Quantel medical

# Activis

**RED 689nm LASER**


**OPHTHALMIC PHOTOACTIVATOR**

CE 0459

***93/42/EEC Directive***

# USER MANUAL

**XL ACTI ME AN** **MAY 2007**

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**QUANTEL MEDICAL SAS**

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# 1 - WARNINGS AND CAUTIONS

This manual is designed to acquaint you with the normal operation and maintenance of the ACTIVIS , red 689 nm PDT laser ophthalmic photoactivator.

The scope of this manual is limited to the operation and maintenance of the instrument and its controls and is not intended to be a guide for the treatment of disorders where ophthalmic laser photoactivation is indicated.

The safe use of this laser system begins with your understanding that the purpose of this laser system is to produce controlled destruction of living tissue. Misuse of the laser system may result in accidental injury to the patient, physician or attendants. Complete information for the safe use of lasers in health care facilities is published in ANSI Standard Z136.3 -1996 which is available at the address given in Appendix 2.

You are encouraged to forward all comments or questions regarding the operation, maintenance or the use of this product to Quantel Medical.

In case of service needs or if you notice a change in the laser efficacy, please contact the Quantel Medical Service Department or your local Distributor.

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***CAUTION :***
Federal (USA) law restricts this device to sale by or on the order of a physician.

***CAUTION :***
Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

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Quantel Medical cannot be held responsible for any damage or injury which results from

a failure to follow, or incorrect use of the instructions contained in this manual.

The guarantee of the equipment will be void if the equipment is opened (even partially), modified or repaired in any way by persons who are not authorised by Quantel Medical.

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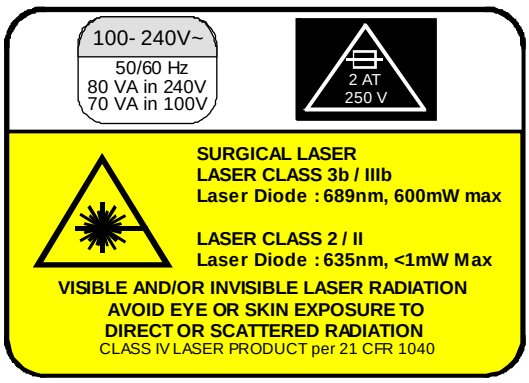
# 1 - WARNINGS AND CAUTIONS

***WARNING :***





***WARNING : see Chapter " 6-3-2 Electrical requirements "***

1) To comply with safety standard requirements for medical electrical equipment, the ACTIVIS plug must be connected alone on a wall grounded socket.
Use of an adaptor (for multiple connections) or power bar is prohibited

2) Do not use a 3-pin adaptor to accommodate an ungrounded 2-pin wall receptacle.

***WARNING :***

Disconnect AC power before cleaning the case :
see Chapter 9 : Maintenance

***CAUTION :***

To preserve the finish of the case, avoid the use of abrasive cleaners. If possible, clean spots before they dry.

***WARNING :***

The instrument calibration must be performed every year by a technician authorized by Quantel Medical or by the doctor by using the power calibration procedure (Appendix 1 of this User's manual).

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# 3 - TECHNICAL SPECIFICATIONS

## 3-1 ELECTRICAL REQUIREMENTS

**- Power supply :** - 100 to 240Vac ± 10%
- Frequency : 50 to 60 Hz ± 3 Hz.
- Power : 70 - 80 VA

**- Single phase (earthed socket) :**
- A standardized plug able to deliver 10A minimum is necessary.

## 3-2 LASER SPECIFICATIONS

**- Laser beam :**

**- Laser class :** - Class IIIb (3B) laser Product.

**- Laser source :** - Red Diode Laser 689 nm

**- Wavelength :** - 689 nm

**- Adaptor Output Power :** - 4 mW to 400 m W

**Note :**
**These features are guaranted only with adaptors provided by Quantel Medical**

**- Exposure time :** - min. : 20 sec - max. : 120 sec

**- Aiming beam :**

**- Laser class :** - Class II
**- Laser source :** - Red Diode laser
**- Wavelength :** - 635 nm
**- Max Output Power :** - 0.9 milliwatts

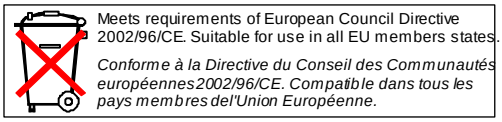
**- Safety :**
- Internal monitoring of all critical systems including redundant safety circuits to monitor shutter system and power control system.
The microprocessor operates a Software Control in parallel.

**- Cooling :**
- Air cooling

## 3-3 COMPLIANCE

- This laser product complies with 21 CFR 1040 as applicable.
- Electrical leakage below UL 544 limits
- Power supply and enclosure designed per IEC 601-1
- Safety of laser products : IEC 825-1
- Safety of therapeutic laser equipment IEC 601-2-22
- European Directive 93/42/EEC
- Electromagnetic compatibility IEC 601-1-2

**Precautions to take concerning wastes and elimination of device and accessories:**
This product complies with the WEEE Directive (**2002/96/EC**) marking requirments. ACTIVIS is an electrical / electronic product and must not discard in domestic household waste.




**Do not dispose with domestic household wastes !**

**Product category:**
With reference to the equipment types in the WEEE Directive annex I, this product is classed as category 8 among the "Medical devices (with the exception of all implanted and infected products)".

To dispose completly of the device and its accessories, contact Quantel Medical.

## 3-4 LASER DIMENSIONS

- Height : 21 cm
- Width : 30 cm
- Length : 25 cm
- Net weight : 5 Kg

## 3-5 OPERATING ENVIRONMENT

T °C Environment : 15 °C < T °C < 30 °C
Humidity Environment (without condensation) : 95%

## 3-6 DELIVERY OPTIONS

Connect only delivery systems provided by Quantel Medical.

- Slit lamp adaptor for 689 nm PDT laser

## 3-7 LASER SAFETY EYEWEAR

Need for safety eyewear based on the Maximum Permissible Exposure (MPE), the Nominal Occular Hazard Distance (NOHD) and the Optical Density (OD).
For additional information, refer to ANSI Z136.1-1993, ANSI Z136.3-1996, or European Standard EN 60825 : 1992, Appendix A.

The following formula was used to calculate the worst case NOHD for ACTIVIS with its slit lamp adaptor 689 PDT laser.The values specified here meet or exceed the laser safety eyewear requirements for the slit lamp adaptor .

$$NOHD = \frac{\sqrt{Pf * (4. Po / (3.14 . E_{MPE}) )} - a}{Ø} + z$$

where,
a = the beam waist diameter ;
z = distance between the laser system and the beam waist ;
Ø = full angle beam divergence ;
Po = maximum laser power available ;
Pf = the profile correction factor ;
$E_{MPE}$ = Maximum Permissible Exposure, in power density units (power per unit area) ;
NOHD = the Nominal Ocular Hazard Distance (measured from laser aperture)
= the distance required to reduce the power density to the MPE.

$E_{MPE} = 42,25 W / m^2$

NOHD = 10.17 m + 0.30 m (focusing distance) = 10.47 m

**Safety Eyewear :**

All personnel who are within the NOHD are considered to be within the controlled area and shall wear eye protection with a minimum optical density (OD) of :

$$O.D. = - LOG (E_{MPE} / \text{ Power density }) = 3.45$$

**For maximum security, the safety eyewear must have a protection class of L4 (EN 207 Standard).**

# 4 - SAFETY PROCEDURES

This section introduces a few elementary steps to follow when using your photoactivator. Understanding of these instructions and compliance with them and procedures outlined in ANSI Standard Z136.3 is required to prevent injury to personnel or damage to the instrument.

1. Never look directly into a laser light source, avoid exposure to reflected or scattered laser light. This is a class IIIb laser product. Direct, reflected, or scattered light may produce injury.

2. The treatment beam emitted from this instrument is a possible source of ignition of flammable materials or explosives. Do not use this system near these materials.

3. Always require safety glasses for anyone present at a treatment, except for the physician and patient. During some procedures it may be advisable to shield untreated eyes.

4. Never leave the system ON when it is unattended. If you must leave, turn the system OFF and take the key with you.

5. When the laser is ON, keep the system in the standby mode except during actual treatment.

6. Use anti-reflection contact lenses treated for 689 nm wavelengths. Contact lenses, particularly those with plano surfaces, can generate dangerous reflections.

7. Never open the laser enclosure. Hazardous levels of visible and invisible optical radiation are present inside. Refer service problems to qualified personnel.

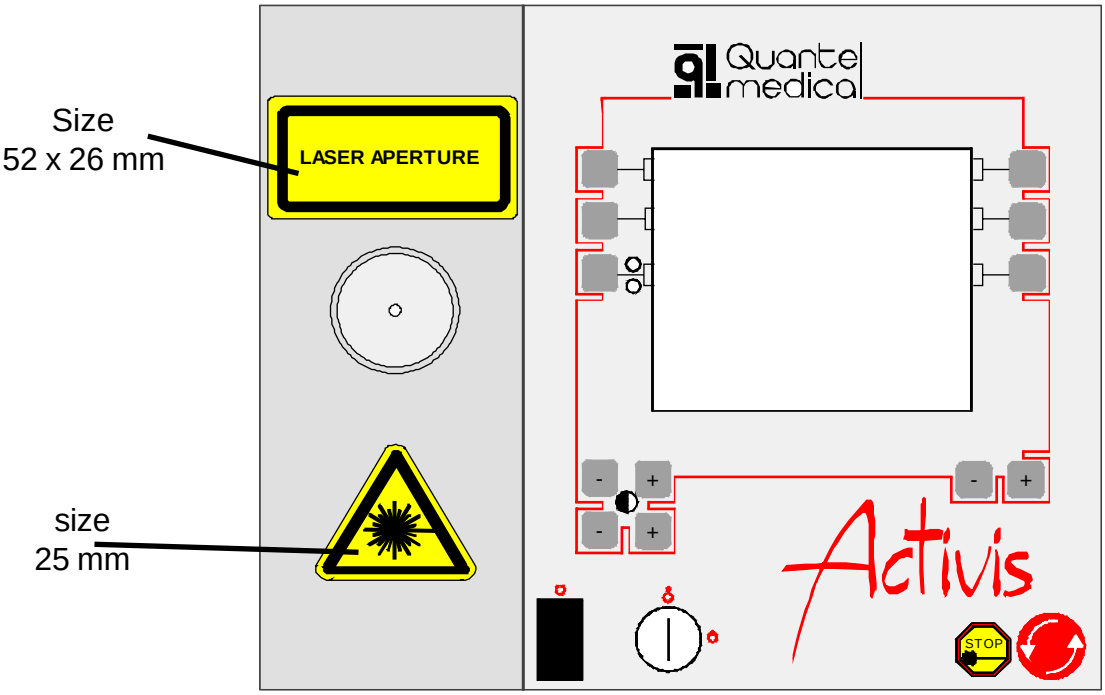
8. Observe warnings on all DANGER, WARNING, or CAUTION labels. Chapter 5 illustrates the location and contents of these labels.

9. Circuitry for connection of a remote interlock is provided. An interlock can be attached to the laser room door or other actuator and can electronically go in standby and cannot firing the laser system if the laser room is entered during use.
Installation instructions are provided in Chapter " 6-3 Recommendations for the room installation ".

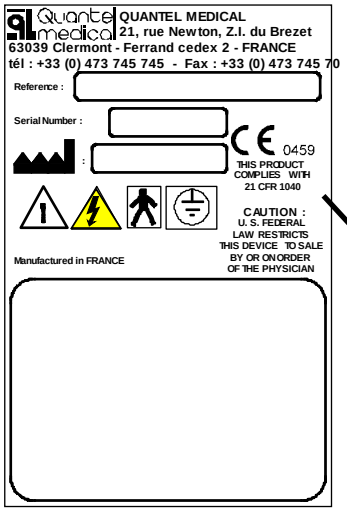
10. Regular maintenance which can be performed by the user is described in the chapter 9. The performance of regular maintenance including calibration checking will help to assure trouble-free operation.

# 5 - LABELS PLACEMENT DIAGRAM

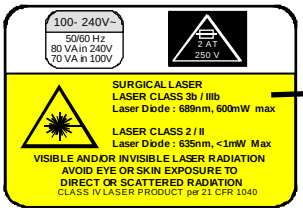
## 5-1 STICKERS ON THE FRONT PANEL




## 5-2 STICKERS ON THE REAR PANEL




size 70 mm x 107 mm




size 68 mm x 48 mm

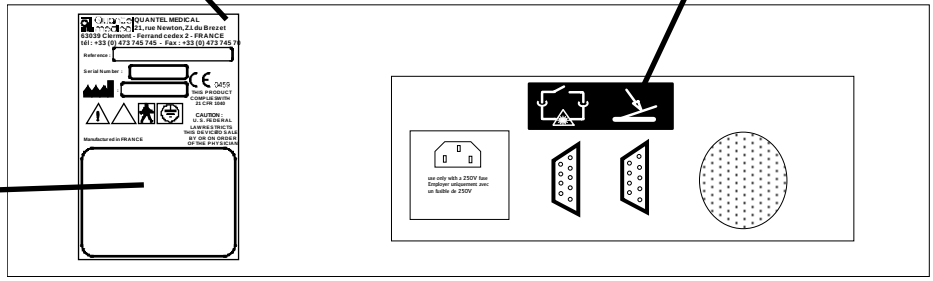


**"BF" Symbol**

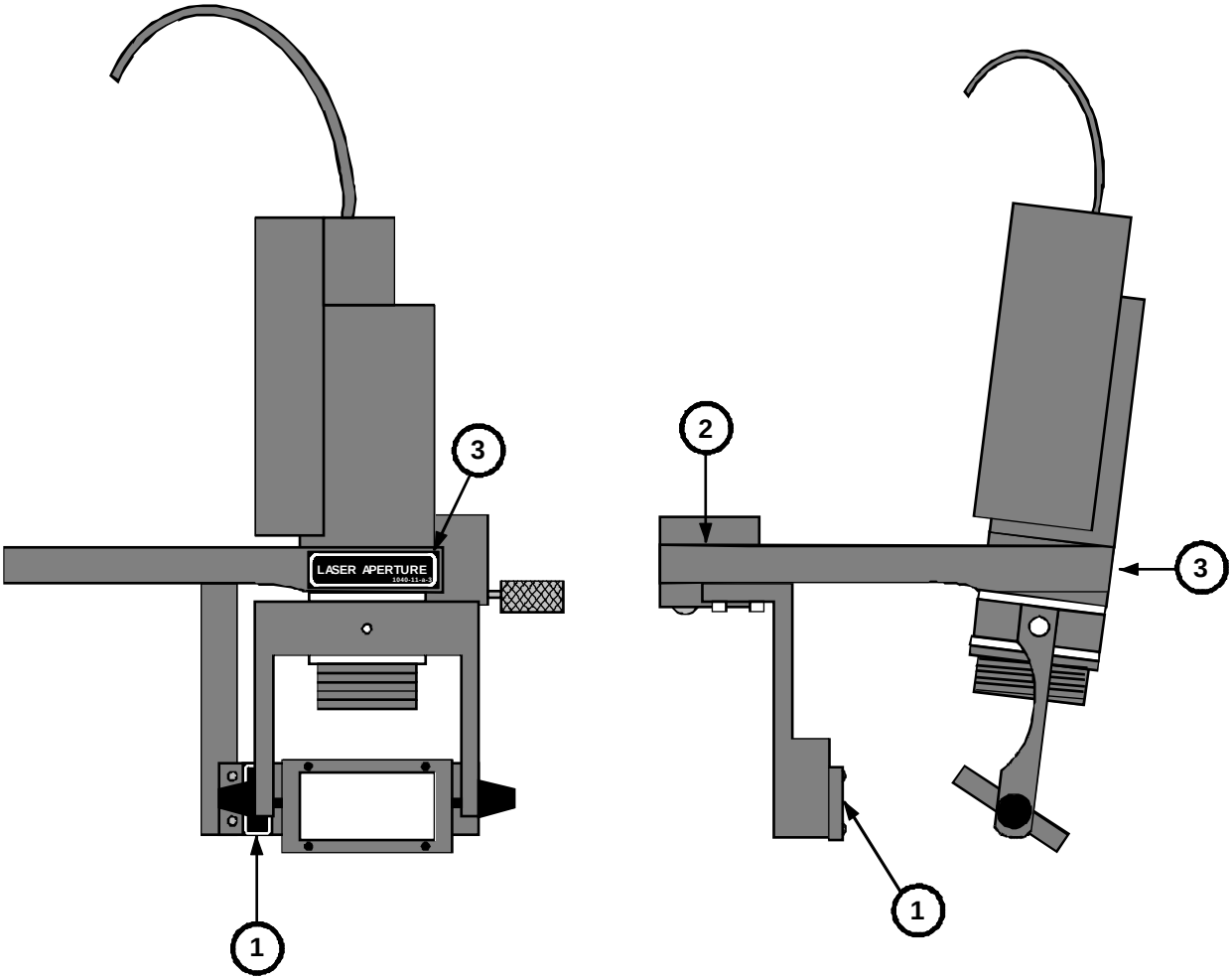
"Classe 1" : Accessible conductive parts are connected to Ground
"Type BF" : Protection against electrical shocks.
The applied parts are isolated from the ground.

IP 20 : Normal device.

size 70 mm x 107 mm



## 5-3 STICKERS ON THE ADAPTATOR




1 

L23 x H9 mm

2 

L15 x H25 mm

3 

L42 x H12 mm

# 6 - INSTALLATION

## 6-1 PACKING LIST

Before assembling the system, make sure the package contains all components ordered.
Hereunder is a list of the components included with the basic console.

- Laser console with its control box
- Footswitch (with male connector)
- Power cord
- User manual (XL ACTI ME AN)
- Keys
- Remote plug connector (with male connector)
- Slit lamp adaptor
- accessories installation kit of the adaptor
- Protection goggles
- Tonometer holder

## 6-2 UNPACKING

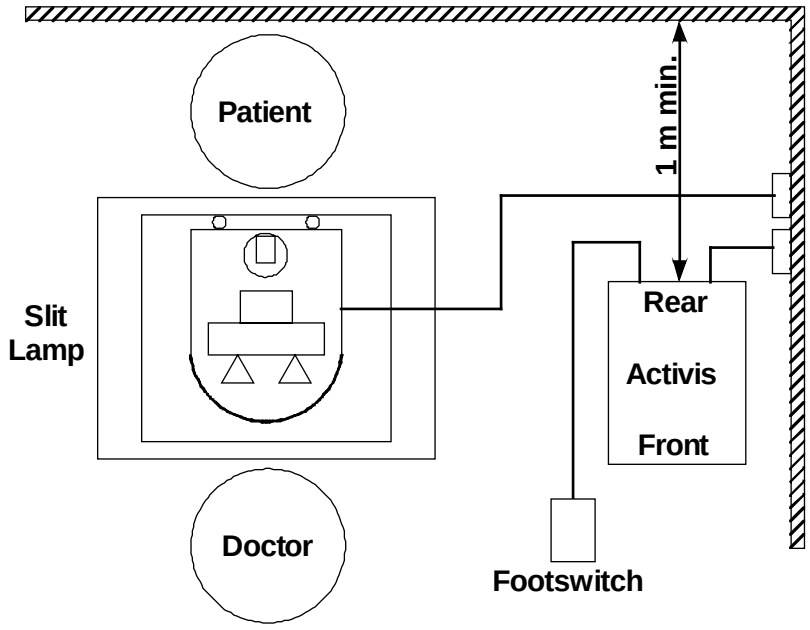
Prior to delivery, this instrument has been packed with special care in order to minimize transport risks.
However, before unpacking your laser, check the packaging for signs of damage or improper handling. If you discover any, contact the shipping company immediately and only remove the packaging in the presence of a representative of the company. Draw up a list of all damaged parts and make sure it is signed by the transport company's representative.

**Warning :** if the instrument is at a temperature less than 10°C, switching on the instrument may cause serious damage. Unpack the instrument and leave it at normal temperature for **at least half a day** to ensure that the internal components warm up gradually.

# 6-3 RECOMMENDATIONS FOR THE ROOM INSTALLATION

### 6-3-1 Location :

- The instrument should be positioned in such a way that the laser beam coming out of the terminal (ex : slit lamp) can not be directed towards an opening (door, window...) or reflecting material.




**Mains specifications :**
**- single-phase grounded socket**
**- voltage : 100 to 240 Vac**
**- frequency : 50/60 Hz**
**- minimum current : 10 A**

- The instrument must be installed in a dust free room and the use of carpets on either the walls or the floor should be avoided.

- When not in use, the system should be covered to avoid dust settling on the optics.

### 6-3-2 Electrical requirements :

2 earthed sockets with single phase :
- Voltage : 100 to 240 Vac
- Frequency : 50 / 60 Hz.
- The plugs must be able to deliver a minimum current of 10 A.

**WARNING** ***: Use two different sockets for the Laser and slit lamp main connections.***

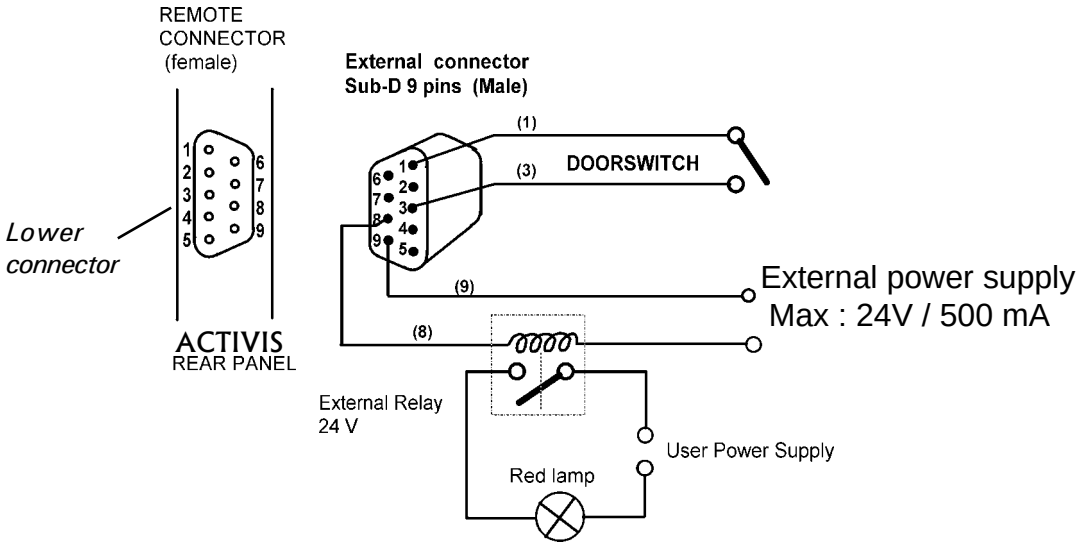
### Earth impedance :

Ensure that the socket is properly earthed.

**WARNING :**
Do not use a 3-pin adaptor to accomodate an ungrounded 2-pin wall receptacle.

### 6-3-3 Doorswitch installation :

The user must provide the actual doorswitch.
It may be a magnetically or mechanically actuated switch which will close its contact when the door is closed and open its contact when the door is open.
The switch and its wiring must be rated for at least 24 Vac and 500 mA .
The wires should terminate with a standard male 9-pin “D” type connector which is commonly used for computer serial port connections.
**One wire should terminate on pin 1, the other on pin 3.**
The order of polarity is not important.
**If this option is not used, the Remote plug connector which shorts pins 1 and 3 must be left in place for the system to go in ready mode.**




To connect the laser system to the doorswitch, simply remove the jumper which is the left 9-pin “D” type connector on the rear face (REMOTE connector). Insert your doorswitch connector in its place.
Be sure to seat it firmly to avoid unexpected interlock safety of the system.

### 6-3-4 External red lamp installation :

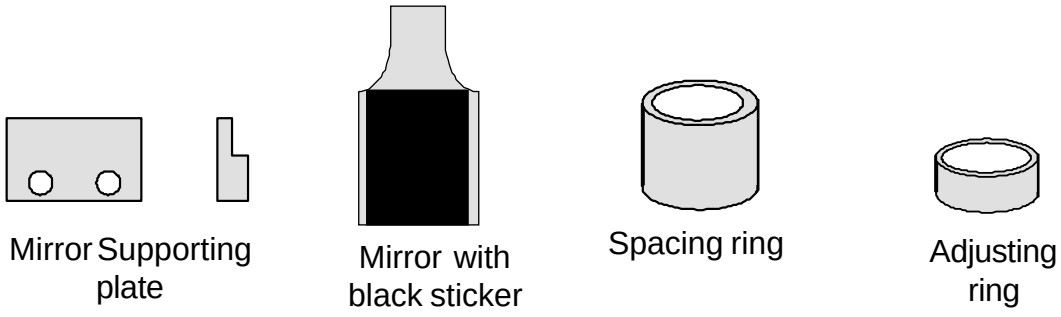
You must drive a red lamp via an external relay (see the figure above).
Inside ACTIVIS, a contact between pins 8 and 9 of the same Sub-D/9 pins REMOTE plug :

The contact is ON when the laser is operating.

An external power supply with a maximum of 24 Vac / 500 mA must be used for external relay activation.
The red lamp circuit power is at the user's choice.

# 6-4 INSTALLATION OF THE PDT ADAPTATION

## 6-4-1 List and position of the adaptation accessories



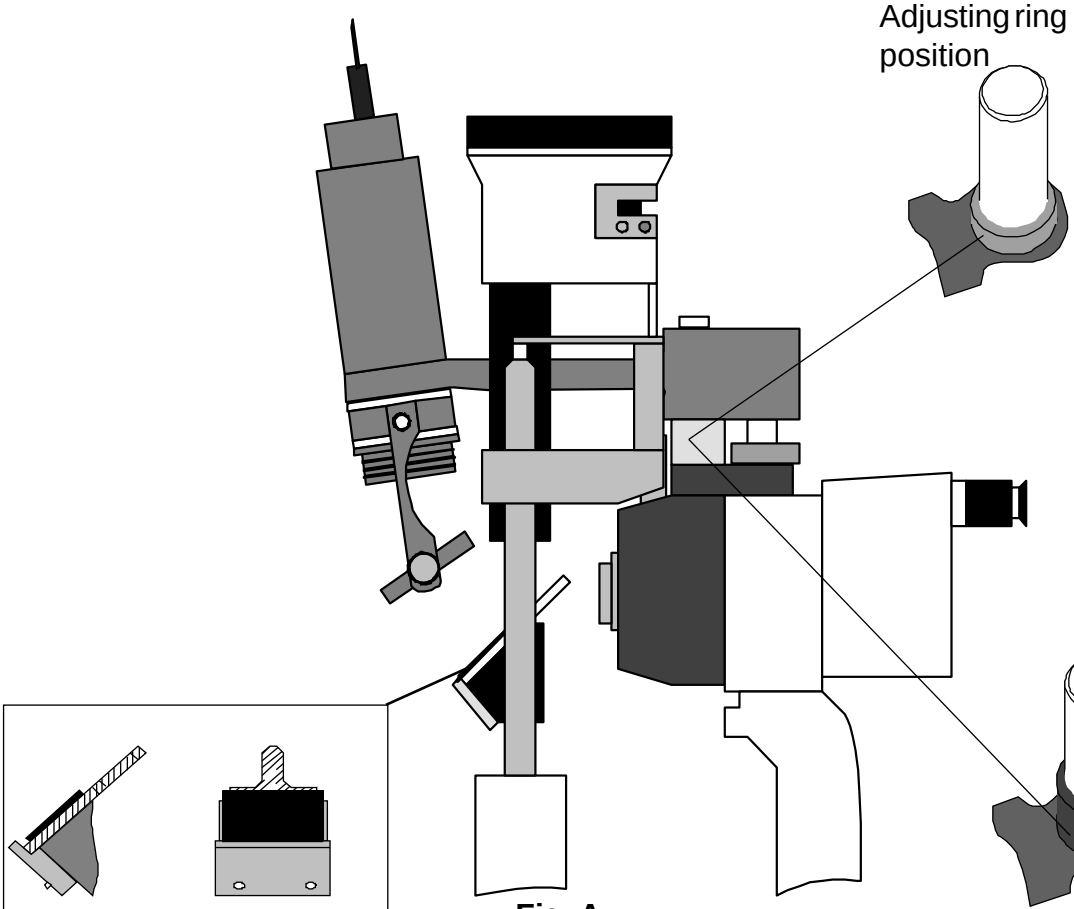



**Fig. 1.a** Mirror position

**Fig. 1.b**
Adjusting ring position

**Fig. A**
Detail of the adaptation positioning with adjusting pieces

**Fig. 1.c**
Spacing ring position
for BQ model

### 6-4-2 Adaptator positioning

The PDT adaptator is designed for Haag Streit 900 BM - BQ or similar.

- Switch off the device.
- If necessary, remove the slit lamp applanation tonometer.
- Rotate the slit lamp projector to the left of the eyepieces.
- Remove the slit lamp lighting mirror, sliding it out his holder and carrying in the suit case.
- Insert the lighting mirror supplied and slide it until the stop (**fig. 1.a**). This mirror is treated to prevent aiming beams.
- In the case where you desire an aiming red intensity increased, place the adjusting ring on the tonometer support (**fig. 1.b**)
- For the BQ models, place the spacing ring on the tonometer support (**fig. 1.c**). It is possible to place the adjusting ring (**fig.1.b**) on top of the spacing ring to increase the light intensity of the red aiming beam.

**The doctor's filter must cover the binocular optics to prevent any risk of transmission of the laser beam trough the binocular.**

- Place carrefully the adaptator on the tonometer support and tighten the screw.

### 6-4-3 Connect the adaptator to the laser system

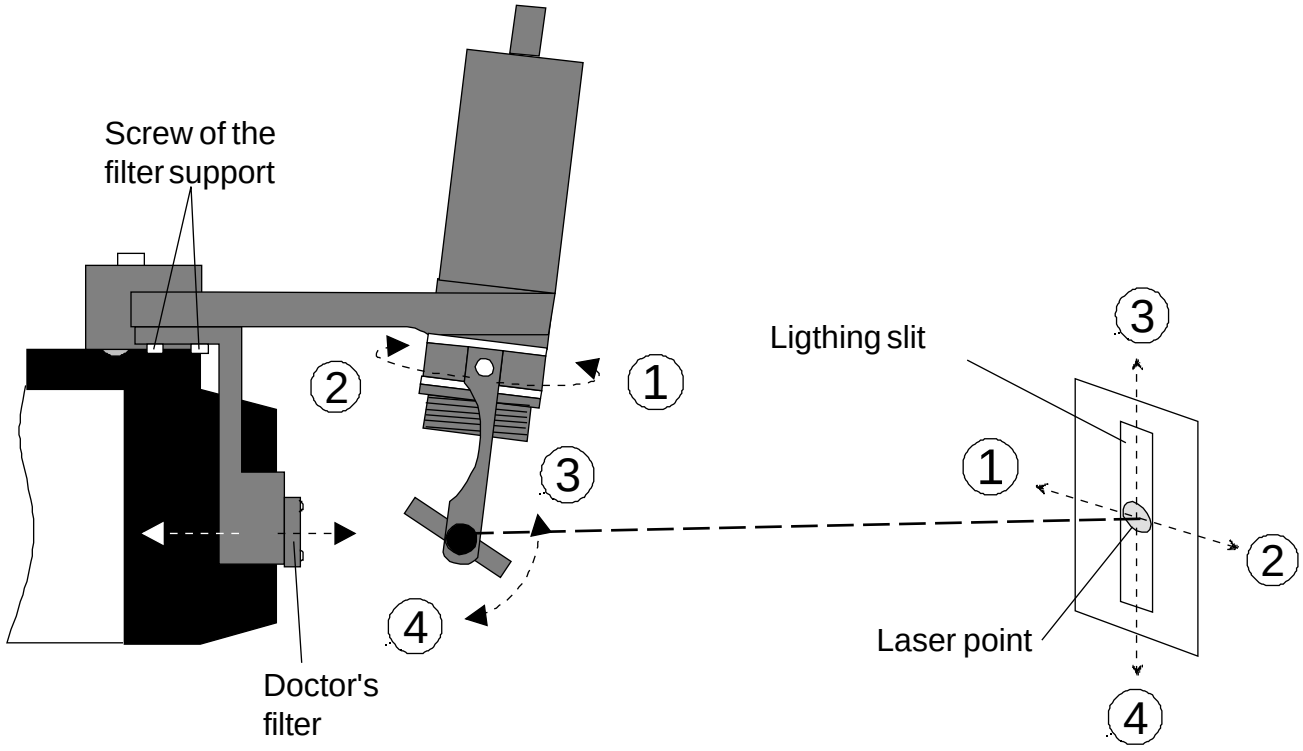
- Switch off the Activis.
- On the back panel of the laser system, ensure that the footswitch and door interlock are properly connected (see § 5-2).
- Remove the dust caps from the laser fiber optic connector and the laser console aperture. Insert the laser fiber optic connector into the laser console aperture. Rotate the threaded connector clockwise until finger-tight to secure the connection. Do not over-tighten. The connector must be fully seated on the receptable. If it is not, the laser cannot be enabled.
- Ensure that the proximal and distal ends of the optical fiber have large bend radiuses. A sharp bend in the optical fiber can cause optical transmission loss resulting in reduced laser power.

### 6-4-4 Adjusting of the adaptation

Two adjustments are realizable to adjust perfectly the slit lamp :

**- Doctor's filter position :**
Unscrew the 2 screws of the filter support and slide the filter forward or backward to adjust precisely the filter position.
A perfect adjustment consist in that the adaptor is easely fitting on the binocular and that the filter does not prevent the rotation of the slit generator.

**- Spot location adjustment :**
The spot location has to be adjusted to place it in the center of the illumination slit.
The adaptor has two axis of rotation for adjustment (see below).
However if the **amplitude of rotation is not enought for adjustment** (spot under location), or if there are **frictions when using slit lamp,** you can place an adjustment washer on the slit lamp tonometer.
Remove the adaptor and see the previous page to place the adjustment washer.

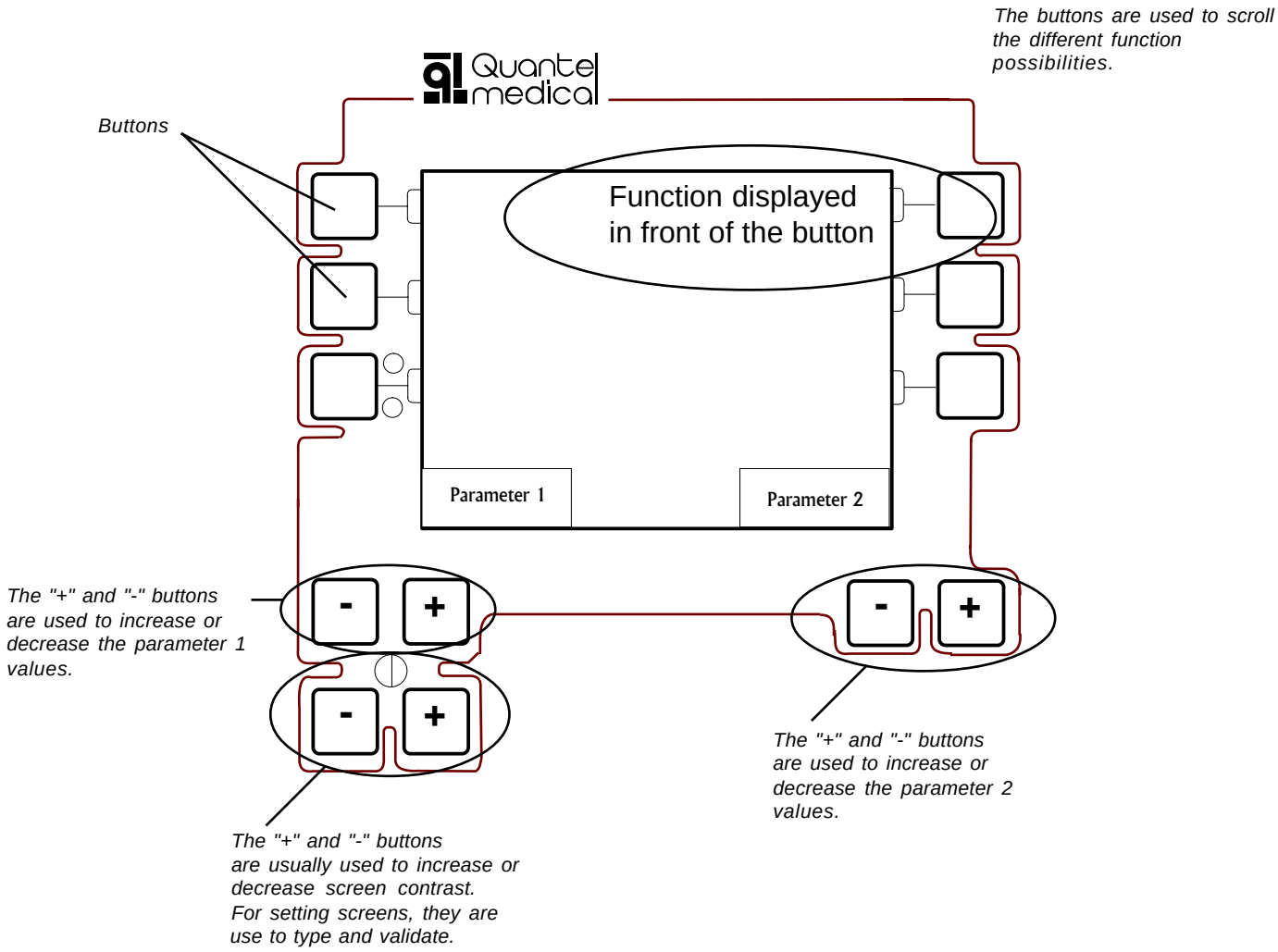



**After a correct installation, there should not have any friction between the adaptator and the slit lamp.**

**The doctor's filter must cover the binocular optics to prevent any risk transmission of laser beam through the binocular.**

## 7-1 CONTROL PANEL DIAGRAM

PRINCIPLE : On each screen page, the buttons have different functions. These functions clearly displayed in front of each button on the Liquid crystal display.



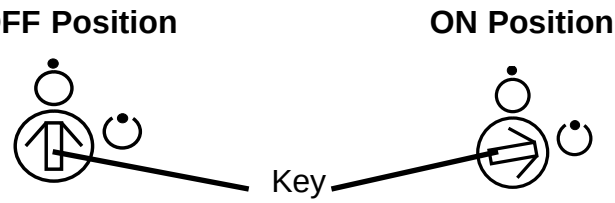
# 8-1 CONTROL PANEL AND SAFETY

The LCD display of the front panel displays different screens depending on the state of the unit.
The first screen displayed when the unit is turned ON (before the KEY CONTROL is ON) is shown in chapter " 8-2 Turning ON the unit ".
The control panel showing all laser parameters is displayed only when the Laser is ON. (See § 8-5)

## SAFETY CONTROLS :

The delivery system has two connections : the optic fiber and the motor driving.
The security fiber is ON only after the delivery system connection is done.
This enables the laser startup by the key control.

**KEYSWITCH ( ON / OFF )**




When activating the main switch of the unit :
- If the key switch is "ON", the message is : "Turn the key to OFF"
- If the key switch is "OFF", the LCD screen displays the message : "Turn the key to 'ON' to turn the Laser ON ".

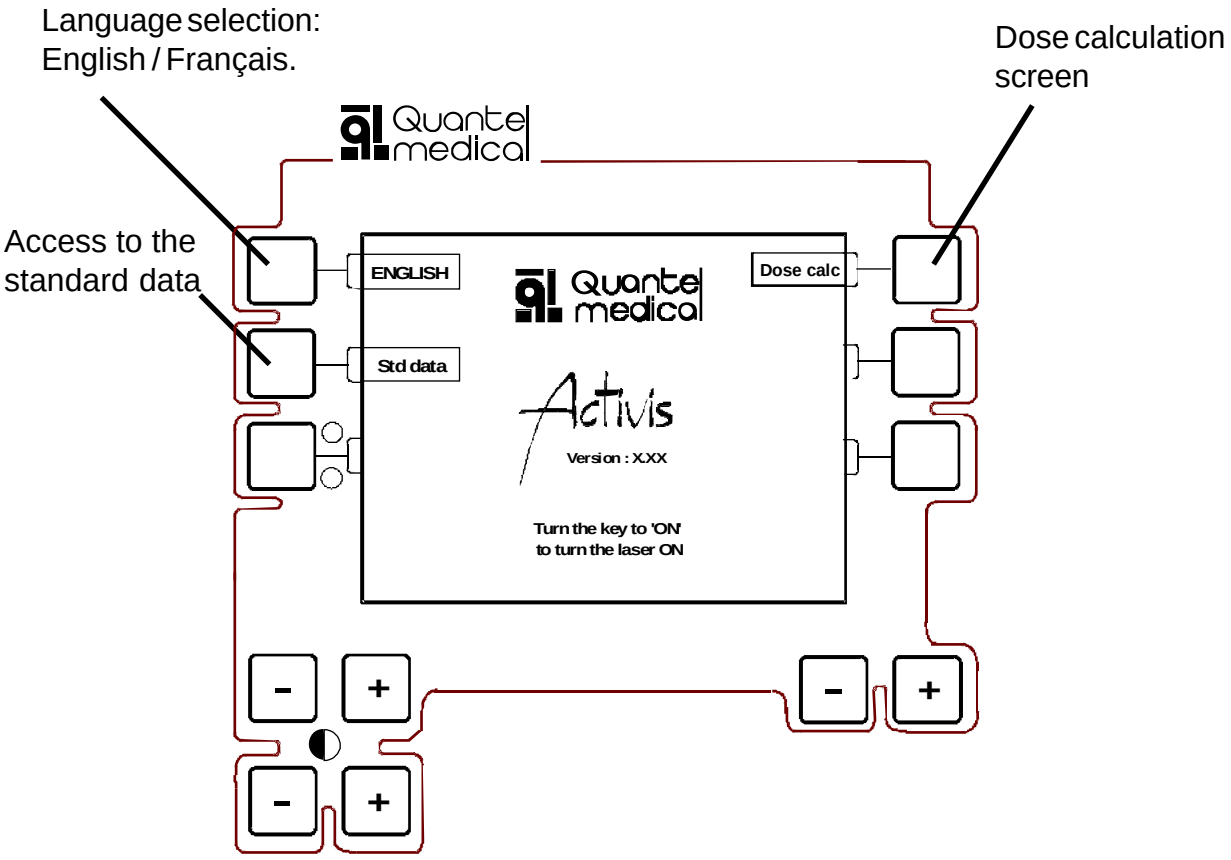
See chapter " 8-2 Turning ON the unit ".
**Note :**
**The key cannot be removed when the laser is activated.**
Turn the key to the "OFF" position to turn the laser OFF.

**STOP**
**The large red STOP button will instantly stop all laser functions when pressed.**
**IMPORTANT :**
**This panic switch must be used ONLY in case of emergency.**
To restart the system :
1 - Twist the button clockwise and allow it to pop back up,
2 - Turn the keyswitch OFF ( 'OFF' position ),
3 - Then restart the system normally.
Timing and power settings will return to their default values.

## 8-2 TURNING ON THE UNIT

- Make sure the main power cable is connected.
- Check the panic Switch is not depressed. If depressed : pull it out turning clockwise.
- Activate the master switch at the front of the unit, a beep is emitted at the same time.

If the key is in the "OFF" position, the following message will appear :

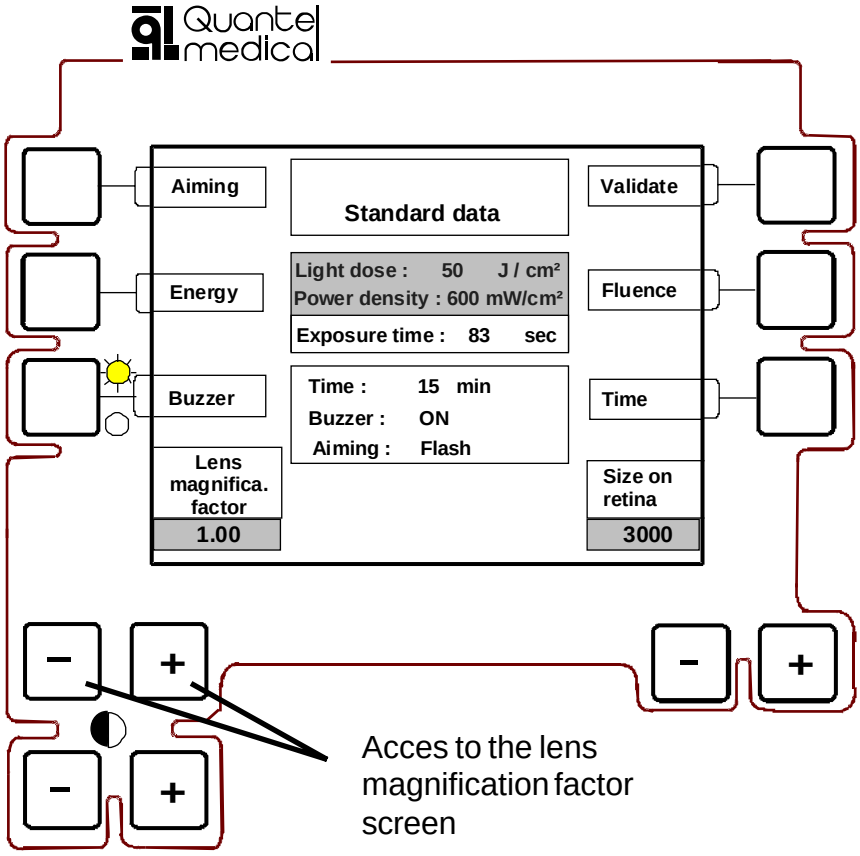



| Conditions | Messages |
|---|---|
| TURNING ON THE UNIT : | |
| If the key is "ON"..... | Turn the key to "OFF" |
| If the key is on "OFF"..... | Turn the key to "ON" to turn the laser ON |
| TO START THE LASER : | |
| Key in position "ON"..... | Please Wait |
| IF THE LASER IS NOT USED : | |
| After 10 mn in Stand - By ..... | Automatic laser turn OFF<br>Turn the key to "OFF" |

## 8-3 STANDARD DATA

On this screen, you can store your standard data. Those parameters are still in the Activis memory, even if the Laser is turned Off.
When changing parameters, use the button 'Validate' to store the new parameters in memory.
On the previous screen, select the Standard data button (Std data). The following screen will appear :

***Default values***




### 8-3-1- Aiming

This function allows you to select a continuous or pulsed aiming beam.
Furthermore, you can do this selection from any screen by pressing both the lower "+" and "-" buttons.

### 8-3-2- Energy

Select the energy used for patient treatment :

from 50 to 800 mW/cm$^2$.

### 8-3-3 Buzzer

You can activate or desactivate the buzzer signal give out during the countdown (see section 8-3-5).

### 8-3-4 Fluence

Select the required light dose by pressing this button :

from 5 to 95 J/cm$^2$.

### 8-3-5 Time

Select the required time between the photosensitizer' infusion and the begining of the Laser treatment. This time allow the drug to be affixed to the CNV affected area: 15 mn for Visudyne® for example.
Range of selection from 5 to 20 mn.
Buzzer signal emitted during the last 15 seconds of countdown.

### 8-3-6 Size on retina

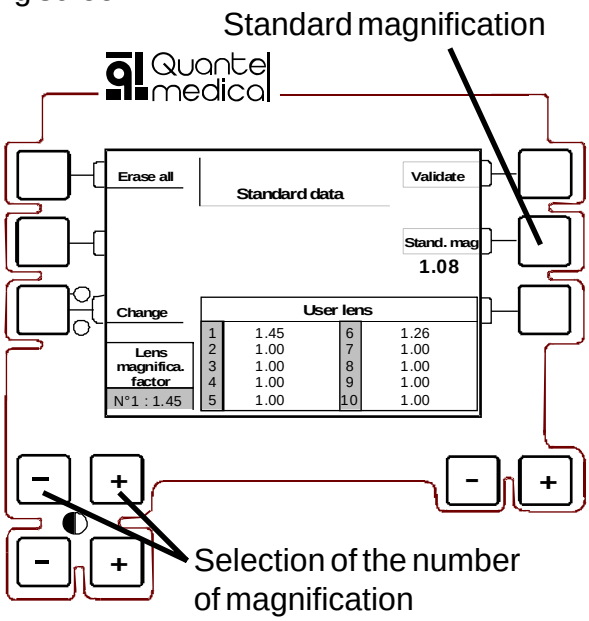
Select the required spot size by pressing the "+" and "-" buttons :

from 1000 to 5400 µm without magnification, possibility going to 8000 µm with a 1.5 magnification.

Note : Size displayed on the screen is the size of the spot on the retina after magnification.

### 8-3-7 Lens Magnification factor

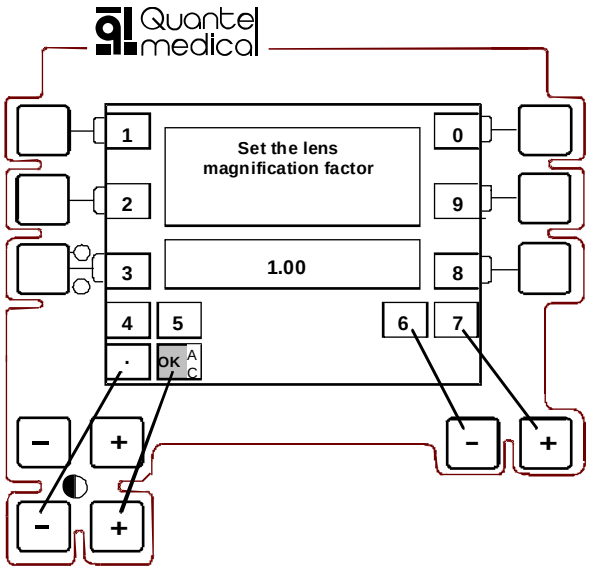
Pressing one of the two "+" or "-" buttons of the "Lens magnification factor" (see previous page ), will display to the following screen :




A table of **10 magnification values** of your personnal lenses can be stored.
Select the desired magnification number to set (1 to 10) with "+" and "-" buttons, and press the "**Change**" button.

**Those values will be added to the existing list of choice of the Activis :** 1.04 ; 1.05 ; 1.08 ; 1.25 ; 1.44 ; 1.47 ; 1.50 ; 1.60 ; 1.75 ; 1.90 ; 2.01 (see chapter 8-5-3).

**Enter a value on setting screen :**




The principle of typing is the following :
Each button correspond to a numeral.
The numeral is displayed in front of the corresponding button.

The lower "-" button corresponds to the comma.
The lower "+" button **validates** the typed value, or **erases** the value if the pressure is maintained (over 2 seconds).

**The range of settings is from 0.5 to 2.5×. An over-range value will not be accepted by the Activis.**

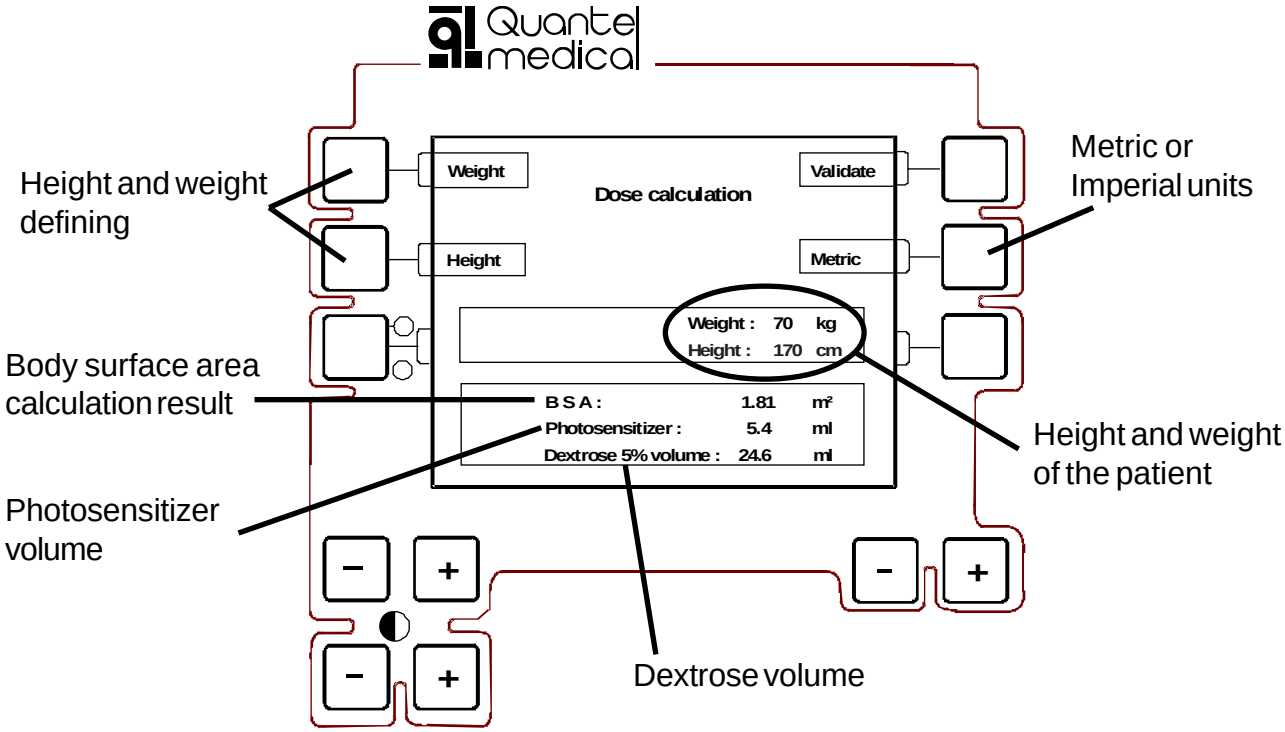
**NOTE :** Another magnification value can be set : The **Standard magnification :** it will be displayed every time you come in the operating mode.
Press on "**Stand mag**." button to modify this value.

When the selection of your standard parameters is completed, then press twice the Validation button to store and get back to the previous screen (see § 8-2 ).

## 8-4 DOSE CALCULATION SCREEN

The "Dose calculation" control of the first page will bring you to the photosensitizer volume calculation function :

**This calculation function is made for Visudyne® photosensitizer volume calculation.**




The photosensitizer volume determination depend on the Body Surface Area (BSA) of the patient. The Activis software offers the possibility to calculate this BSA from two parameters :
The height and the weight of the patient.

Press on the Weight or on the height button to set the values. You will find the setting screen, as shown on the previous page.

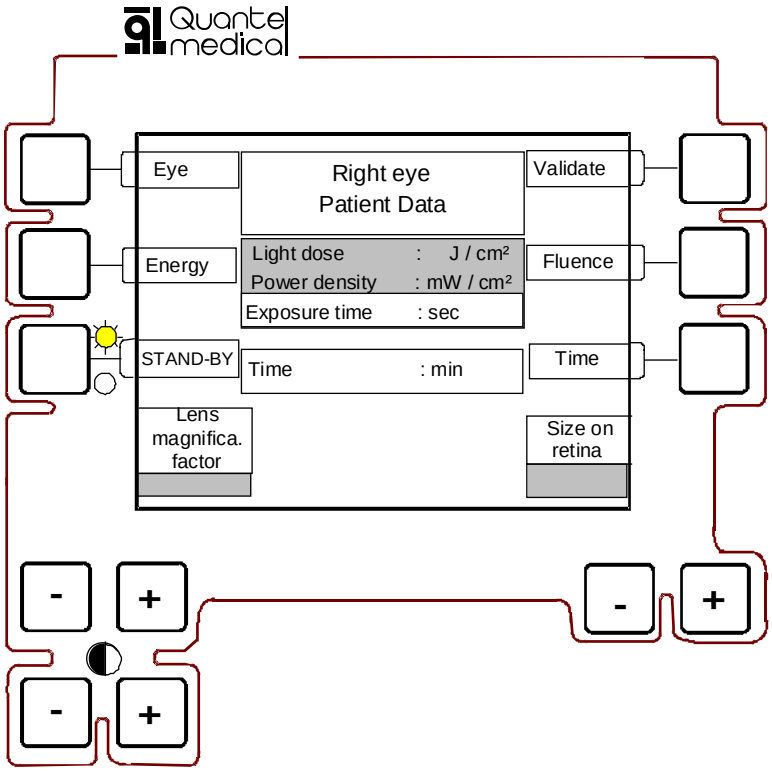
Those parameters can be entered with Metric (Kilograms and centimeters) or Imperial units (feet, inches).

## 8-5 STARTING-UP THE LASER

- A compatible QUANTEL MEDICAL delivery system shall always be connected to the laser console before the laser is energized. Before connecting the delivery system as intructed in the next section, a knowledge of the following operation sequences are required :

1- Insert the key in the key switch and rotate to "ON". A sytem self test begins as indicated by the continuous illumination of the test indicator.

2- After approximately 20 seconds, paramaters of treatment laser radiation are accessible. The screen here under will appear : It shows the screen where you can enter parameters.




When the self test is complete, the system will be in the standby mode as indicated on screen.

### 8-5-1 Eye

It allows you to select the eye which will have to be treated.
By pressing, a message will appear in front of it : "Right eye" or "Left eye".

# 8 - OPERATING PROCEDURES

**After selected the eye, enter the parameters hereunder.**

**NOTE : You can select the treament parameters independently from one eye to the other.**

**The parameters will be displayed in the Operating screen.**

### 8-5-2 Energy

Select the required energy by pressing this button : 50 à 800 mW/cm$^2$.

### 8-5-3 Lens magnification factor

Using "+" and "-" buttons, select a magnification by sweeping all the values :
Stored list of values of the Activis
+ your own list set in standard screen (displayed N°1 to N°10)
+ standard value set in the standard screen (displayed Std).

*Stored list :*

Example : 1.04 1.05 1.08 1.25 1.44 1.47 1.50 1.60 1.75 1.90 2.01

*Personnal list :*

\+ N°1:1.06 N°2:1.16 N°8:1.30 N°5:1.55 N°9:1.80

*Standard value :*

\+ Std : 1.10

So that a total of 22 magnifications maximum can be swept in this screen.

### 8-5-4 Fluence

Select the required light dose by pressing this button :

from 5 to 95 J/cm$^2$.

### 8-5-5 Time

Select the required time between the photosensitizer's infusion and the begining of the Laser treatment. This time allow the photoactivator to be affixed to the CNV affected area.
Range of selection from 5 to 20 mn.

### 8-5-6 Size on retina

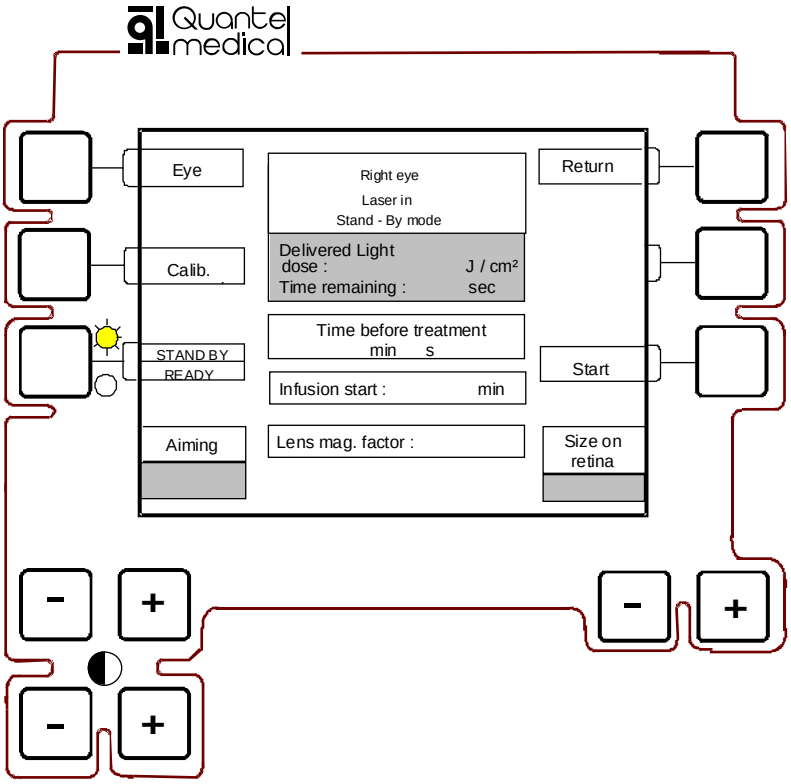
Select the required spot size by pressing the "+" and "-" buttons :

from 1000 to 5400 µm without magnification, possibility going to 8000 µm with a 1.5 magnification.

**Note : Size displayed on the screen is the size of the spot on the retina after magnification. See chapter 8-7 for further informations.**

## 8-6 OPERATING MODE

When you have select all the parameters, press the Validate button to get to the screen here under : It shows the screen where you can display parameters for each eye.




### 8-6-1 Eye

You remind parameters for right or left eye by pressing this button.
**A buzzer emit a signal if the magnification values of the contact lenses are differents from one eye to the other.**

### 8-6-2 Size on retina

You have the opportuny on the above screen to modify the spot size of the treatment laser beam by pressing "+" and "-" buttons.

In both case, the slit lamp adaptor is **automaticaly replace** on the exact position in order to have the laser beam spot size required.
See chapter 8-7 for further informations.

### 8-6-3 Aiming

The red beam of the diode laser has a maximun power of 0.9 milliwatts in the highest position (12). Use the "+" and "-" buttons to increase or decrease the aiming intensity from 1 to 12. Press both buttons to switch OFF the aiming beam. To switch ON aiming beam again, press the "+" button.

NB : Turning the aiming beam OFF switches the treatment laser to the stand - by mode : **the treatment beam cannot be delivered when aiming beam is turned OFF.**

### 8-6-4 Calib.

Access button to the calibration menu : see appendix 1.
Press this button more than 2 seconds.

### 8-6-5 Start

At the beginning of the photosensitizer's infusion, press START button to activate the 'Infusion Start' and 'Time before treatment' counters.
'Infusion start' is an unlimited counter. It is a reliable time reference for the various actions sequencing.
'Time before treatment' is a countdown, this time is set on the previous screen.
Example for Visudyne photosensitizer (infusion : 10mn; treatment from +15 to 20 mn) :


0.....*'Infusion Start' counter* .....10 mn.....15 mn.....20 mn
15mn.....*'Time before treatment' counter*.....0

A buzzer signal is emitted during the last 5 mn of the 'Time before treatment' countdown. The signal is emitted every second in the last 15 seconds.
To reset and activate the counters (count and countdown), maintain the Start button pressed for more than 2 seconds. **All counters are reset.**

### 8-6-6 Return

This button will allow you to return to the previous page in order to change parameters between two patients or change other parameters.

### 8-6-7 Laser Standby / ready

The button enables or disables the firing of the treatment beam.

The laser is in Standby : Green LED ON
The laser is Ready to fire : Yellow LED ON

You are now ready to treat the patient, see chapter 8-8 for information on the Operating procedure.

# 8-7 SPOT SIZE SELECTION

The ACTIVIS spot size selector control is drived by the laser console. So when you select spot size required, the spot size selector will automaticaly go in place.

### 8-7-1 Spot size and power density

Power density at the treatment site largely determines the degree of interaction of the laser beam with tissue. Power density is defined as laser power divided by the area of the spot size. Power density can be increased by increasing the laser power or by decreasing the spot size.

CAUTION :

The relationship between spot size and power density is not linear. Reducing the spot size by 50% will quadruple the power density. The laser clinician must understand the relationships between spot size, laser power, power density, thermal interaction, and photochemical interaction of the laser beam with living tissue before using the laser system and the delivery system.
The table here under shows how the power density at the treatment site changes with increasing or decreasing laser beam spot sizes. It is a guide to the relationships between laser power, spot size, and laser beam power density at the treatment site

| Spot size (Millimeters) | Laser power level (Milliwatts) 1 | 5 | 20 | 50 |
|---|---|---|---|---|
| 1.0 | 127 | 637 | 2547 | 6368 |
| 2.0 | 32 | 159 | 637 | 1594 |
| 3.0 | 14 | 71 | 283 | 707 |
| 4.0 | 8 | 40 | 159 | 398 |

Laser power density table - Milliwatts / Centimeter$^2$

## 8-8 GENERAL OPERATION

- Position the patient, laser system, and the delivery system.

- Target the aiming beam on the desired treatment site.

- Fixate the patient's eye and position the aiming beam on the zone to be treated.
  Select the required aiming beam intensity.
  At this point you can check that the spot is in focus.

- When the countdown reaches the last 15 sec, a beep is emitted every second.

- On the Operating mode (§ 8-6), press the “READY” Mode button to enable firing : the Yellow light goes ON.

- Depress the footswitch to deliver the treatment beam to the tissue.

Keep the footswitch depressed during all the exposure time. When the requested energy has been delivered, the treatment beam stops.

If you want to stop the treatement release the footswitch. If treatment is paused by depressing the footswitch before the counter limit is reached, and then continued with another footswitch depression, the exposure will resume and counters will continue to increment from the current value until the requested limit is reached.

**Between two patients :**

At the end of the treatment, press the STAND-BY Mode : the green light goes ON
In this position the footswitch is not active.

## 8-9 SHUTDOWN

1- Turn the key switch to position "OFF" : to turn the laser OFF.
2- Remove the key.
3- Switch OFF the unit with the master switch on the front panel.
4- In the case the delivery system is disconnected, do not forget to put the cap back on the optical fiber output to avoid dust.

**IMPORTANT** : The panic switch must be used only **in case of emergency**.
It is located on front of the laser console. After use, it must be twisted and pulled out to allow the laser to function again.

## 9-1 LASER CONSOLE

**WARNING :**
Disconnect AC power before cleaning the case :

**a.** The air is pulled out to the rear access holes on the back of the laser console.
Any dust build up should be cleaned as necessary.
Use a dry cloth to remove dust from these surfaces.

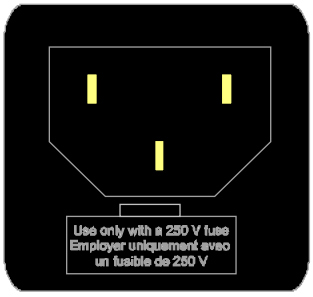
**b.** The laser console is constructed from an ABS plastic material.
This part is coated with an epoxy paint.
Use only a damp cloth for cleaning. Do not use either solvents or alcohol.

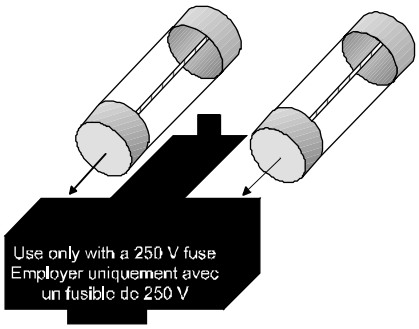
All surfaces should be thoroughly dried after cleaning.

## 9-2 FUSES REPLACEMENT

- Switch off the device and disconnect the power cord.

Spécifications : glass fuse
2 AT - 250 V
6 x 32 mm




## 9-3- CLEAN THE EXTERNAL SURFACES

Periodically clean the laser system as describe below.

1) Turn off the laser system.

2) If necessary, allow the laser system several minutes to cool.

3) Wipe using a cloth dampened with a non-caustic cleaning solution such as soap and water, isopropyl alcohol, or a “hospital-grade” disinfectant. Do not spray or pour cleaning agents directly on the system. Dry with a clean, dry cloth or allow to air dry.

## 9-4- INSPECT AND CLEAN THE FIBER OPTIC

Periodically inspect the fiber optic and if necessary clean it as described below.

**CAUTION:** **When using a fiber optic delivery device, always inspect the fiber optic cable to ensure that it has not been kinked, punctured, fractured, or otherwise damaged. The fiber optic cable may be damaged if stepped on, pulled, left lying in a vulnerable position, kinked, or tightly coiled. Do not clamp the cable with a hemostat or other instruments.**

1) Turn off the laser system.
2) Wrap a piece of lens tissue (Kodak® or equivalent) around one end of a cotton-tipped swab.
3) Place several drops of 100% ethanol, 100% methanol, or high-grade acetone on the tissue.
4) Clean the fiber optic connector.

**AIMING BEAM VERIFICATION**

1- Ensure the fiber optic is properly connected to the laser as described in the connection instructions section of this manual.
2- Turn the laser ON.
3- Verify that the “no fiber” message is not displayed on the control screen. If it does, tighten the laser connector until the message is no longer displayed.
4- Set the aiming beam to the highest intensity, as described in your laser operator’s manual.
5- Hold a non-reflective surface, such as a tongue depressor, in front of the fiber tip. If you see a red spot, the aiming beam is weak; verity that the aiming beam is set to the highest intensity.

**CAUTION:** **Do not use the system if the aiming beam is set to the highest intensity and is still weak or not visible, as the fiber optic cable may be damaged. A damaged cable may cause accidental laser exposure to the treatment room personnel or patient, and/orset fire in the treatment room.**

6- Set the laser treatment parameters as described in your laser operator’s manual.

## 9-5- SERVICE VISITS

Contact your Authorized Quantel Medical Distributor every twelve months to carry out a preventive maintenance visit to confirm the correct function of your system.

At each six-monthly visit, your Authorized Quantel Medical Distributor will clean the optics and check general performance, alignment and calibration.

At least once every twelve months the Quantel Medical Distributor will fully re-calibrate the system.

# LIST OF DEFECTS 689 nm AND POSSIBLE SOLUTIONS

| Message | Explanation and solutions |
|---|---|
| Remote interlock safety | The remote is open or is not properly closed (External door or other device)<br>- Close the remote.<br>Verify the remote control connection :<br>Connector at the back of the unit, near the power cord. |
| The pedal is pressed | The footswitch is pressed during the "Warming up" or in the "Key to Off" states :<br>- Release the footswitch<br>It could be in short-circuit :<br>- disconnect the footswitch and check that the message disappears. |
| Too much humidity in cavity | Too high humidity rate may cause a misfunction of the Laser. If the laser has been in a cool atmosphere the humidity may come from condensation:<br>- let it warm up for 3 hours at ambient temperature. |
| Cavity temperature out of tolerance | Cavity temperature too high or too low :<br>- The instrument must be only used within the advocated temperature range : 15°C to 30°C ( 59°F to 86°F)<br>After an intensive use ACTIVIS may be over heating.<br>- Let it cool down for a few minutes. |
| Height waiting | - Check the adaptation connecting. |
| Terminal not well connected | The delivery system is not correctly connected<br>- Verify the connection |

# 10 - ERROR MESSAGES

| Message | Explanation and solutions |
|---|---|
| Non calibrated terminal<br>Call for SERVICE | The Delivery system is not calibrated :<br>- It must be done by authorized person only : Call for service. |
| Hard: P< (-20%) 689 | A too LOW power is measured : below (-20 %) the expected one<br>- Call for Service. |
| Hard : P>(+20%) 689 | A too HIGH power is measured : over (+20 %) the expected one<br>- Call for Service. |
| Hard: 24V < (-20 %) | A too low +24V voltage is measured : below (-20 %) the expected one<br>- Call for Service. |
| Hard: 24V > (+20 %) | A too high +24V voltage is measured : over (+20 %) the expected one<br>- Call for Service. |
| Hard : Security 689 | The External cell detects a 689 nm laser beam whereas it should not.<br>- Call for Service. |
| Soft: : Pow. Out ± 20% in shot | The measured power fluctuates more than ±20% the expected value.<br>- Call for Service. |

**To order the following systems, contact Quantel Medical or your local distributor.**

## 11-1 DELIVERY SYSTEM OPTIONS : LIST & CODES

| **Delivery system options for ACTIVIS laser photoactivator 689 nm QUANTEL MEDICAL ordering codes** | |
|---|---|
| Slit lamp adaptor | |
| Adaptor for 900 - BM/BQ HAAG-STREIT slit lamp (réf : BMBQ) | XL689 BMBQ |

## 11-2 ACCESSORIES : LIST & CODES

| **Accessories for ACTIVIS laser photoactivator 689 nm QUANTEL MEDICAL ordering codes** | |
|---|---|
| For ancillary personnel protection : | |
| Laser safety goggles for 689 nm | XL689PROT |
| For calibration purposes : | |
| Laser power measurement system | XLAAAWATTMETRE |

# 12 - PROFESSIONAL CLINICAL INFORMATION

The use of Activis Laser for PhotoDynamic Therapy purpose, involves the whole knowledge of Visudyne® photosensitizer.
Refer to the CIBA Vision documentation about Visudyne product.

**Intended use :**

PDT is indicated for age-related macular degeneration (AMD) treatment on patients with classic subfoveal choroidal neovascularization.

**Precaution :** Cataracts and retinal tears must be treated before AMD treatment.

**Contraindications :**

Relative to Visudyne® : Visudyne therapy is contraindicated in patients with porphyria, or patients with known hypersensitivity to verteporfin or any other component of the lipid-based formulation as well as patient with severe liver disease.

Relative to Laser : Patients with following symptoms which prevent visualisation of target tissue are contraindicated for Laser treatment :
- cloudy cornea or extreme haze of the aqueous humor of the anterior chamber.

**Light application :**

The spot size is determined by measuring the greatest linear dimension of the lesion on which is added 1000 µm to allow a 500 µm margin to ensure full coverage of the lesion and to allow for small eye movements.
The light spot covering the lesion must come no closer than 200 µm to the temporal edge of the optic disc even if the lesion is located closer to it.

The 689 nm Laser application begins 15 mn after the beginning of the infusion.

Select the recommended intensity of 600 mW/cm². The time to deliver the 50 J/cm² light dose is 83 seconds (0.6×83=50).

To treat both eye with one infusion of Visudyne®, the application of light on the second eye must start at the latest 20 mn after the beginning of the infusion.

The Activis allows you to select the parameters for each eye independently and before the treatment, so that you can easely treat the second eye in the 5 mn after the first.
However, if the patient has never been treated, it is more suitable to select one eye and to assess the outcome after a week.

**Retreatement :**
Patients should return for a follow-up examination after 3 months. Patients who have not experienced any serious adverse events likely to be associated with prior therapy are retreated if necessary.
Further follow-up examinations are scheduled at 3-month intervals with a maximum number of 4 treatments a year.
Patients who experience severe vision loss from their previous therapy should not be retreated until their vision has returned to pretreatment levels.

**Adverse effects :**
**The adverses effects of Visudyne® are describe in CIBA-Vision documentation**
Patients may develop transcient vision disorders such as vision deterioration or visual field defects that can impair their ability to drive motor vehicles or operate machinery.

Adverses effects may occur as a result of Laser treatment :
- Corneal burns and inflammations.
- Transcient elevation of intraocular pressure.
Excessive combinations of power and exposure can cause undesirable tissue vaporization and charring.

**Warnings and cautions :**
**Refer to the Visudyne® documentation for any information.**
Patients are advised to avoid exposure of unprotected skin or eyes to direct sunlight or bright indoor light, especially halogen lighting, for 48 hours after treatment.

The aiming beam, while low power, is an intense light source so that retinal exposure must be limited to the minimum required for target aquisition.

**Protection for personnel :**
Backscattered radiations are not harmfull when viewed through the protective filter. Make sur this one is in place on the adaptor and is not damaged (splinter, crack).
Protective eyewear designed for the selected wavelength (689 nm) should be worn by everybody present inside the NOHD (see § 3-7).

Specifications : 689 nm / OD > 3,5, Quantel goggles 689 nm / OD 5 + ref XL 689 PROT.

**CAUTION:**
**Federal (US) law states that only a physician may buy this device.**

**CAUTION:**
**Making adjustments, or performing procedures other than thosespecified in the instruction manual, can result in hazardous radiation exposure.**

# POWER CALIBRATION TEST

## POWER CALIBRATION TEST

Recalibrate only when indicated by the results of the calibration test as outlined below.

Equipment Required:
Ophir Laser Joulemeter Model NOVADISPLAY, or equivalent.
Quantel Medical Code : " XL AAA WATTMETRE ".
The meter should be calibrated periodically according to the manufacturer's recommendations.

**Do not use Silicon Photocell type meters.**

**When performing calibrations, wear appropriate eye protection (689 nm goggles of L4 class).**

Step 1 : Start the laser, turning the KEYSWITCH to the "ON" position.

Step 2 : If you are using the Ophir power meter, select **0.1 s**econd exposure duration and set the meter to operate in the **"ENERGY" mode.**

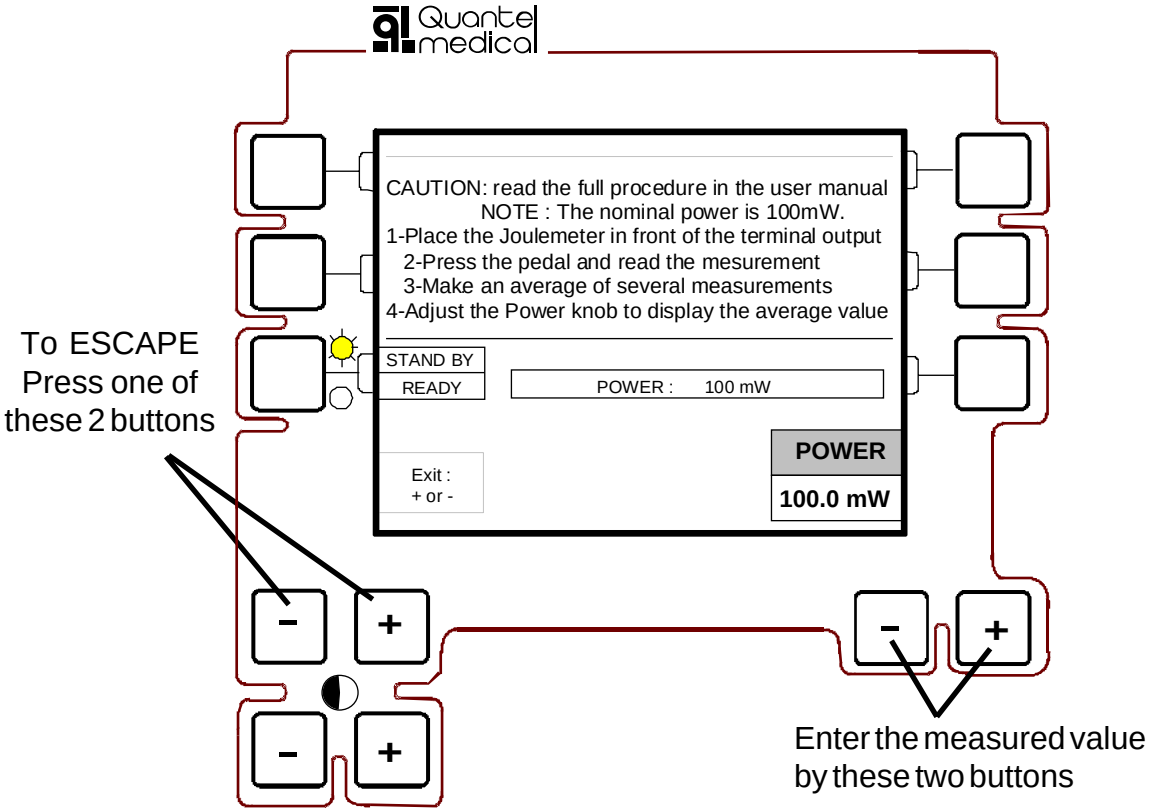
Step 3 : Direct the adaptor aiming beam output into the photodetector of the laser power meter to obtain a **defocussed aiming beam spot** occupying the largest possible part of the sensitive surface.
Always assure that the full diameter of the defocussed beam is striking the active surface of the power meter's photodetector.
**NOTE : A tightly focussed beam may damage the photodetector.**

Step 4 : For non-Ophir power meters, set the measurement range of the meter as required by the power meter owner's manual.

Step 5 : In the operating screen (see § 8-6), press the CALIB. function button in front during more than 3 seconds until the calibration display apppears.

# DELIVERY SYSTEM OUTPUT POWER CALIBRATION

The delivery system terminal is determined by the choice that you have done before.
the calibration is made at 100mW power and 0.10s exposure time.
Energy = (power) x (Expos.). The Joulemeter will give the readings in mJ.
The nominal value adjustment is limited to +/- 20%: from 80 to 120 mW.




**PROCEDURE :**

**Note** : To be sure of the measurement validity, the Joulemeter must have been calibrated periodically by a registered laboratory according to the manufacturer's recommendations.

1- Place the joulemeter in front of the laser beam, at the terminal output, so that the spot occupies the largest possible part of the sensitive surface : Do not place it at the focal distance.

2- Protect yourself from the laser reflexions with the 689 nm goggles (Class L4).
Press the pedal to obtain the measurement.

3- Make an average of 10 measurements (for example). Note these values : the differences should not exceed 5%.

4- Calculate the average and display this value by pressing the left "+" and "-" buttons.
This correction will then be applied over all the power range.

5- To store the NEW calibration value, ESCAPE pressing the right "+" or "-" buttons.

APPENDIX - 2

# VENDORS

## 1- ANSI Z136.3 -1996

Standards for the Safe Use of Lasers in Health Care Facilities

Order from : Laser Institute of America
5151 Monroe Street
Toledo, OH 43623
U.S.A.

## 2- LASER SAFETY GOGGLES FOR 689NM

( Ref (EN 207) : DIR 676-842 L4)

Retailer:
Noir Laser Company, L.L.C
P.O. Box 159 South Lyon
Michigan 48178
Phone: 734-769-1708

Manufacturer:
YAMAMOTO KOGAKU CO. LTD
Safety and Health Care Division
25-8, Chodo - 3, Higashi-OSAKA City
OSAKA 577 - JAPAN

## 3- LASER JOULEMETER

**model :** **NOVA - DISPLAY**
**Head model :** **PD300-3W**

Ophir Optronics, Inc.
200 Corporate Place # 7
Peabody,
MA. 01960
U.S.A.
Phone : (508) 535-5777
Fax : (508) 535-5999

# VALIDATION SHEET

| | |
|---|---|
| ***SOFTWARE VERSION*** | ***Version : 3.xx*** |
| **Publishing date** | **May 2007** |
| **Revision** | **May 2007** |
| **Written by R. DION** |  |
| **Checked by C. CHABRIER** |  |
| **Validated by P. QUERO** |  |