USER MANUAL

AlgiScan®

USER MANUAL
AlgiScan
Version 3.2 - EN
Last update 2023/10/11
Ref: ALG-IFU_EN

idmed
an eye on your patient

idmed
an eye on your patient

CONTENTS

About this manual

This operating manual contains all the information necessary to set up and use the portable pupillometer AlgiScan 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 AlgiScan. It serves as a maintenance and repair manual.

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

Intended Use

The AlgiScan is a portable video pupillometer and algesimeter which enables patients' pupils variation to be measured following three types of stimulation:
- Pupil Light Reflex (PLR) evaluation thanks to light-stimulation
- Pupillary Pain Index (PPI) evaluation thanks to electrical stimulation
- Pupillary Reflex Dilatation (PRD) evaluation thanks to external stimulation

Indication for use

The Algiscan is used to assess:
- The neurological conditions of conscious, unconscious or sedated patients
- The analgesical conditions of unconscious or sedated patients.

It measures in a quick and simple way the pupil of the patient.

The AlgiScan measures patient pupil size at rest as well as:
- its minimal/maximal size, latency to constriction and percentage variation during a light stimulation.
- its minimal/maximal size and its percentage of dilation during nociceptive stimulation.

There is one part of the AlgiScan that is or may be applied to the patient: the eyecup.

Expected technical performance

The following features are the essential performance characteristics of the AlgiScan:
- 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.
- Generate electrical skin stimulation in the form of pulse train of 200µs, 100Hz, with an amplitude between 0 and 60mA and a total duration between 0 and 8s.

Its characteristics are produced with an accuracy of +/- 10%.

Clinical performances

AlgiScan provides reliable, accurate and reproducible measurements to be used as supplementary data to evaluate:
- The neurological conditions thanks to the pupillary light reflex.
- The analgesical conditions thanks to the pupillary pain index and amplitude of the PRD (pupillary reflex dilatation).

Clinical Benefits

The clinical benefits of the AlgiScan are:
- An objective evaluation of the Pupillary Light Reflex
- An adequate dosage of analgesic agents (according to the patients' own needs)

Important information about the use of AlgiScan

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

The system, and all 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 the responsiveness of their pupils to various stimuli. There is no limitation for use regarding patient gender. Regarding the age, the patient must be at least 2 years old.

The measurements performed by the AlgiScan on the pupillary reactivity of the patient can be used to monitor the effects of certain anaesthetic products.

The interpretation of the results provided by the AlgiScan should always be subjected to clinical judgement and compared with other clinical signs observed. We strongly advise against relying solely on the results or values provided by the AlgiScan for monitoring sedated or anaesthetised patients. The values provided by the AlgiScan should also be interpreted with care when in the presence of certain products such as Barbiturate, Nitrous oxide, etc. It is also necessary to interpret with care values measured on patients suffering from neurological problems.

The AlgiScan 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 AlgiScan via their website WWW.IDMED.FR or by post to the following address:

IDMED
Hôtel Technoptic
2 rue M. DONADILLE
13013 MARSEILLE
FRANCE
Phone : +33 (0)4.91.11.87.84

I Safety measures

INTRODUCTION

The user must read carefully the whole manual before operating the AlgiScan.

WARNING, CAUTION, NOTES
The terms Warning, Caution and Notes have precise meanings in this manual.

- **WARNING** warns against certain actions or situations likely to cause injury or death.
- **CAUTION** warns against actions or situations likely to damage the equipment, produce inaccurate data or cancel a procedure, even if injury is unlikely.
- A **NOTE** provides useful information about a function or procedure.

EXPLANATION OF SYMBOLS
The symbols that may appear on the AlgiScan 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 AlgiScan in a flammable atmosphere or in places where flammable anaesthetic products may accumulate.

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

The electrode wires, electrodes or connectors should not come into contact with other conductors.

Never use the Electrical Stimulation of the AlgiScan while using high frequency surgical appliances.

To reduce the risk of burns when using high frequency surgical appliances, do not place the AlgiScan stimulation electrodes between the surgical site and the return electrode to the electro surgery unit.

The connection to a patient at the same time as a high frequency surgery appliance can cause burns at the points of contact of the AlgiScan electrodes and damage the appliance.

Never use the AlgiScan simultaneously with the use of defibrillation appliances.

The AlgiScan should never be connected continuously to electrodes positioned on the patient but only for the period of measurement. Before and after the measurement, the electric cable should be disconnected from the electrodes.

The AlgiScan must be connected to pacing electrodes or ECG electrodes supporting voltages up to 300 Volts with a current of 60 mA. The contact area of the electrodes must be greater than 1.8cm².

The power of the Electrical Stimulation causes nociceptive stimuli the intensity of which should be appropriate to the patient's analgesic level.

Never use the AlgiScan on a patient wearing a Pacemaker.

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

Before using check that no other equipment, device or appliance is in contact with the electrodes.

The electrodes may only be in contact with healthy, non-injured skin.

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

The AlgiScan in electrical stimulation mode (Tetanus, PPI) performs tetanus electrical stimulus as well as increasing tetanus stimulations for a duration of 1 to 8 seconds. In Tetanus and PPI mode, the AlgiScan provide electrical stimulation. When using a monitoring system of neuromuscular blockade, the user should take care to wait 5 minutes after a Tetanus or PPI test before making a measurement of the patient's level of neuromuscular blockade. In order not to bias the estimation of the measure of level of neuromuscular blockade.

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 electrodes will never be placed on the patient's head or any other part of the body that is judged to be potentially sensitive to electrical stimulation or may result in a risk of injury to the patient.

Do not apply stimulation or place electrodes on the patient's face and head (especially the eyes, lips, entire neck). Do not position the electrodes on either side of the heart.

The use of the AlgiScan should not result in any significant pressure of its eyecup 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 this manual thoroughly and attentively before using the AlgiScan.

AlgiScan should be handled with medical gloves.

Do not autoclave the AlgiScan 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 AlgiScan 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 AlgiScan given in the "Cleaning and Disinfection" chapter.

The AlgiScan contains a lithium-ion battery. The AlgiScan battery must never in any circumstances be removed, modified or replaced. Any intervention on the battery presents a risk of fire or explosion, only qualified technicians or IDMED company technicians are competent to do such work.

After a long period of non-use (storage), recharge the battery of the AlgiScan for at least 4 hours before use. If the AlgiScan does not start when the device is picked up (motion detection), the AlgiScan must not be used and must imperatively undergo maintenance operations.

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

The connection to a patient at the same time as a high frequency surgery appliance can cause burns at the points of contact of the AlgiScan electrodes, and damage the appliance.

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 AlgiScan's users must take care not to be in contact with any other electrical appliances when using the AlgiScan.

Before any stimulation the practitioner will evaluate the compatibility of the stimulation intensity to the level of analgesia and sedation of the patient as well as the site of stimulation.

We strongly advise against placing the electrodes on the patient's thorax because of the additional risks of cardiac fibrillation.

Never touch the electrodes during the stimulation phases. The electrodes are only surface electrodes and are compatible with the application of electrical stimulation (CE marking adapted).

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.

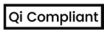
The equipment has been tested and found to comply with the norm IEC60601-1-2 for medical electrical equipment.

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

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

I.3 Explanation of symbols

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

Symbols on AlgiScan screen

	Main button		Home button
	Settings menu		Previous step
	Delete measurements or file		Confirmation of the recording of the measurement

Pause activated

Patient menu / Access to patient records

Battery Charge level (full)

Battery Charge level (empty)

AlgiScan ready for taking a measurement

Hide details

« Tetanus» mode

« PPI© » mode

Green electrode symbol. Correct electrode conduction level / skin.

Red electrode symbol. Non-functional electrical stimulation, conduction problem.

Left eye/right eye comparison

Navigation arrows

Transport mode

Bar code scanning function

Data transfer function

Reliability of the measure: Poor

Show records

Add new patient's file

Battery Charge level (intermediary)

Mode selection

Measurement impossible

Show details

« Flash » mode

« PRD » mode

Yellow electrode symbol. Moderate electrode conduction level / skin.

Grey electrode symbol. Conduction problem, short circuit, non-functional electrical stimulation.

Trend for the « Flash Mode »

Time and date setting

3h / 24h data display

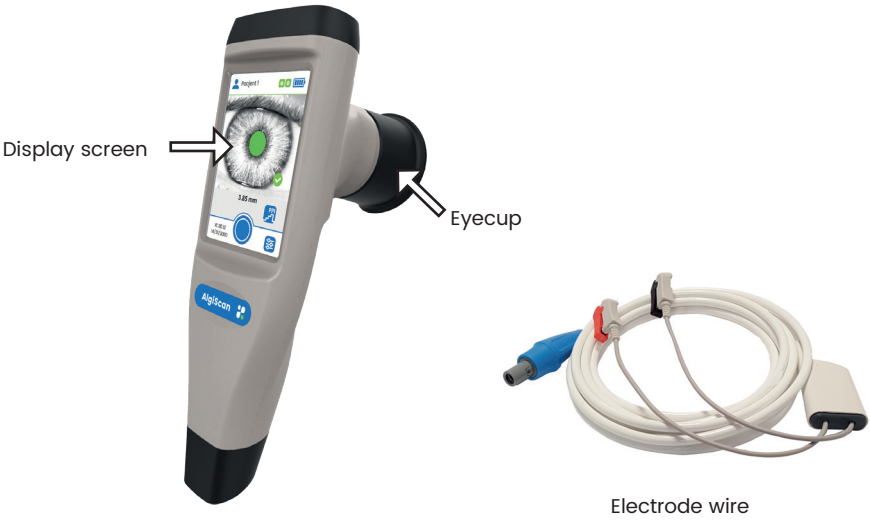
Data transfer menu / Communication

Reliability of the measure: Good

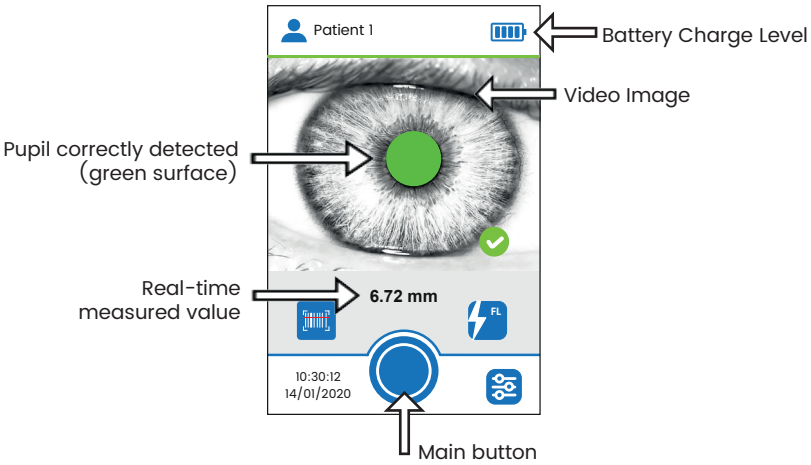
Reliability of the measure: Average

II General description

Overview of the AlgiScan and its accessories



Display screen



Note : display screen in the Flash mode (measurement mode used for measuring the pupillary light reflex)

Touch screen

The AlgiScan is designed in such a way that all controls are accessible with a simple touch of a given area of the AlgiScan screen. This area is called the 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 AlgiScan can be used with a large number of different practices and protocols. It can be used on all patients without any age limit. It allows exact measurement of the pupillary light reflex and the pupillary reflex dilation. Hence the user should take care to confirm these two reflexes and their pertinence for every patient before using the AlgiScan.

It should be noted that in all cases, use of the appliance on the patient (with the eye open) should not exceed 15 seconds continuously for the Tetanus, PPI and Flash modes. For the PRD mode, the user starts the recording and stops it whenever needed. The maximum recording time is 59sec. The number of measurements performed on the same patient should not exceed 10 per hour.

Instantaneous measurement: an instantaneous measurement is a direct reading of the pupil size by the user in real time on the AlgiScan screen.

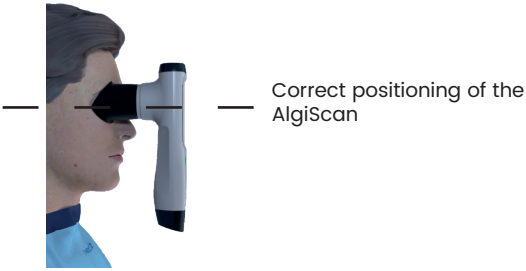
Dynamic measurements consist of recording measurements under conditions predefined by the user by selecting one of the available modes of the AlgiScan. This type of measurement will then give a series of results with figures and a curve representing the variation in the size of the pupil. Algiscan offers 4 different modes (Flash, Tetanus, PPI and PRD).

Fitting the positioning eyecup

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

Installation and positioning of the AlgiScan

The correct positioning of the AlgiScan in relation to the filmed eye of the patient enables more accurate measurements to be obtained. The black silicone end-piece on the AlgiScan 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. The appliance should be held vertically and firmly so that it does not move in relation to the patient's head.



Turning the device ON/OFF

The AlgiScan 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 AlgiScan 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 AlgiScan 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

Setting the time on the AlgiScan

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

• Select the “settings” menu 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 button , the changes will be automatically validated.

Changing the language

If necessary, the operator can change the language of the AlgiScan. 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 AlgiScan 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 AlgiScan

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

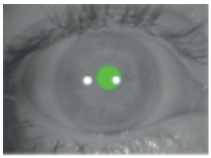
Positioning the device on the patient's face is an important step to obtain reliable measurements (see: "Installation and positioning of the AlgiScan" section).

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.

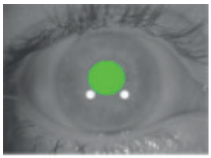
If the patient is unconscious or not able to cooperate, the operator may need to raise and/or lower the patient's eyelids so that the pupil measured by the AlgiScan appears completely unobstructed.

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 AlgiScan. If this is not the case, reposition or position differently the AlgiScan.

It is important when measuring a very small pupil to position the AlgiScan 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 AlgiScan 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 AlgiScan when taking measurements

Taking a measurement

Once the device correctly positioned, the AlgiScan 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

When a mode ("Flash", "Tetanus", "PPI" or "PRD") is selected, it is possible to freeze the analysed image of the pupil by putting the AlgiScan on pause. To do this, press the video image for a long time, which freezes the measured pupil value as well as the filmed image. Press again on to deactivate the pause mode.

Measurement protocols

The different modes will allow the pupil to be measured over a variable period of time depending on the protocol chosen, with or without stimulation. In these different modes, the operator starts measuring by pressing the main button continuously (the button is held down throughout the measurement) after selecting the desired mode ("Flash", "Tetanus", "PRD", "PPI"). While recording, the seconds are counted down and displayed on the AlgiScan screen. An audible beep indicates the start and finish of the recording (or measurement).

To ensure the quality of the results, the same precautions need to be respected as for an instantaneous measurement:

- The pupil must be fully visible throughout the recording
- The pupil must be centred on the AlgiScan screen
- The green zone covering the pupil must remain homogeneous and stable.

« Flash » mode: Display of the QPi score. The pupil reactivity is tested with a calibrated flash of light (photomotor reflex). Press the main button for 4 sec to start acquiring data. The stimulation is done with a flash of light. The objective is to measure the pupillary reactivity to light.

« Tetanus » mode: It is a test of the patient's pupil reactivity to an adjustable continuous electrical stimulation (the reactivity of the patient's pupil is recorded simultaneously to the electrical stimulation).
This mode is used to measure the pupil reactivity to a standardized electrical stimulation. Before starting the user selects the intensity of the electrical stimulation which will be applied and makes sure it is innocuous for the patient.
(see Section : Selecting the measurement protocol)

« PRD » mode: It is a protocol to record the pupil size variation (the pupil is filmed with no stimulation).
With this mode the variations of the pupil size are recorded during 60s in the course of medical or surgery acts.

« PPI » mode: Evaluation of the patient's level of sensitivity to nociception.
With this mode the patient's level of analgesia is measured with the PPI scale. Before use, the operator will check that the patient is in suitable conditions to withstand the different levels of PPI mode stimulation and ensure that they are safe for the patient.

Before launching a measurement protocol, check that the selected protocol corresponds to the desired one ("Flash", "Tetanus", "PRD" or "PPI"). If it is not the case, select the symbol of the desired test (see the section: Selecting the Measurement Protocol).

The default protocol is shown on the right side of the screen. Before starting recording the AlgiScan must be positioned on the patient and must detect the pupil correctly for at least 2 seconds to leave time to the pupil to adapt its size with the darkness.

Caution: before using the device, check the type of stimulation chosen, its intensity and its innocuousness regarding the patient. For more information on these operations refer to the following chapter.

Selecting the Measurement Protocol

The AlgiScan uses four different symbols to show the mode in use.

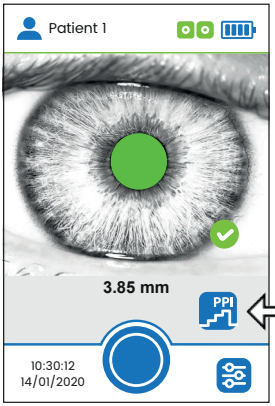
"Flash" mode

"PRD" mode

"PPI" mode

"Tetanus" mode

By pressing the symbol displayed, you access the menu enabling you to select a mode. Once in the "Mode Selection" menu, press the symbol of the desired mode. For Tetanus mode you must specify the level of stimulation.



Display of the selected menu

Menu « Mode selection »

"Flash" mode

The Light Flash protocol is used to check the efficiency of the pupillary light reflex. The QPi (Quantitative Pupillometry Index) is the score allowing a quick interpretation of the pupillary light reflex of patients. The AlgiScan stimulates the patient's pupil with a light flash. This lighting or light Flash has a duration of 1 second. Its strength is fixed at 320 Lux. The overall duration of the test is 4 seconds.

The QPi score simply differentiates, on a scale from 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

Selection of light stimulation

To select light stimulation and adjust its power:

- Press the symbol on the screen representing the mode used
- Once in the menu “mode selection” press the “ Flash “ symbol
- Flash mode icon selected 

- Return to the measurement screen by pressing the following symbol 

Starting a measurement with light stimulation

Once the ‘Flash’ mode has been selected, it is possible to start the measurement by pressing the main button.

Before starting the measurement, the user must take care to position the appliance for 2 seconds and check that the patient’s pupil is fully visible on the AlgiScan screen; the eye not being filmed should be closed (for more information on the implementation of the measurement refer to the chapter: “Taking a measurement”).

It is necessary to press and hold down the main button to perform the measurement. Then the AlgiScan emits a beep indicating the start of the measurement. During this time, the AlgiScan should not be moved or the patient should close their eyelids. If this is the case, a new measurement must be taken.

While the test is in progress (recording), the AlgiScan displays a countdown of the remaining recording time (in seconds) during which it is necessary to keep the main button pressed. A final beep indicates the end of the measurement.

“PRD” mode

This mode allows to measure (record) the pupil size changes during 60s at maximum. This operating mode does not require for the stimulation cable to be connected to the device.

The AlgiScan does not generate any stimulation during this test.

The interest of this mode is to accurately measure pupil reactions during nociceptive stimuli (surgical or medical care) via the pupil reflex dilation. The pupil dilation thus measured makes it possible to quantify the intensity of the stimuli and to evaluate their impact on the patient and their actual opioid needs.

Starting “PRD” mode

- Select the desired patient file.
- Select PRD mode (icon: 

) via the menu “mode selection”.
- Position the device on the patient’s eye.
- Return to the measurement screen by pressing the following symbol  .
- Check as pupil is correctly detected and coloured in green on the screen.
- Start recording by pressing the main button
- Press and hold the main button for the duration of the recording.

Recording stops automatically at 60s or when the user releases the main button.

The result is not valid if the recording time is less than 2 seconds, and will not be displayed.

“Tetanus” mode

This protocol measures the dilation of the pupil of a patient subjected to electrical stimulation. The duration of this test is 10s. It is essential to take into account the patient’s analgesic and/or sedation level to determine the optimal stimulation intensity. In case of doubt we advise using the lowest intensity stimulation possible.

Characteristics of electrical stimulation
The electrical stimulation generated by the AlgiScan is the stimulation regularly used by NMT Monitor and "peripheral nerve stimulators". This stimulation is called "Tetanus 100Hz".
The characteristics are detailed in the «Technical Specifications» section.

It is a nociceptive stimulation that should be adapted in intensity to the patient's analgesic level.

It is common practice to retain the following stimulation intensity thresholds :

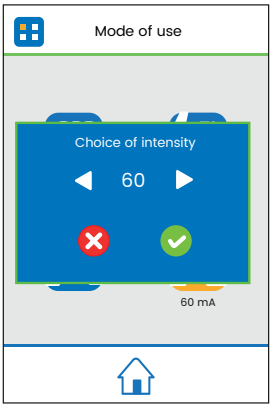
- Non-sedated person, below 10mA
- Normally sedated person, 0 to 40mA (patient in ICU or operating theatre)
- Heavily sedated person 0 to 60mA (ICU or Operating theatre)

Caution: these values are only observations and should in no circumstances serve as a prescription. Only a qualified practitioner can determine the appropriate stimulation level to be applied to the patient.

If necessary, the tetanus stimulation stops as soon as the user releases the main button.
The result is not valid if the recording is stopped less than 2 seconds after the end of the electrical stimulation, and will not be displayed.

Selection of electrical stimulation and its intensity
To select electrical stimulation and adjust its intensity:

- Press the symbol on the screen representing the mode used
- Select "Tetanus" mode.
- Select the intensity of the electrical stimulation by pressing the navigation arrows



Select the stimulation intensity by pressing the navigation arrows until the desired value is displayed.

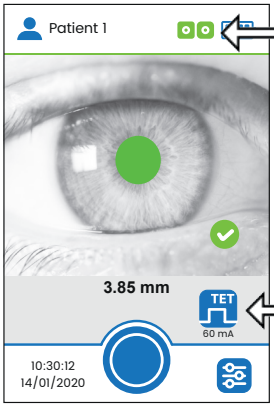
- Confirm your selection by pressing the following symbol

Note: To exit the pop-up window or cancel the intensity selection, press the following symbol

Once the intensity has been adjusted, the 'selection mode' screen is being displayed again. The user can then visually check the selected intensity.

In the example above, the user has selected a 60 mA electrical stimulation.
The user returns to the measurement screen by pressing the following symbol

The AlgiScan indicates continuously the level of conduction of the patient's electrodes.



Verification of the level of conduction of the electrodes. In this example the conduction is OK (green).

Electrical stimulation selected with a current of 60 mA

« PPI » Mode

The PPI test gives the depth of patient's analgesia through the PPI score.
The PPI score is used only for sedated, non-communicative patients with an analgesia level that allows them to tolerate a minimum level of infra-nociceptive stimulus (minimum Tetanus stimulus 10 mA, 100 Hz with a duration of 1s).

The operating principle is to apply to the patient a continuous infra-nociceptive stimulation and increasing it in intensity until a pupillary variation upper 13%. When the pupil size variation is over 13% the stimulation is stopped and AlgiScan calculates the PPI score.

Each stage of electrical stimuli has a duration of 1s with stages at 10, 20, 30, 40, 50 and 60 mA.

PPI score scale:

Maximum intensity achieved by stimulation in mA	PPI Scale	Level of pupillary reactivity in the patient
10	9	The pupil's variation is more than 13% during the 10 mA stimulation stage
20	8	The pupil's variation is more than 13% during the 20 mA stimulation stage
30	7	The pupil's variation is more than 13% during the 30 mA stimulation stage
40	6	The pupil's variation is more than 13% during the 40 mA stimulation stage
50	5	The pupil's variation is more than 13% during the 50 mA stimulation stage
60 (1s)	4	The pupil's variation is more than 13% during the 60 mA stimulation stage
60 (1s)	3	The pupil's variation is more than 13% during the second 60 mA stimulation stage

60 (5%<pupillary dilation)	2	The pupil's variation is more than 5% during the last 60 mA stimulation stage
60 (Pupillary dilation <=5%)	1	The pupil's variation is less than 5% during the last 60 mA stimulation stage

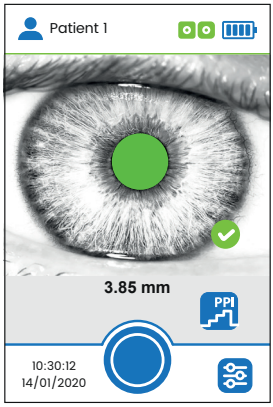
Adjustment of PPI score: One point is added to PPI score if the dilation of the pupil is over 20% .

To select « PPI » mode

To start a PPI mode:

- Select the required recording folder
- Position the AlgiScan in PPI mode via the "Mode Selection" menu
- Return to the measurement screen by pressing the following symbol
- Set up Algiscan on the selected patient's eye
- Patient's pupil must be centred on the screen and completely coloured green
- Start recording by pressing the main button (Caution: the test only start if the electrode conduction/impedance indicator is green)
- Hold the main button throughout the recording

Screenshot PPI Mode:



Notes: for a correct use of PPI and Tetanus modes, the user must validate at least the following three steps:

Connection and positioning of stimulation electrodes
Connecting the AlgiScan stimulation cable to the electrodes
Patient electrode conduction control

As soon as the AlgiScan is positioned in "Tetanus" or "PPI" mode, it is possible to activate the measurement by pressing the main button, if the conduction of the electrodes is adequate (green electrode icon).

To start the measurement, press and hold down on the main button. The user hold his finger pushed on the button during all the time.

If the user removes his finger of the button during the test, AlgiScan stops immediately the test and the stimulation (PPI or Tetanus tests). The result is not valid, and therefore not displayed, if the recording stops less than 2 seconds after the end of the electrical stimulation.

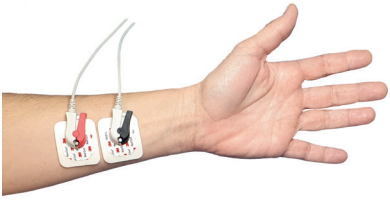
Note that the AlgiScan emits a first beep when the electrical stimulation starts. During the stimulation, the device emits a beep at each new level, the tone of which increases with the intensity. A final beep indicates the end of the stimulation.

During this time interval, it is essential that the AlgiScan is not moved and that the patient does not close his eye. If this does happen, a new measurement must be performed.
During the test the AlgiScan display shows a countdown of the time remaining.

Connection and positioning of the stimulation electrodes

The electrodes can be positioned on different sites on the patient's body. The practitioner must choose a relevant site for the desired measurement while ensuring there are no injury risk for the patient. In many situations, the anterior forearm as well as the C5 and T2 dermatomes can be valid sites.

It is important to remember that in order to obtain a correct stimulation, a good connection between the electrodes and the patient's skin as well as correctly stuck electrodes are essential.



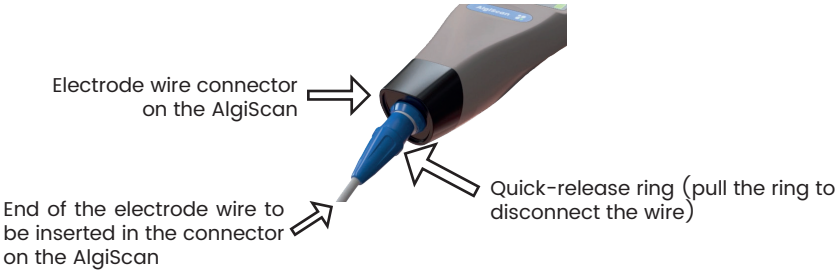
Example of electrodes positioning

Caution:

Electrical stimulation can cause muscle contraction and thus an involuntary movement. The practitioner will take care that this movement does not cause injury to the patient or bring him/her into contact with other objects or devices.

Connection of the electrode wire from the AlgiScan to the electrodes

Before touching the electrodes, always make sure that the AlgiScan is not in a stimulation phase.
First, connect the electrode cable to the AlgiScan by pushing in the end of the cable equipped with the connector in.
The proximal electrode should be connected to the red clip. The distal electrode should be connected to the black clip.



Note:

The user can disconnect the electrode wire from the AlgiScan at any time to stop a stimulation or for any other operation that is necessary. The connector is fitted with a quick-release ring enabling the wire to be disconnected from the AlgiScan by simply pulling the ring.

Patient/Electrodes conduction level and skin resistance

The level of conduction of the electrodes is checked by the AlgiScan as soon as an electrical

stimulation with a non-zero current is selected. This control is carried out continuously until the main button is pressed by the user to start the measurement.

The skin resistance is one of the components of the total resistance in the stimulation circuit, which also includes the resistance of the electrodes. The AlgiScan generates constant current stimulations. This means that the stimulation voltage increases automatically according to the resistance. The voltage is limited to a maximum value of 300 V. For a current fixed at 60 mA; the maximum acceptable resistance is 5 k Ohms.

If the skin resistance is adequate, the AlgiScan displays the electrode symbol in green. Thus the value of the stimulation applied to the patient will correspond to the value selected. If the skin resistance value is high, the AlgiScan displays the electrode symbol in yellow which signifies that the electrical stimulation applied to the patient will be less than the electrical stimulation selected.

If the resistance is much too high or if the circuit is open (electrode cable is damaged, electrode not connected to the patient), the AlgiScan displays the electrode symbol in red.

Symbols representing the connection status of the electrodes to the AlgiScan patient:

Green electrode symbol: Correct conduction, optimal stimulation.

Yellow electrode symbol: Insufficient conduction, stimulation may not correspond the expected value.

Red electrode symbol: Conduction problem, short-circuit (electrode cable damaged, not connected, or electrodes not connected to patient) or poor electrode-patient contact.

Grey electrode symbol: Conduction problem, short-circuit (damaged electrode cable,...), the electrodes are in direct contact.

It should be noted that if the electrodes are in contact with each other or if the cable is damaged causing a short circuit, the AlgiScan displays an electrode symbol in grey with a red line symbolising an inter-electrode connection.

Insufficient cleaning of the skin may cause excessive skin resistance; hence we strongly advise placing the electrodes on clean skin free of injury. It should be noted that a high skin resistance does not necessarily cause problems in obtaining electric stimulation.

Display of the results

The AlgiScan displays the results of the measurement of the eye that has been filmed. The results and measurements displayed depend on the protocol used. It is important to control the quality of the displayed curve and to verify that measurement values are not artefacts. Thus the blue and black horizontal lines indicate respectively the baseline value of the pupil (pupil size before stimulation) and the minimum pupil size during measurement (maximum pupil change). The lines must be appended to the curve and not to an isolated point (artefact).

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

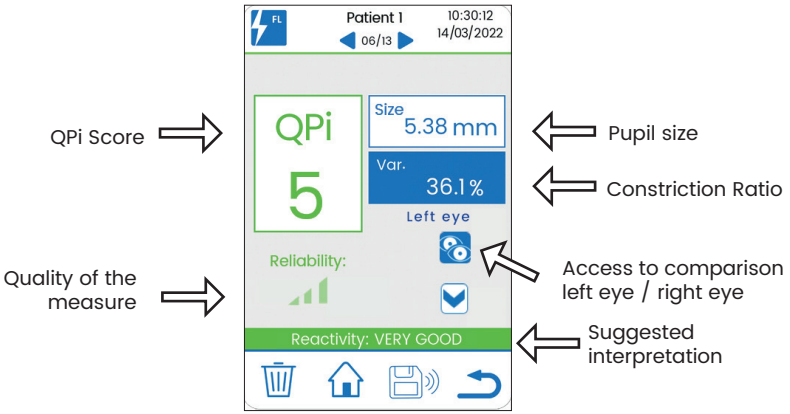
Press the 'Delete' icon to delete the results

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.

Results in the "flash" mode - QPi Score

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



Example of a result: light stimulation mode

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.

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)
- Maximal size variation of the pupil (value in mm in brackets)
- Constriction Velocity (speed in mm/s)
- Latency of constriction (latency in ms)

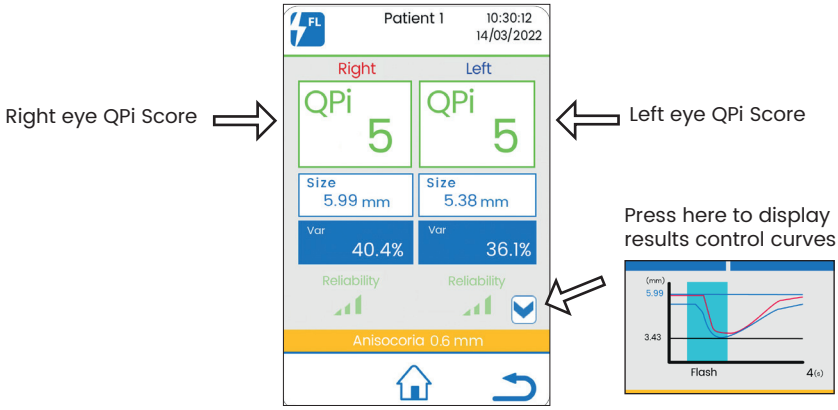
Comparison and trend monitoring in Flash mode

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:

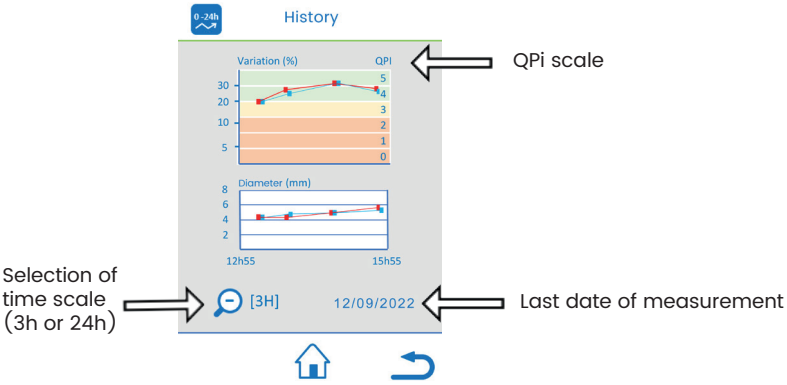
- o Duration of the flash (light blue area)
- o Size of the pupil (blue horizontal line)
- o Maximum variation in pupil size (black horizontal line)

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 QPi score for the same file.

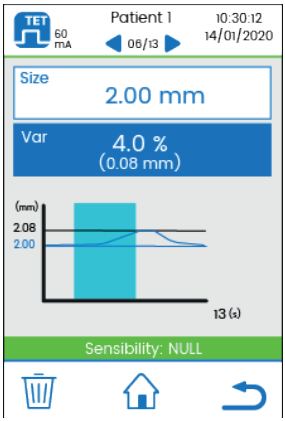


Note: right eye values are in red, and blue for the left eye.

Results in the “Tetanus” mode

In this mode, the results displayed after 11 seconds of record are:

- The recording monitoring curve with the following markers:
  - o Duration of the stimulation (light blue area)
  - o Size of the pupil (blue horizontal line)
  - o Maximum variation in pupil size (black horizontal line)
- The pupil size before stimulation (in mm)
- The percentage pupil's variation obtained (Var. in %)
  (Var. %=((Max.-Min.)/Min.*100)
- Maximal size variation of the pupil (value in mm in brackets)
  The AlgiScan displays the intensity of the used stimulation



Example of a result: “Tetanus” mode with a current of 60mA

After the values measured the AlgiScan displays a comment about the intensity of the dilatation reflex (here the comment is “NULL”; it is highlighted in green).

The comment displayed and its highlighting colour is obtained via the quantitative and qualitative scale of the dilatation reflex explained below.

Qualitative/Quantitative scale of the Pupillary Reflex Dilation (4 levels, 3 colours)

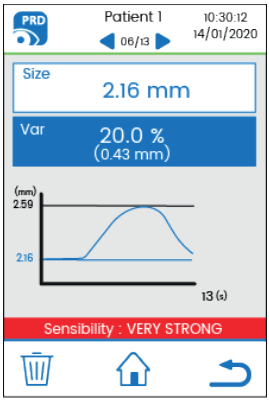
The value taken into account for the qualitative/quantitative scale of the Pupillary Reflex Dilation and for the display of the comment is the amplitude of the reflex (value as a percentage). They are only indicative and must be corroborated with other physiological indicators commonly used.

Amplitude of the PRD reflex (in %)	PRD < 5%	5%<=PRD<12%	12%<=PRD<20%	PRD>20
Comment and display colour	Null sensibility (Green)	Weak sensibility (Green)	Strong sensibility (Yellow)	Very strong sensibility (Red)

Results in “PRD” mode

In this mode, the results displayed are:

- The recording monitoring curve with the following markers:
  - o Size of the pupil (blue horizontal line)
  - o Percentage pupil’s variation obtained (Var. in %)
- The pupil size before stimulation (in mm)
- The percentage pupil’s variation obtained (Var. in %)
  (Var. %=((Max.-Min.)/Min.*100).
- Maximal size variation of the pupil (value in mm in brackets)



Example of a result: “PRD”

After the values measured the AlgiScan displays a comment about the intensity of the dilatation reflex (here the comment is “Very Strong”; it is highlighted in red).

The comment displayed and its highlighting colour is obtained via the quantitative and qualitative scale of the dilatation reflex explained below.

Qualitative/Quantitative scale of the Pupillary Reflex Dilation (4 levels, 3 colours)

The value taken into account for the qualitative/quantitative scale of the Pupillary Reflex Dilation and for the display of the comment is the amplitude of the reflex (value as a percentage). They are only indicative and must be corroborated with other physiological indicators commonly used.

Amplitude of the PRD reflex (in %)	PRD < 5%	5%<=PRD<12%	12%<=PRD<20%	PRD>20
Comment and display colour	Null sensibility (Green)	Weak sensibility (Green)	Strong sensibility (Yellow)	Very strong sensibility (Red)

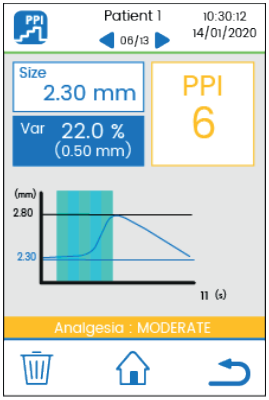
Results in the “PPI” mode

In this mode, the results displayed after record are:

- The recording monitoring curve with the following markers:
  - o The different levels of electric stimulation by color bands (light blue and light green) and the value of stimulus
  - o Pupil size (blue horizontal line)

o Maximal size variation of the pupil size (black horizontal line)

- The pupil size before stimulation (in mm)
- The percentage pupil's variation obtained (Var. in %)
  (Var. %=((Max.-Min.)/Min.*100).
- Maximal size variation of the pupil (value in mm in brackets)
- PPI score

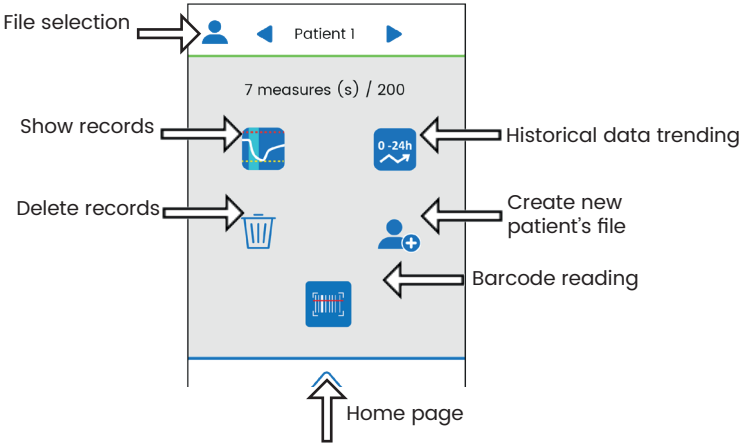


Example of a result: "PPI"

Note : The calculation and PPI score scale are detailed in "PPI mode" section.

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 send all the patient's data to the configured receiver module.

Selecting a patient's file

The measurement's folder or patient's file enables to save a set of measurements of the same patient in a single file.
By scanning the patient identification barcode, the AlgiScan is positioned on the patient's file desired.

The patient folder can be selected manually with the "Patient" menu icon 

Once positioned in the «registration folder» menu, the user can use the navigation arrows to select the desired patient folder.

IV Preventive maintenance, cleaning and disinfection

Preventive maintenance

To be sure 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 condition of the electrode wire, its terminal clips and its connector
- Check the absolute values measured (of the pupil in mm)
- Check the light stimulation
- Check the values of the electrical stimulations
- Battery replacement

The lifetime of the AlgiScan, 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 AlgiScan 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 AlgiScan shows the state of charge of the battery by means of 3 icons.

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

The battery is covered by a 6 month warranty.

Note:
Only qualified technicians trained by IDMED are authorised to change the battery or check its operation.

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.

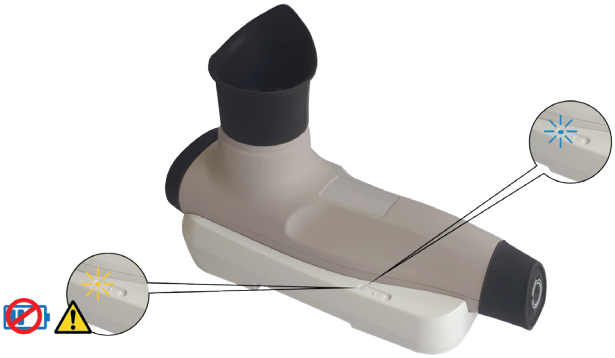
The recharging process can be performed regardless of the battery charge level. If the AlgiScan displays the discharged battery symbol it is imperative to recharge the battery as soon as possible. When the low battery symbol is being displayed, the light or electrical stimuli are no longer functional.

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

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

Charging in progress

Charging station indicator



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

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

Cleaning and Disinfection

Attention :
Do not autoclave the AlgiScan or any of its components or accessories except for the eyecup.

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

The surface of the AlgiScan 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.
Example of recommended products :
- Incidin™ OxyWipe from the manufacturer Ecolab Inc.
- 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

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 AlgiScan and cleaned in the same way as the AlgiScan and then put back in place on the clean AlgiScan. 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 AlgiScan 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.

The electrode wire used with the AlgiScan should not come **into direct contact, be submerged, sprayed or filled with a liquid and should be cleaned in the same way as the AlgiScan.**

When cleaning the cables of the AlgiScan, be careful not to create excessive traction on the electrode cables that could cause premature breakage of the wires inside the sheath.

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 and Disinfection»)
The AlgiScan displays the red electrode symbol and refuses to start recording in the "Electrical Stimulation» mode	Check the positioning of the electrodes and their coupling to the patient (refer to the paragraph: "Connexion and positioning of the stimulation electrodes")
The recording dates and times are not up to date.	Adjust the appliance date and time (refer to the chapter: "Setting the time on the AlgiScan"

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 AlgiScan.

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 AlgiScan 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	500 hPa to 1060 hPa

The original factory packaging should be used for storage and transport.

Protect the AlgiScan from sudden temperature changes that could cause condensation.

Operating environment

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

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

Never use the AlgiScan while it is charging.

The AlgiScan 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	700 hPa to 1060 hPa

Technical specifications

Safety

- Eyecup (part in contact with the patient). Latex free
- Compliant with 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 standards IEC 60601-1. Class II equipment.
- Compliant with standards IEC 60601-2-10.
- EMC: IEC 60601-1-2

EMC Emission

Emission test	Compliance	EMC Instructions/cautions
RF Emissions CISPR 11	Group 1	The AlgiScan 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 AlgiScan must be used in professional healthcare facility environment
Voltage fluctuations	Class A	
and flicker IEC 61000-3-3	Compliant	The AlgiScan 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 ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV air	In order to reduce ESD, the device must be used in a 35% humidity environment or more
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 observedtoverifythattheyareoperating 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 AlgiScan may temporarily not display result during transient electromagnetic disturbances such as the use of electrosurgery device. In that case, the AlgiScan 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

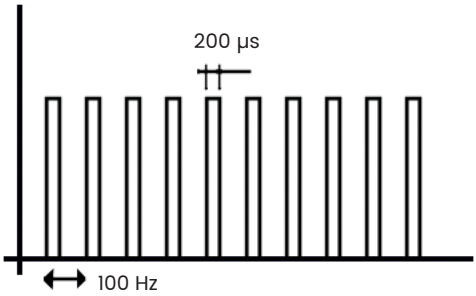
- Measurement system by video camera and in-built data processor
- Measurement range: 1 to 9 mm (pupil diameter)
- Precision 0.1 mm or 5% , Resolution 0.01 mm (pupil size)
- Measurement and image acquisition frequency 60 images/s
- PPI® score
- 10000 measures can be stored in memory

Data transfer

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

Stimulations

- Output current between 0 to 60 mA (accuracy +/- 10% on an actual load of 4 K ohms), single-phase, 100 Hz, Pulse width 200 microseconds.



- Duration of stimulation 5 seconds maximum in TETANUS mode.
- Duration of stimulation between 1 and 8 seconds in PPI mode.
- Stimulation or ECG electrodes:
  - Capable of supporting up to 300 volts with 60 mA current.
  - Contact surface must be greater than 1.8cm².

Examples of recommended electrodes:

- RED DOT electrodes ref.2560 from the company 3M

- F9047 electrodes from the company FIAB

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

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 (battery warranty: 6 months)

VII Appendix 3 : accessories

The AlgiScan (reference: ALG-MU) can be supplied with a number of accessories. Here is the list of the accessories with their names and IDMED references.

Medical accessories of the AlgiScan

Reference	Description
STA-W2	Wireless charging station for AlgiScan
CAB-STIM3	Electric stimulation cable for AlgiScan

Other accessories

Reference	Description
EMB-NL	Eyecup for AlgiScan
PWR5-1_XX	Charger/Power supplies : XX type code for plug types
NL-WDT	Wireless receiver for PC for data transfer
IDM-GTW	HL7 gateway for pupillometers

idmed
an eye on your patient

CE
0459