USER MANUAL

NeuroLight®

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NeuroLight
Version 3.2 - EN
Last Update 2023/08/04
Ref: NL-IFU_EN

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an eye on your patient

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CONTENTS

About this manual

This operating manual contains all the information necessary to set up and use the portable pupillometer NeuroLight manufactured by IDMED. It also describes the specific cleaning and checking procedures that you may need to perform. This manual is intended for use by qualified medical personnel only (state registered Nurses, Anaesthetists and Doctors).

Keep this operating manual with the NeuroLight. It serves as a maintenance and repair manual.

Read the safety information in this manual carefully before using the NeuroLight.

Intended Use

The NeuroLight is a portable video pupillometer which enables to measure:
- the pupil of the patient
- the patients' pupils variation (Pupil Light Reflex - PLR) following a light stimulation.

Indication for use

The NeuroLight is used to assess the neurological conditions of conscious, unconscious or sedated patients.
It measures in a quick and simple way the pupil of the patient. The NeuroLight measures patient pupil size at rest as well as its minimal/maximal size, latency to constriction and percentage variation during a light stimulation.
There is one part of the NeuroLight that is or may be applied to the patient: the eyecup.

Expected technical performance

The following features are the essential performance characteristics of the NeuroLight:
- Measure the average diameter of a patient's pupil to an accuracy of +/- 0.1 mm (simulated pupil of 3 mm diameter).
- Generate a white light stimulation with an intensity of 320 lux +/- 10%, and a duration of 1 sec +/- 0.1 sec.

Clinical Performances

The NeuroLight provides reliable, accurate and reproducible measurements to be used as supplementary data to evaluate the neurological conditions thanks to the pupillary light reflex.

Clinical Benefit

The clinical benefit of NeuroLight is to provide objective evaluation of the Pupillary Light Reflex.

Important information about the use of NeuroLight

The NeuroLight compact video pupillometer is designed to be used by an authorised health professional (anaesthetist, ophthalmologist or state registered nurse - anaesthetist nurse) who has received special training in its use.

The system and all the associated parameters are designed to be used in general population – conscious, unconscious or sedated patients in a hospital or health care facility (operating room, recovery or critical care) to monitor pupil size and reactivity. There is no limitation for use regarding patient gender. Regarding the age, the patient must be at least 2 years old.

The NeuroLight measurement results on pupil size and reactivity can be used to complete the neurological assessment of the patient.

The interpretation of the results obtained with the NeuroLight must always be clinically appraised and compared to other clinical signs observed.

The NeuroLight conforms to the European directive covering medical devices and to the regulations in force in the country of distribution

For further information please contact IDMED, the manufacturer of the NeuroLight via their website WWW.IDMED.FR or by post to the following address:

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2 rue M.DONADILLE
13013 MARSEILLE
FRANCE
Telephone: +33 (0)4.91.11.87.84

I SAFETY MEASURES

INTRODUCTION

<u>The user must read carefully the whole manual before operating the NeuroLight.</u>

WARNING, CAUTION, REMARK
All parts of this manual contains warning, caution and remark statements about the NeuroLight.

WARNING statements give important information that, if ignored, could lead directly to personal injury or death
CAUTION statements give important information that, if ignored, could lead directly to equipment damage, erroneous data or cancelled procedure and indirectly to personal injury
REMARK statements provide useful information for a function or a procedure

EXPLANATION OF SYMBOLS
The symbols that may appear on the NeuroLight display are compiled and explained at the end of this chapter.

Any serious incident occurring in connection with the device must be notified to the manufacturer and to the competent authority of the Member State or country in which the user and the patient are established.

I.1 Warnings

Explosion risk: do not use the NeuroLight in a flammable atmosphere or in places where flammable anaesthetic products may accumulate.

The NeuroLight is not designed to operate in the environment of a SCANNER, M.R.I or any

other appliance creating powerful magnetic fields.

Never use the NeuroLight in the vicinity of short-wave or micro-wave therapy appliances.

Before use, check the device, display and cable for damage. Never use the unit if any defect or damage is found.

After taking any measurements, check the patient's complete eyelid closure to protect the eye from dryness and cornea alteration.

In order to prevent electromagnetic disturbance, keep minimum separation from RF communication equipment of 30cm.

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Any hardware or software modifications to the device are prohibited.

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or de-creased electromagnetic immunity of this equipment and result in improper operation.

The use of the NeuroLight should not result in any significant pressure of its eye cup on the patient's face but only putting it in contact. If too much pressure is applied, light marks or red patches may appear on the skin in the contact area due to pressure points. They should remain limited and not related to an injury.

I.2 Caution

Read the complete manual carefully before using the NeuroLight.

NeuroLight should be handled with medical gloves.

Do not autoclave the NeuroLight or any of its components or accessories other than the eyecup.

Never submerge the appliance or any of its components in liquid, or spray it or clean it with liquid.

The NeuroLight and its components are not compatible with sterilisation processes by gas, radiation (gamma or other), baths, steam or heat.

Follow the instructions for cleaning and disinfecting the NeuroLight given in the "Cleaning and Disinfection" chapter.

The NeuroLight contains a lithium-ion battery. The NeuroLight battery must never in any circumstances be removed, modified or replaced. Any intervention on the battery presents a risk of combustion or explosion, only a qualified technician or from the IDMED company is competent to intervene.

After a long period of non-use (storage), recharge the battery of the NeuroLight for at least

4 hours before use. If the NeuroLight does not start when the device is picked up (motion detection), the NeuroLight must not be used and must imperatively undergo maintenance operations.

Only qualified biomedical technicians are qualified to do repairs and maintenance, after obtaining permission from IDMED.

It should be noted that in all cases, in order to avoid any risk of corneal dryness, the use of the device on the patient (open eye) should not exceed 60 seconds continuously. In order to avoid any risk of corneal or retinal damage, the number of measurements performed on a single patient should not exceed 10 per hour.

The user of NeuroLight must take care not to be in contact with any other electrical appliances when using the NeuroLight.

Use only the accessories/components supplied by IDMED.

In order to prevent electrostatic shock, the device must be used in an electrostatic limited environment. (see Environment section).

Notice on Electromagnetic Compatibility (EMC) : This device generates, uses, and can radiate radio frequency energy. If not set up and used in accordance with the instructions in this manual, electromagnetic interferences may result.

The equipment has been tested and found to comply with the norm IEC60601-1-2 for medical electrical equipment.

These limits provide reasonable protection against electromagnetic interferences when operated in the intended environments (e.g. hospitals)

Known contraindications to use the NeuroLight: orbit structure damaged, surrounding soft tissue oedematous, abraded skin.

I.3 Symbols definition

Symbols are on the labels

	Caution		Serial Number
	Indicates the necessity for a separate processing from household waste.		Marking for conformity with the European regulation covering medical appliances Date of first CE marking: 2010
	Manufacturer	**IP 30**	Protection class against solid foreign bodies and liquids. Not protected against liquids.
	Refer to the user manual		Type BF Applied Part
	Catalog reference		Direct Current DC

Rx Only	Prescription use only in the USA		Curtis-Straus Mark (USA and Canada)
	Manufacturing date	MD	Medical device
Qi Compliant	Qi Compliant	Contains FCC ID	Bluetooth module compliant with the FCC regulation part 15
	Bluetooth module compliant with Japanese regulation	MM YYYY	Manufacturing date, Manufacturer

Symbols on NeuroLight screen

	Main button		Home button
	Settings menu		Previous step
	Delete measurements or file		Confirmation of the recording of the measurement
	Pause activated		Show records
	Patient menu / Access to patient records		Add new patient's file
	Battery Charge level (full)		Battery Charge level (intermediary)
	Battery Charge level (empty)		Mode selection
	NeuroLight ready for taking a measurement		Measurement impossible
	Left eye/right eye comparison	0 -24h	Trend for the « Flash Mode »
	Navigation arrows		Time and date setting
	Transport mode		3h / 24h data display
	Bar code scanning function	FL	« Flash » mode
	Data transfer function		Data transfer menu / Communication

Reliability of the measure: Poor

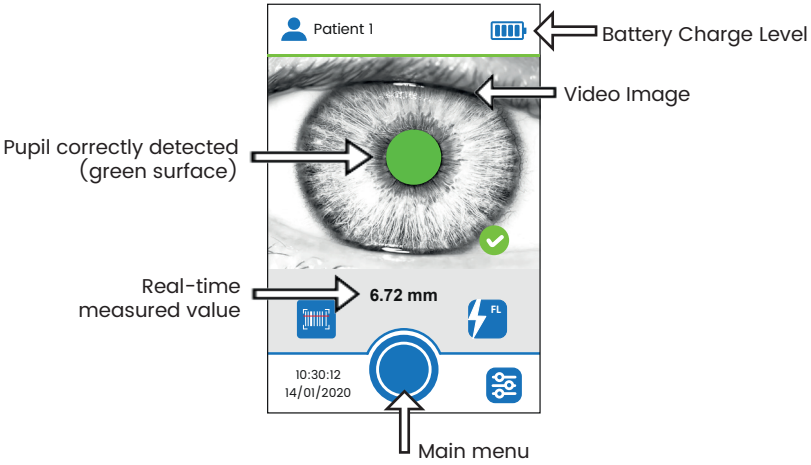
Reliability of the measure: Average

Reliability of the measure: Good

II GENERAL DESCRIPTION

Overview of the NeuroLight and its accessories

Display screen



Touch Screen

The NeuroLight is designed in such a way that all controls are accessible with a simple touch of a symbol or icon. The touch screen is designed to work even if the operator is wearing gloves for the examination.

Note: The normal time to press the screen is approximately 1 to 60 seconds. Do not stay in contact with the screen for more than 1 minute.

General Use

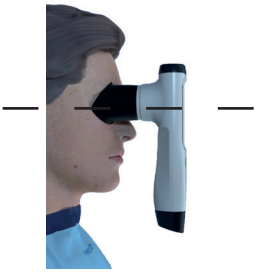
The NeuroLight measures pupil size and reactivity (photomotor reflex) of a patient. The QPi score can help for a quick read of the measures (see p14-15).

Fitting the positioning eyecup

The NeuroLight has a silicone eyecup so it can be positioned on the patient's face. Before each use, the operator must clean this part. For more information about cleaning, refer to the "CLEANING AND DISINFECTION" chapter. This eyecup is the only part in contact with the patient. The eyecup is to be placed on the NeuroLight by simply pushing it onto the black lens.

Installation and positioning of the NeuroLight

To obtain accurate measurements the NeuroLight must be positioned correctly on the filmed eye of the patient. The black silicone eyecup on the NeuroLight must be in contact with the upper and lower part of the eye socket bone without pressing. In this way there will never be any pressure on the eye-ball itself. It should never be in contact with the patient's eye. The operator must hold the device vertically and firmly to prevent any movements while filming.



Correct positioning of the NeuroLight

Turning the device ON/OFF

The NeuroLight switches on automatically when the device is held in the hand (movement detection).

Note: the device switches off automatically if it is not used for 2 minutes or if it is repositioned on its charging station.

Patient Files / Measurements identification

The NeuroLight has a barcode reader. Activation of the red light beam for reading barcodes identifying the patient is done by pressing and holding the dedicated button and directing the light beam towards the barcode.

When a label is read, it creates a file with the label encoded ID number or retrieves an existing file created by a previous scan of that same label.

The NeuroLight has also 20 pre-set files numbered 1 to 20. If there is no barcode scanning, the user will either choose one of those files or create additional files numbered 21 and above to save the measurement results.

Settings Menu

Setting date and time

The NeuroLight contains a clock that is set at the factory. The operator can update the date and time of the NeuroLight. To access the time setting and date change menu proceed as follows:

• Select the menu "settings" by pressing the following icon

Then select this icon : . Use the navigation arrows , to adjust the "date", the "time" and "format" of the date as desired.

By pressing the icon , the changes will be automatically validated.

Changing the language

If necessary, the operator can change the language of the NeuroLight. To access the menu for changing the language, follow the procedure below:

• Select the "Settings" menu by pressing the following icon

Then use the navigation arrows to select the desired "language".

Right Eye/ Left Eye Indicator

In the Flash mode, at the end of the measurement, a pop-up window appears allowing the user to identify the eye used thanks to the following indications: Right, Left.

Transport Mode

The operator can set the NeuroLight to "transport mode." This mode switches off the unit for transport or storage. It prevents the unit from switching on every time a motion is detected.

To access the “transport mode”, follow the procedure below:

• Select the “Settings” menu by pressing the following icon 

• Then select the transport mode by pressing  .

To deactivate the transport mode, position the device on its charging station. The device will automatically switch on when it is removed from the station.

Data transfer / Communication

The user can select the mode and the data destination.

To access the data transfer menu, follow the steps below:

• Select settings menu by pressing on 

• Then select data transfer by pressing on  .

• Using the arrows select the transfer mode (PC/HL7)
• Connect your receiver module ; on PC (ref: NL-WDT) or HL7 (ref: IDM-GTW)

• Validate your choice by pressing on 

Note: When activating the data transfer, the user must be at less than 1m (3ft) away from the receiver.
When pairing, the type and identification (ID) at the bottom left of the screen must fill automatically.
If not, get closer of the module and press again the following icon  .

III USING THE NEUROLIGHT

Create or select a patient’s file

It is strongly advised to create a patient’s file or select an existing one to be able to save the measurements.

To select an existing patient’s file:
- Press the icon “Patient File” and select the correct file with the left or right arrow

Or
- Scan the patient’s barcode that was previously used to create the file

To create a new patient’s file:
- Press the icon “Patient File” and select the icon “New patient’s file”. Numbering starts at 21.

Or
- Create a patient file by reading a barcode identifying a patient.

Taking a measurement

Positioning of the device and detection of the pupil

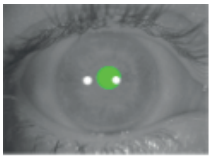
Positioning the device on the patient’s face is an important step to obtain reliable measurements (see: Installation and positioning).

If the patient is conscious, ask him/her to keep his/her head straight, open the filmed eye wide and look straight ahead without blinking. The other eye is closed.

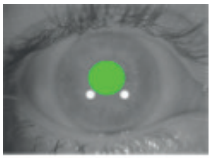
If the patient is unconscious or not able to cooperate, the operator may need to raise and/or lower the patient's eyelids so that the pupil measured by the NeuroLight appears completely unobstructed.

The patient's pupil should be centered on the screen and totally in green color. Only the pupil will be colored in the image displayed by the NeuroLight. If this is not the case, reposition or position differently the NeuroLight.

It is important when measuring a very small pupil to position the NeuroLight so that the white spots (reflections of the infra-red diodes) do not deform the detected pupil contour. If this is the case reposition the NeuroLight or position it differently.



NO
White spots deform the pupil



YES
Correct positioning and detection of the pupil

NO
Poor pupil detection

When the pupillometer is ready for a measure the following icon will appear at the bottom right of the video image.

Note : when the pupil detection is not correct, the red icon will appear at the bottom right of the video image. The pupillometer does not detect the pupil in the video image.
Do not move the NeuroLight when taking measurements

Taking a measurement

Once the device correctly positioned, the NeuroLight displays the green icon when the pupil is detected. It is necessary to ensure that the size of the pupil is stable before taking the measurement.

Start taking the measurement by pressing continuously on the main button until the countdown at the bottom right corner of the screen reaches 0.

A beep will indicate the start and end of the measurement period. In "Flash" mode, at the end of the measurement, the user can select the patient's eye used for the measurement (right or left).

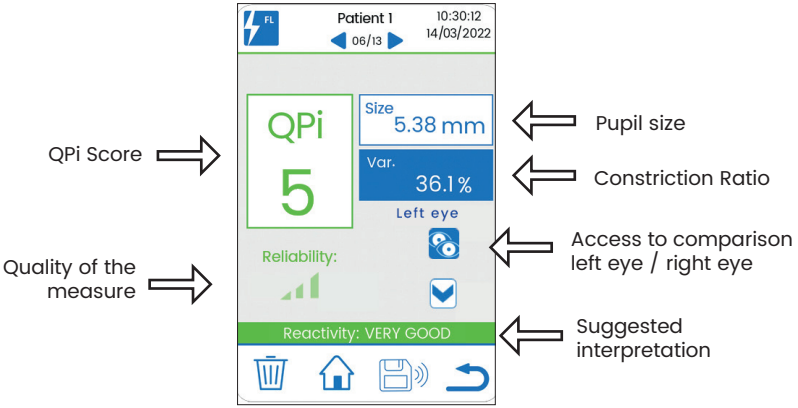
Bilateral Pupil Exam: If a measurement on the other eye is done within 2 minutes of the first one, a comparison chart of the bilateral pupil exam will be displayed.

Hold function

It is possible to freeze the analysed image of the pupil by putting the NeuroLight on pause. To pause press on the video image. It freezes the pupil size and the image. Press again on to deactivate the pause mode.

Display of the results

The NeuroLight displays the results of the measurement of the eye that has been filmed. The results and measurements displayed depend on the mode used.



Example of a result

If the reliability of the measure is poor ( ) , the user has to do the measure again.
If the reliability of the measure is average ( ), the user must ensure that the measurement is clinically relevant.

After each measurements, results can be saved or deleted. These measurements will be recorded in the current folder.

Press the 'Save' icon to validate and keep the results.

Press the 'Delete' icon to delete the results.

Note: If a data transfer mode is active, the following icon is displayed on the screen. It allows to save and send the data to the configured receiver module.

The results displayed are:

- QPi Score (between 0 and 5)
- Pupil size before stimulation (Diameter in mm)
- Variation percentage (Var. in %):
  (Var%=(Abs(Variation(mm))/size (mm))*100)
- A commentary on reactivity level
- Selected eye for the measurement
- Reliability of the measure

When pressing the icon , more information appears:

- Results control curve with the following markers:
  - o Duration of the flash (light blue area)
  - o Size of the pupil (blue horizontal line)
  - o Maximum variation in pupil size (black horizontal line)
- Maximum variation in pupil size in mm
- Constriction Velocity (speed in mm/s)
- Latency of constriction (latency in ms)

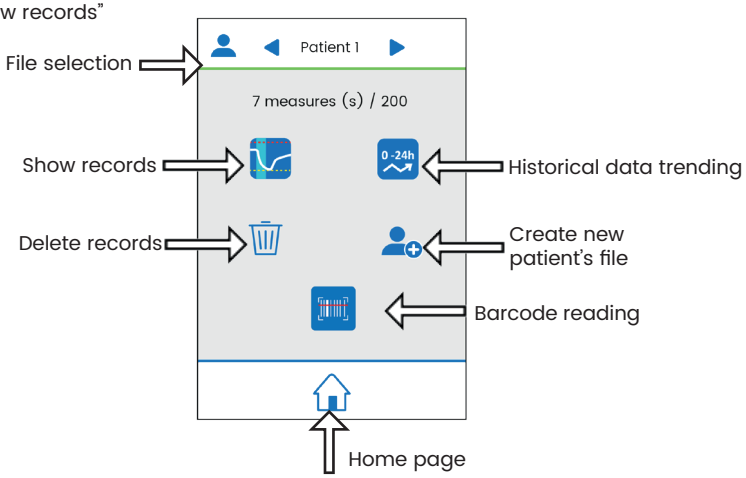
The QPi is the score allowing a quick interpretation of the photomotor reflex of patients. It simply differentiates, on a scale of 0 to 5, the reactivity of the photomotor reflex. It comes with a colour code of 3 levels (red, orange, green) and a commentary to facilitate interpretation.

QPi SCORE
pupil reactivity

0-1-2	3	4-5
Non reactive / Weak	Reduced	Good / very good

Review saved files / Trend charts

Press the icon "patient's file", select a file with the left/right arrow and access results with "show records"



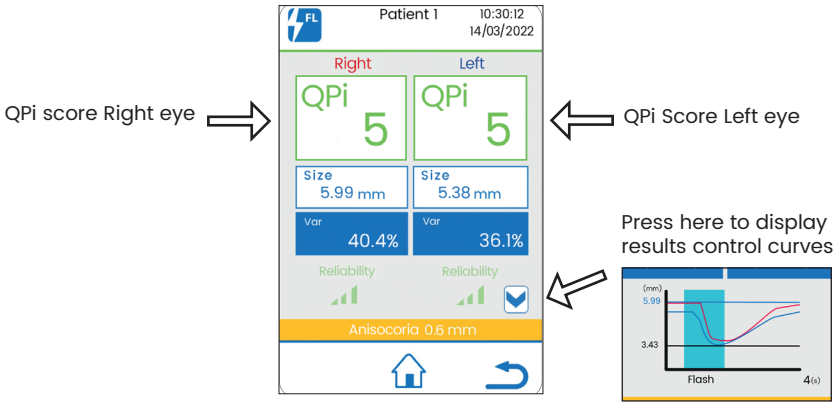
Note: If a data transfer mode is active, the following icon is displayed on the screen. It allows to send all the patient's data to the configured receiver module.

Comparison and trend monitoring

The display of the recordings is done through 2 pages.
Press on the icons and 0 -24h to access comparison and historical data.

Left eye / right eye comparison page

This page allows to compare the measures performed on each eye (within a maximum of 2 minutes between the two measurements): QPi score, baseline sizes, photomotor reflex amplitude and reliability of the measurement.



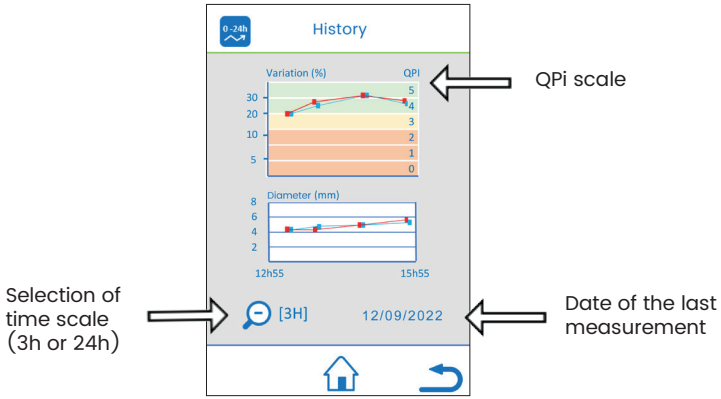
When pressing the icon , more information appears:

Results control curve for each eye (red curve for right eye and blue curve for left eye) with the following markers:

- o Duration of the flash (light blue area)
- o Size of the pupil (blue horizontal line)
- o Maximum variation in pupil size (black horizontal line)

Trending 0-24h

On the patient selection page press the "Trend" icon.
This page allows you to visualize the evolution of the diameters of both eyes over the last 24 hours or last 3 hours.
It also displays the evolution of the variations in pupil size and of the QPi score for the same file.



Note: right eye values are in red, and blue for the left eye.

Selecting a patient registration file

The measurement's folder or patient's file enables to save a set of measurements of the same patient in a single file. The selection of the file can be done very simply by scanning the identification bar code of the electrode used for patient stimulation. Thus by identifying the patient, the NeuroLight is positioned on the patient's file.

Alternatively the user can select the patient's file manually by selecting the «registration folder» icon  .

Once positioned in the «registration folder» menu, the user can select the desired patient's file by using the navigation arrows.

IV PREVENTIVE MAINTENANCE, CLEANING AND DISINFECTION

Preventive maintenance

To be sure of maintaining the performance level, we strongly recommend having the appliance checked every two years on the following points:

- Check the casing, the screen and the labels for damage
- Check the quality of the filmed image (sharpness and contrast)
- Check the cleanliness of the lens
- Check the battery charging process
- Check the absolute values measured
- Check the light stimulation
- Battery replacement

The lifetime of the NeuroLight, under the required conditions of use and maintenance, is 5 years (2 years for accessories).

Caution:

Only technicians trained by IDMED are authorised to carry out repairs or maintenance operations

Battery and battery charging

Battery

The NeuroLight contains a rechargeable Lithium-Ion battery. It is fitted with thermal protection and protection against short-circuits.

Battery specifications

- 2900 mA/h (or higher)
- Nominal value 3.7 V (3.6- 4.2 V)
- Contains a thermal protection system (overheating)
- Contains a short-circuit protection system.

The NeuroLight indicates the battery charge level using icons

	Charge level OK
	Intermediate battery charge level
	Discharged battery symbol. If this symbol appears the NeuroLight must be recharged immediately (Battery red)

The battery has a 6-month warranty.

Note :
Only qualified technicians trained by IDMED or IDMED personnel are authorised to carry out repairs or maintenance operations on the battery.

Battery recharging and maintenance
The battery can be recharged using IDMED wireless charger (ref: STA-W2). The complete charge time is about 10 hours. Charger specifications are given in the «power supply» paragraph under the «Technical Specifications» section.

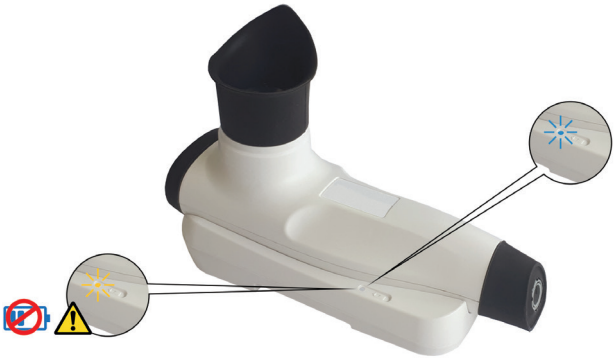
The battery can be recharged regardless the current level of charge.

To recharge the battery, place the unit on its charging station.


Caution: if the indicator light is orange
Remove and reposition the NeuroLight on the charging station.


Charging in progress


Charging station indicator



No maintenance is required for the NeuroLight battery but it is recommended to change it every two years.

Note :
Only qualified technicians trained by IDMED or IDMED personnel are authorised to carry out repairs or maintenance operations on the battery.

Cleaning and Disinfection

Caution :
Do not autoclave the NeuroLight or any of its components or accessories except for the eyecup.

Under no circumstances should the NeuroLight or any of its components or accessories other than the eyecup, be in direct contact, immersed, sprayed or filled with any liquid.

In order to avoid inadvertently changing the settings of the device, we advise you to put it in transport mode before cleaning it.

The NeuroLight, its parts and accessories are non-sterile. In no circumstances should the NeuroLight be sterilized.

The surface of the NeuroLight has to be cleaned with a lint-free cloth moistened with a quaternary ammonium disinfectant, 70% isopropyl alcohol or a cold decontamination solution (e.g. ANIOS). Before using any of these solutions, refer to the manufacturer's documentation and carry out a test on a small area.

Examples of recommended products :
- Septalkan from the manufacturer Alkapharm.
- Clinell® Universal Spray from the manufacturer Gama Healthcare Ltd.
- CLEANISEPT from the manufacturer Dr. Schumacher.
- Mikrozid Sensitive Liquid from the manufacturer Schülke &Mayr GmbH.
- Incidin™ OxyWipe from the manufacturer Ecolab Inc.

Please check with your local authorized distributor or the manufacturer which products are available and approved in your country.

The eyecup, the only part in contact with the patient, will be removed from the NeuroLight and cleaned in the same way as the NeuroLight and then put back in place on the clean NeuroLight. It can also be cleaned by autoclaving (maximum temperature 135°C). The eyecup can withstand 50 autoclave washing cycles. Any alteration, degradation or modification of the eyecup must lead to its replacement.

The eyecup must be cleaned or changed between each patient.
The NeuroLight must be cleaned and disinfected between each patient. Low-level disinfection is usually sufficient.

The lens should always be free of stains or scratches to avoid the risk of distorting the measurements made. It should be cleaned with a lint-free cloth and wiped carefully to avoid any stains or reflections.

V APPENDIX 1

Troubleshooting

The table below is a list of possible malfunctions as well as the solution to be implemented for their resolution.

Issue	Solution
Device will not turn ON, or turn OFF by itself after a few seconds	Charge the battery by positioning the device on the charger (See «Battery and battery charging chapter»)
The LED charge indicator will not illuminate while charging the device	Remove and reposition the device on its charger.
The video image is blurred	Check the cleanliness (see « Cleaning / Disinfection»)

Note :

All other malfunctions must be handled by the manufacturer (IDMED) or by qualified biomedical technicians trained by IDMED and authorised to carry out repairs or maintenance operations on the NeuroLight.

VI APPENDIX 2

End of life equipment / Recycling

In order to protect the environment, it is mandatory to hand over your worn out system to a collecting body capable of processing appliances containing electronic components and Lithium-Ion accumulators.

For the disposal or recycling of the appliance components, contact a company specialising in the recycling of electronic appliances.
Electronic goods that have not been selectively sorted are potentially dangerous for the environment.
Packaging materials should be disposed of or recycled according to the regulations in force.

Specification and warranty
Environment

Storage and expedition

The NeuroLight and its accessories should be stored or transported within the limits of the following conditions. These conditions apply to storage and transport situations excluding operation.

Temperature	10°C to +50°C
Humidity	15% to 95% (without condensation)
Pressure	500hPa to 1060 hPa

The original factory packaging should be used for storage and transport.
Protect the NeuroLight from sudden temperature changes that could cause condensation.

Operating environment

Reminders:
Explosion risk: do not use the NeuroLight in a flammable atmosphere or in places where flammable anaesthetic products could concentrate.

The NeuroLight is not designed to operate in the environment of a SCANNER, M.RI or any other appliance creating powerful magnetic fields.

The NeuroLight is designed to operate in complete safety in the following conditions. Any situation outside those described is likely to affect the reliability of the appliance.

Temperature	10°C to +40°C
Humidity	35% to 90% (without condensation)
Pressure	700hPa to 1060 hPa

Technical specifications

Safety

- Eyecup (part in contact with the patient). Latex free
- Conforms to European regulation 2017/745
- Visible and infrared lighting conforms to IEC 62471 safety standards
- CE marking (certifying body 0459 LNE/G-Med) – Class 2a.
- Compliant with standard IEC 60601-1. Class II equipment. / Continuous mode of operation
- EMC: IEC 60601-1-2

EMC Emission

Emission test	Compliance	EMC Instructions/cautions
RF Emissions CISPR 11	Group 1	The NeuroLight uses RF energy only for internal functions. Therefore RF emissions are very low and should not disturb other nearby devices.
RF Emissions CISPR 11		
Harmonics IEC 61000-3-2	Class B	The NeuroLight must be used in professional healthcare facility environment
Voltage fluctuations	Class A	
and flicker IEC 61000-3-3	Compliant	The NeuroLight can be connected to the public mains network

EMC Immunity

Phenomenon	Basic EMC standard	Professional healthcare facility environment Immunity Test Levels	Compliance levels	EMC Instructions/precautions
ELECTROSTATIC DISCHARGE (ESD)	IEC 61000-4-2	± 8 kV contact	± 8 kV contact	In order to reduce ESD, the device must be used in a 35% humidity environment or more
		± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 2 kV, ± 4 kV, ± 8 kV air	
Radiated RF EM Fields	IEC 61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Complies to table 9 of IEC 60601-1-2 (2014)	Complies to table 9 of IEC 60601-1-2 (2014)	In order to prevent electromagnetic disturbance, keep minimum separation from RF communication equipment of 30cm

Electrical fast transients / bursts	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	± 2 kV 100 kHz repetition frequency	The NeuroLight may temporarily not display result during transient electromagnetic disturbances such as the use of electrosurgery device. In that case, the NeuroLight will maintain the safety of the patient and the user.
Surges Line-to-line	IEC 61000-4-5	± 0,5 kV, ± 1 kV	± 0,5 kV, ± 1 kV	Mains power quality should be that of a typical residential, commercial or hospital environment.
Surges Line-to-ground	IEC 61000-4-5	± 0,5 kV, ± 1 kV, ± 2 kV	± 0,5 kV, ± 1 kV, ± 2 kV	Mains power quality should be that of a typical residential, commercial or hospital environment.
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	In order to prevent electromagnetic disturbance, keep minimum separation from RF communication equipment of 30cm
RATED power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Mains power quality should be that of a typical residential, commercial or hospital environment
Voltage dips	IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Mains power quality should be that of a typical residential, commercial or hospital environment.
		0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	
Voltage interruptions	IEC 61000-4-11			Mains power quality should be that of a typical residential, commercial or hospital environment.

Measurements

- Measurement system by video camera and in-built data processor
- Measurement range: 1 to 9 mm (pupil diameter)
- Accuracy 0.1 mm or 5%, resolution 0.01 mm (pupil size)
- Measurement and image acquisition frequency 60 images/s

Data transfer

- Data transfer via Bluetooth (depending on data collection system)
  - Frequency band : [2400 - 2483.5] MHz
  - Maximum output power: 8 dBm

Light Stimulation

- Duration 1 second
- Intensity fixed at 320 Lux (precision +/-10%)

Measurements management

- Folder creation by barcode reading
- Number of recordable measurements: approx. 10000

Power Supply

- 3,7V DC Lithium-Ion battery 2900 mAh or above (with in-built thermal and short-circuit protection), autonomy approx. one week in normal use (20 measurements per day).
- IDMED STA-W2 charging base:
  - Qi standards compliant 5W min
  - AC adapter ref. PWR5_1, 5V / 1.3 A min. Compliant IEC60601-1
    Input: 100-240V, 50-60 Hz, 160-80 mA
    Output: 5V DC / 1400 mA

Weight

- 280 g (approx.)

Warranty

- Length of the warranty: 2 years (except battery warranty: 6 months)

VII APPENDIX 3: ACCESSORIES

The NeuroLight (reference : NL-MU) can be delivered with a number of accessories. Here is the list of the main accessories with their names and IDMED references.

Medical accessories of the NeuroLight

Reference	Description
STA-W2	Wireless charging station for NeuroLight

Other accessories

Reference	Description
EMB-NL	Eyecup for NeuroLight
PWR5-1_XX	Charger / Power supply: XX code for plug types
NL-SW_PRD	PRD» software module for recording of the pupillary size variation (dilatation)
NL-WDT	Wireless receiver for PC for data transfer
IDM-GTW	HL7 gateway for pupillometers

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