 J/cm² per application.

1.I Expected Clinical benefits

The CareMin650™ phototherapy system helps to prevent and reduce pain due to mucositis and dermatitis and to improve patient's quality of life.

1.J Undesirable side-effects

The expected undesirable side effects of the use of the device are:

- Sensation of heat on the surface in contact with the patient;
- Discomfort in the mouth.

Application of on dense hair, dark skin and tattoo could induce discomfort, because melanin and dye absorb the energy and might get warm.

1.K Use of the Device

⚠	It is suggested and recommended to avoid the direct exposure of tumour site during phototherapy treatment by CareMin650™.
⚠	Due to the lack of safety data in the literature, direct application on thyroid and the treatment on pregnant women are not recommended.

The Lightbox should be used on a proper stable surface. It is not a portable nor an ambulatory device. It shall not be stacked, the fan vent on the side of the Lightbox should be free of obstacles. Before using Caremin650™ phototherapy system, please check if the connexion between the applicator and the Lightbox is correct. If not correct, the CareMin650™ phototherapy system will not start a session.

- Turn on the Lightbox using its On/Off button (cf. Figure 3).

  An introductory screen appears for a few seconds, and then the screen with the main menu is displayed. The pink light under the screen is on, confirming the device is electrically supplied. If no applicator is inserted, the blue light flashes.

Figure 3 ON/OFF button

- Choose the right applicator (Oral-pad for mucous membranes or Derma-pad for skin). Please ensure that the applicator is cleaned before use.
- Insert the connector into CareMin650™'s optical connection, keeping the luminous textile part of the applicator (opposite the connector) clean. Make sure you insert the mistake proofing slot correctly. The arrow on the connector should be on the top on the connector. **Insertion is easy, please don't force**. If it is not easy, turn slightly the connector to ensure correct positioning (cf. Figure 4)


Figure 4 Connector insersion: the mistake profing slot (left picture) should be set onto the fense (right picture)

- Open the packaging of the sleeve appropriated to the type of applicator you choose and insert it carefully on the applicator. It is recommended to wear gloves for this operation. The operator must be careful to prevent any contact of the disposable protection with external objects in order to avoid contamination. For Oral-pad you need 2 sleeves (1 for each textile pad). For an easier insertion, the textile is flexible and can be twisted lengthwise. Sleeves should be fully inserted.
- Press the "Selected Joule Dose" touch button on the home screen.

- Choose the dose to be delivered. The duration of the treatment is calculated automatically by the device, depending on the dose required and the performance of the applicator. To validate, press the "validation" button.

Be careful not to disconnect the applicator

- Hold the device and the applicator correctly. Indeed, the connector of the applicator can easily get out of the optical connection.
- Gently position the pad in contact with the mucous membrane or skin to be treated. The patient, under the control of the operator, can help to position the pad and keep it in place.

- Once the applicator is well positioned, press the session start button.
- During the period of treatment, the applicator can be maintained by the operator or by the patient. If a pause is required, the operator can press the pause button. To resume the session, re-press the start button, and the remaining time count resumes until the dose is received by the patient.
- Patients and operators wait until the end of the session.
- If necessary, a new session can be launched on a different area following the same procedure. If the same applicator is needed, the applicator should be repositioned on the new area to be processed and the new session should be launched in the same way as the previous one. If this relocation is done by simply dragging the applicator over a new area, there is no need to change the disposable protection. If a pause is made (if the applicator comes into contact with a surface other than the mucous membrane or skin to be treated), the protection must be changed. If you have to switch from the Derma-pad to the Oral-pad (or vice versa), you have to unplug the applicator, plug in the new applicator, cover the pad with *ad hoc* disposable protection and start the session as before.
- End of session and cleaning
    - Unplug the applicator;
    - Switch off the Lightbox and unplugg it;
    - Remove the sleeves, and discard them;
    - Clean the pad according to the cleaning procedure;
    - Keep the applicators and ensure they are stored in a clean condition;
    - Clean the Lightbox according to the cleaning procedure.

⚠	Check the good functionality and the integrity of the Lightbox, the applicators and the sleeves after delivery. Check as well as the integrity of the packaging.
⚠	The use of disposable protections to cover applicators is mandatory. Do not reuse disposable protections as they are single use. After the treatment session, gently remove the applicator from the patient's mouth or the patient's skin, holding the end of the protection so that it does not detach from the applicator. Avoid contacting the unprotected applicator with the patient's skin or mucous membrane.
⚠	To prevent from a risk of electric shock, this device must only be connected to a power supply network equipped with a protective earth.
⚠	Don't drop the Lightbox or applicators. If it happens, no longer use them and inform NeoMedLight to see what to do with them.
⚠	The device is not an ambulatory device. However, if it is transported, please use a rolling table on which the device would be stable. Please take care during the manipulation.

⚠	If the applicator is unplugged before the end of the session, the session is stopped. The remaining time displayed on the screen will be erased. Take precautions to make sure you don't unplug the applicator while de session is running. If such event happens, proceed according to the judgment of the prescriptor.
⚠	If the applicator is not functioning, gently remove it and retest it. If the failure happens again, change the applicator. If it is still not working, contact your local distributor.
⚠	Check regularly the integrity of the applicator and the sleeve, and especially the polyurethane coating which should have no scratch, no hole, no opening.
⚠	Check the vent in order to avoid overheating. Check the overheating warning regularly.
⚠	When connecting or deconnecting the applicator please handle firmly the Lightbox with one hand and pull the connector, not the optical cable.
⚠	When manipulating the applicators don't scratch, pull or bend the optical cable of the applicatior with a radius lower than 2 cm, as it will damage the optical cable.
⚠	Use indoors exclusively. Operating condition (use): ○ Temperature min 10°C and max 35°C; ○ Relative humidity: 13% to 75% without condensation.
⚠	Contact the manufacturer in case of abnormal operation.

1.L Additional information for use

- Lightbox is reusable until up to 4000 hours of use. The applicators have limited numbers of applications (maximum 150 applications per applicator), and sleeves are strictly of single use.
- Only use for the duration indicated in the treatment protocol with medical prescription.
- Beware, please don't use CareMin650™ Phototherapy system if any visible damage appears on the Lightbox or on the power cable.
- The Lightbox should not be stacked with any other devices. If this happens, please control and verify its safety and its performance under the medical's staff responsibility.
- Pad handle and Lightbox connecting port can be hot after use. Be careful when manipulating them after use. Keep way from children.

1.M Maintenance

⚠ Not following the maintenance rules may induce CareMin650™ Phototherapy system's failure and induce risks for the patient and for the user of the system

The maintenance at user's level is limited to a correct cleaning of the Lightbox and the applicators. In case of problems such as screen misaligment, powering issues or low irradiance values, or any other problems please contact your local distributor or NeoMedLight.

1.N Cleaning and storage

Storage conditions

Storage conditions between uses:

- Temperature min -20°C and max 50°C;
- Relative humidity: 13% to 75% without condensation;
- The applicator should not be left under the sun.

Transportation condition and storage before deconditioning:

- Temperature min -20°C and max 50°C;
- Relative humidity: 13% to 75% without condensation.

Between session, the applicator should be stored in a clean box. Do not store or use near a flammable element.

⚠ Store the lightbox in non-dusty storage zone.

Cleaning procedure

The Lightbox should be cleaned after each use. The applicator should be cleaned before and after each application. Please follow usual hygienic measures when using CareMin650™ Phototherapy system to avoid contamination or cross contamination. CareMin650™ Phototherapy system is designed to be usable with gloves. When disconnected, the Light Box'optical plug connecting surfaces may be hot. Please wait 5 minutes before cleaning the optical plug.

⚠ Beware when cleaning the optical plug: optical components are fragile.

Cleaning procedure for the Lightbox.

- Make sure the Lightbox is turned off. If not, turn the Lightbox off. Unplug the power cable.
- Make sure no applicator is connected. If not, disconnect the applicator from the Lightbox.
- Take a non-woven material which is clean and dry. Spray "Surfa'Safe" (or a product similar to Surfa'Safe) on it (around 3 sprays).
- Apply on the whole surface of the Lightbox. Give special attention to hard to reach areas and dirtiest parts of the device. Take care not to damage the optical lens when cleaning.
- Let the device dry.
- Perform a visual inspection. If needed, repeat the previous instruction until there is no more dirt observed.
- Before use, make sure the device is completely dry.

Cleaning procedure for the Applicator.

- Make sure the applicator is disconnected from the Light Box. If not, disconnect the applicator from the Lightbox.
- Lay the applicator flat on a clean table (cleaned with the Surfa'Safe).
- Spray "Surfa'Safe" on applicator.
- Apply on the whole surface of the applicator (Pad, connector and between them) with a non-woven material which is clean and dry.
- Let a laying time of 5 minutes.
- Rinse the whole surface of applicator with a clean cloth soaked in water.
- Let the applicator dry.
- Perform a visual inspection. If needed, repeat the previous instruction until there is no more dirt observed.
- Before use, make sure the device is completely dry.

⚠ Never dip the Lightbox or the connector of the applicator. Do not spray directly on the Lightbox. Lightbox is IP21, the connector of the applicator is IPX3, and the pad of the applicator is IPX7.

⚠ Do not sterilize (gas, gamma ray, autoclave) any part of Caremin 650.

⚠ It has been demonstrated and validated that Surfa'Safe from Anios does not impair Pad plastic housing. Thereby, to clean and disinfect the product, use an hospital disinfectant such as Surfa'Safe.
Do not use products containing:

- Caustic or abrasive cleaners (Isopropanol, Alcohol, Acetone, Acetic Acid, Sodium Hydroxide (even less than 5%));
- Powerful cleaning solutions (acidic or alkaline solutions);
- Iodine-based solutions.

⚠ Unplug the power cable from the Lightbox before cleaning the Lightbox.

⚠ Before reusing the Lightbox, please ensure yourself that the Lightbox is clean.

⚠ Discard the single use sleeves when the session is over according to the health center's regulation for possibly contaminated devices. Discard the Lightbox and the Pad according to the health center's regulation for electrical medical devices.

2 SAFETY INFORMATION

2.A Led warnings of the Lightbox

There are 5 warnings (5 LEDs), driven even if the microcontroller is out of control.

- **Pink LED**: Continuous pink light on means that there is no powering problem.
- **Green LED**: Continuous green light on indicates that CareMin650™ has started a session.
- **Red LED**: Continuous red light on warns that a power LED is not functioning. If the red light is ON, CareMin650™ is out of order. Contact the manufacturer.
- **Yellow LED blinking light:** Blinking yellow light on means overheating of the device. Please check that the air vents are not obstructed. If not, please restart CareMin650™'s Lightbox. If the defect still occurs, please switch off the Lightbox for 15 minutes. If the defect still occurs after switching on, please contact the manufacturer.
- **Yellow LED continuous light:** Continuous yellow light on significates a ventilator defect. In this case please contact the manufacturer. In both cases (point 4. or 5.), the session is off.
- **Blue LED**: Blue LED lights ON when an applicator is not well connected or in case of disconnection. If an applicator is not plugged, the blue LED blinks.

If those warnings occur, the Lightbox stops the light and the session is stopped.

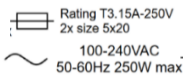
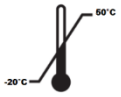
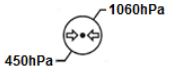
2.B Warnings

⚠	Duration of session Use the device only for the prescribed dose. A use that does not take into account the treatment plan may lead to an ineffective treatment or to potential risks to the patient's health
⚠	**No modification of the CareMin650™ Phototherapy System is allowed**. Do not use any accessories, spare parts and materials not described in these instructions. The use of a System which has been modified in terms of performances or by replacing its parts disregarding the manufacturer's indications may lead to risks to the patient (e.g. adverse events), the user, other people or properties.
⚠	Blocking the light source or reducing the exposed body surface must be avoided
⚠	Risk of Glare Avoid looking at the light source (Pad Connection Port) when the Device is switched ON and the Pad is not connected. However, in normal conditions there is no risk that the light source emits light when pads are not connected. The red light can cause glare BUT is not dangerous. If the patient or the user feels discomfort, he can wear blue, green or solar glasses.
⚠	Labels Integrity and Readability In case labels are degraded, the information addressing the safety of the patient, users, third parties, and properties can be found in this document. Contact the supplier if information concerning the identification of the product or of associated products is not visible anymore.
⚠	Make sure that there is no entanglement of the electric cord or cable at any time.

2.C Precaution of use

⚠	The CareMin650™ phototherapy system must only be used by clinicians who are qualified and aware of the treatment- and device-associated risks and benefits; The CareMin650™ phototherapy device is not to be used for other medical indications or on different body parts than those recommended. Improper use may lead to an ineffective treatment (i.e. no benefits) or to potential risks to the patient's health (adverse events).
	Clinical performances have been assessed according to the MASCC (Multinational Association of Supportive Care in Cancer). It provides guidelines to help in the prescription. The prescription of the dose and the number of sessions should be done by a physician for each patient according to his knowledge on photobiomodulation.
	The CareMin650™ System is designed so as not to interfere with the operation of other surrounding electro-medical devices.
⚠	Please be careful not to overlap treatment zones when there are several applications during the same session of treatment.

2.D Symbols

Symbol	Description	Symbol	Description	Symbol	Description
	Manufacturer		CE Marking declaration according to Directive 93/42/EEC		Do not spray directly over the Connection
	Consult instructions for use		Do not use if the packaging is damaged		Do not bend the fibers at right angles
	Lightbox electrical properties		Date of manufacture		LED failure indicator
	Storage temperature range		Catalogue number		Device overheating indicator
	Type B equipment		Serial number		Maintain the carton vertically following the arrows
	Caution: indicates a risk of damage to the Device.		Lot		The device is non sterile
	Applicator disconnected		Do not store more than 20 cartons on top of one another for Pad packaging		Do not store more than 2 cartons on top of one another For Lightbox packaging
	Waste of electrical and electronic equipment		Fragile, to be handled with care		Keep dry
	Storage humidity range		Single Use	IPX3	PAD Protection rating
				IP21	Lightbox Protection rating
	Storage astmospheric pressure range		Session is running		Medical Device

Abbreviation, Units and Description			Abbreviation, Units and Description		
°C	Celsius Degrees	(Unit of temperature)	mm	Millimeter	(Unit of length)
kg	Kilograms	(Unit of mass)	W	Watt	(Unit of power)
$mW \cdot cm^{-2}$	Microwatt per square centimeter	(Unit of power flux-density)	Hz	Hertz	(Unit of frequency)
λ	Wavelength	(Unit of wavelength)	VAC	Alternating current Volt	(Unit of voltage)
h	Hour	(Unit of time)	dB(A)	Decibel : Sound level – A weighting	(Unit of acoustic intensity)
min	Minute	(Unit of time)	hPa	Hectopascal	(Unit of atmospheric pressure)
nm	Nanometer	(Unit of length)	$J\ cm^{-2}$	Joule per square centimeter	(Unit of energy per surface)