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User Manual
PXL Platinum 330

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Table of Content

1 General

	To indicate that caution is necessary when operating the device or control close to where symbols places, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	Instruction that the user has to read manual before using this medical device.
	Additional information
	This symbol located on the PXL Platinum 330 indicates that the equipment consists of electronic assemblies and other components that may be subject to Directives 2002/96/EC, 2003/108/EC, and 2002/95/EC of the European parliament, which advises that electrical and electronic devices must not be disposed of as normal domestic waste. In order to prevent environmental risks or endangerments by non-professional disposal, the disposal of this product, including any accessories, must comply with valid practices as outlined in Directives 2002/96/EC, 2003/108/EC, and 2002/95/EC and local regulations. All electronic components and systems should be returned to the manufacturer for disposal.
	12V / 25W DC Power.
	Device with protection class II. (Protective insulation without protective earth conductor)
	Using only inside of buildings.
	This symbol indicates that Group AG is the manufacturer of the PXL Platinum 330 device. The YYYY under the symbol indicates the year the device was manufactured.
	This mark indicates that Notified Body 0297 (DQS Med GmbH, Germany) has certified that the management system of Group AG meets the requirements of Directive 93/42/EEC Annex II (excluding section 4) for ophthalmological devices.
REF	This symbol indicates that the model number of this device is 903772.
SN	This symbol indicates the serial number of the device. YYYY indicates the year of manufacture and XXXX indicates the unit number.

2 Introduction

2.1 Intended Use

The PXL Platinum 330 device is a portable medical device intended to emit UV light of wavelength 365 nm using a light emitting diode (LED) and irradiating patients' cornea with this light after instillation of a photosensitizer fluid to generate a photochemical effect and stabilizing the cornea. Its working principle is based on the effect of the so-called "collagen cross-linking", which works by the absorption of UV light by means of a solution of vitamin B2 and the photochemical generation of free oxygen radicals, causing the collagen tissue to expose additional chemical bonds which in turn stabilize the tissue mechanically. The indication for this procedure is the treatment of ecstatic corneal diseases, such as keratoconus, and to change a progressive form into a forme fruste.

The photosensitizer solution (vitamin B2) is not part of the device. The vitamin B2 photosensitizer is excluded from the declaration of conformity to this device.

2.2 Contraindications

UV radiation may cause cell damage to sensible tissues of the eye. 95% of the UV radiation is absorbed in conjunction with the photosensitizer vitamin B2 solution in the corneal stroma. Corneal endothelial cells, located on the back of the cornea, have a damage threshold of 0.36mW/cm^2. This value is not reached during the irradiation with vitamin B2 solution at a depth of the cornea of more than 300 microns. Minimum thickness of the cornea is specified as a criterion for the feasibility of treatment with the UV irradiation + vitamin B2 solution. The thickness has to be at least 400 microns [Kohlhaas M1, Spoerl E, Schilde T, Unger G, Wittig C, Pillunat LE.; Department of Ophthalmology, Universitätsklinikum CGC, Dresden, Germany; Biomechanical evidence of the distribution of cross-links in corneas treated with riboflavin and ultraviolet A light; J Cataract Refract Surg. 2006 Feb]

Patients having corneas with a central pachymetry of less than 400 microns may not be treated. Patients with active medical implants such as cardiac pacemakers must not be treated. Patients with aphakic-/ pseudoaphakic eyes must not be treated. Pregnant women must not be treated.

2.3 Known Side Effects

Treatment failure that occurs in 8.1–33.3 % of the cases is usually defined as continued progression with an increase in maximum K readings of 1.0 D over the preoperative value [Shalchi Z, Wang X, Nanavaty MA. Safety and efficacy of epithelium removal and transepithelial corneal collagen crosslinking for keratoconus. Eye (Lond). 2015]
After standard CXL procedure, corneal haze is a relatively common complication reported by 10-90 % of patients. However, to date the etiology and the natural course of clinical corneal haze after epi-off procedure has not been clearly defined [Craig JA, Mahon J, Yellowlees A, Barata T, Glanville J, Arber M, et al. Epithelium-off photochemical corneal collagen cross-linkage using riboflavin and ultraviolet a for keratoconus and keratectasia: a systematic review and meta-analysis. Ocul Surf. 2014].
In vivo confocal microscopy showed an increased stromal reflectivity associated to edema and keratocyte activation mainly evident 3–6 months after treatment, while in the late postoperative period, anterior and intermediate stromal layers showed a reduction of cellular density and fibrosis of extracellular matrix [Mastropasqua L, Nubile M, Lanzini M, Calienno R, Mastropasqua R, Agnifili L, et al. Morphological modification of the cornea after standard and transepithelial corneal cross-linking as imaged by anterior segment optical coherence tomography and laser scanning in vivo confocal microscopy. Cornea. 2013].
Several cases of infective keratitis following CXL treatment have been described including bacterial, protozoal, herpetic, and fungal keratitis. [Abbouda A, Abicca I, Alio JL. Infectious keratitis following corneal crosslinking: a systematic review of reported cases: management, visual outcome, and treatment proposed. Semin Ophthalmol. 2014].

Other common ocular adverse reactions in any CXL-treated eye is punctate keratitis, photophobia, corneal striae, corneal epithelium defect, eye pain, reduced visual acuity, and blurred vision. These events are expected sequelae following epithelial corneal debridement and occurred at a higher incidence than observed in control patients, who did not undergo debridement or exposure to UVA light. The majority of adverse events reported resolved during the first month, while events such as corneal epithelium defect, corneal striae, punctate keratitis, photophobia, dry eye and eye pain, and decreased visual acuity took up to 6 months to resolve and corneal opacity or haze took up to 12 months to resolve. In 1-2% of patients, corneal epithelium defect, corneal edema, corneal opacity and corneal scar continued to be observed at 12 months. The rare serious adverse events following traditional CXL that have been reported included diffuse lamellar keratitis at LASIK interface, corneal melting and persistent corneal edema due to endothelial failure [Kymionis GD, Bouzoukis DI, Diakonis VF, Portaliou DM, Pallikaris AI, Yoo SH. Diffuse lamellar keratitis after corneal crosslinking in a patient with post-laser in situ keratomileusis corneal ectasia. J Cataract Refract Surg. 2007].

3 Safety

3.1 Operator Qualifications

Before using the device please read the instruction manual!
This PXL Platinum 330 is intended to be used by trained medical professionals.
The medical professional operating the PXL Platinum 330 must have a general knowledge of the use of cross-linking medical devices.
The PXL Platinum 330 uses audio and visual feedbacks to inform the operator of the treatment status.

3.2 General Safety Remarks

The device may be used only in conjunction with a photosensitizer vitamin B2 solution! Do not perform a treatment without the photosensitizer. Ratio of ingredients for photosensitizer: >0,1 % vitamin B2 solution 20 % Dextran T500 in isotonic NaCI-solution (ph 7,0)
A treatment with no or an incorrect photosensitizer can cause severe damage to the patient‘s eye!
Take proper care of the device. Avoid strong shocks or falls. In consequence of this there may be damage to internal electronics or optical components! Store the device always in the carrying case and store it dry when it is not in use. For the return use always the transport case and the original or adequate packaging carton.
Do not open the device and do not repair the device on your own. In case of technical problems please contact your distributor.
Warning: Changes on the medical device are not allowed.
Check the device and components before use for physical damage (e.g. housing or cable damage, loose parts, rattling noise, optics damage...). In case of a damage don‘t switch the device on. Please contact your distributor.
Make records of all damages, incidents or other occurrences, please use the form in section 12.2 for information transfer. Make a copy of this template.

3.3 Safety Remarks for User

Avoid touching the optics.
Do not look into the lamp while activated UV emission. UV illumination can cause damage to the eye. The activated UV emission is shown on the display during operation.

3.4 Safety Remarks for Application at Patient

Make sure that the device is firmly and securely attached to the floor stand or on the patient bed or table respectively. Improper attachment can lead to injury of the patient! Mount the cable in a way that you do not stumble during treatment.

The device has an integrated output power measurement circuit for surveillance of the actual output power. It will switch off and provide an error message in case of mismatch of the commanded value with the actual measured power output.
A radiation dose of 5400 (mJ/cm2) in the treatment with the PXL Platinum 330 must not be exceeded! This results in following treatment times:

Power level	Treatment time
3 mW/cm^2	30 minutes
9 mW/cm^2	10 minutes
18 mW/cm^2	5 minutes
30 mW/cm^2	3 minutes

Exceeding the treatment time may lead to patient harm!
Do not operate the device unattended! Monitor the device during treatment, Monitor the proper functioning of the device, the positioning and spacing of the device to the patient's eye and the correct size of the UV-Spot on the patient's eye.

The treatment timer on the device is used only to support the user. The proper treatment sequence is in the responsibility of the user. Control the treatment time with a suitable clock and make a note of potential treatment interruptions in order to ensure the correct dosage of UV radiation.

3.5 Limitation of Use

The device must only be used with the included and suitably labeled components. All components were tested for the operation of the PXL Platinum 330 system and are admitted. Any usage of other components can result in an undue hazard to the user and patient. The device must be used only within the following environmental conditions: 18-28°C, max. 70% rel. humidity, non-condensing, 700 – 1013 mbar (sea level up to 3000 m). The device may only be transported or stored in the following environmental conditions: -10-50°C, max. 80% rel. humidity. Allow min. 3 hrs. of acclimatization before operating the device. The device must be used only in designated areas for medical procedures that conform to national guidelines and standards.
People with active implanted medical devices (e.g. pacemakers) should make sure that they have sufficient distance to the device while operation.
If the PXL Platinum 330 has to be installed in the neighbourhood to other devices, please do not operate it unattended.

3.6 Electrical Hazards

Use only the included power adapter
The provided AC adaptor is matched to the connected load of the device. The use of another AC adaptor may lead to risk to the patient and damage to the device. In case of obvious damage of the power supply (housing or cable) do not use it. In case of any damage please contact your distributor.
Do not use the unit in case of excessive moisture in the environment. Otherwise, there is a risk of electric shock.

3.7 Fire Hazards

Do not use the device in the vicinity of flammable liquids, gases, etc.

3.8 EMC Hazards

The device PXL Platinum 330 system corresponds to the EMC Class B according to EN 60601-1-2 and should be operated only in the appropriate environmental conditions.
HF (high-frequency) surgical equipment can influence the operation of the device and may not be operated in combination with PXL Platinum 330.
Portable wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkie etc. can affect the PXL Platinum 330 and should be kept at least a distance of 30 cm (12 inches) to any part of PXL Platinum 330.
Some disturbances causes by portable wireless communications equipment which are located close to the PXL Platinum 330 (at a distance down to 30 cm, i.e. 12 inches) may cause the treatment to be stopped. In this case, keep the interfering device as far away as possible from the PXL Platinum 330.
The PXL Platinum 330 system should not be used adjacent to or stacked with other equipment.
Make sure to avoid electrostatic discharges (ESD) to the unit. High ESD discharges may cause the treatment to be stopped.
The use of another AC adaptor than provided with the PXL Platinum 330 system may result in increased EMISSIONS or decreased IMMUNITY of the PXL Platinum 330.

Declaration for electromagnetic compatibility see chapter 11.

4 Description of the Device

4.1 Components of the Device

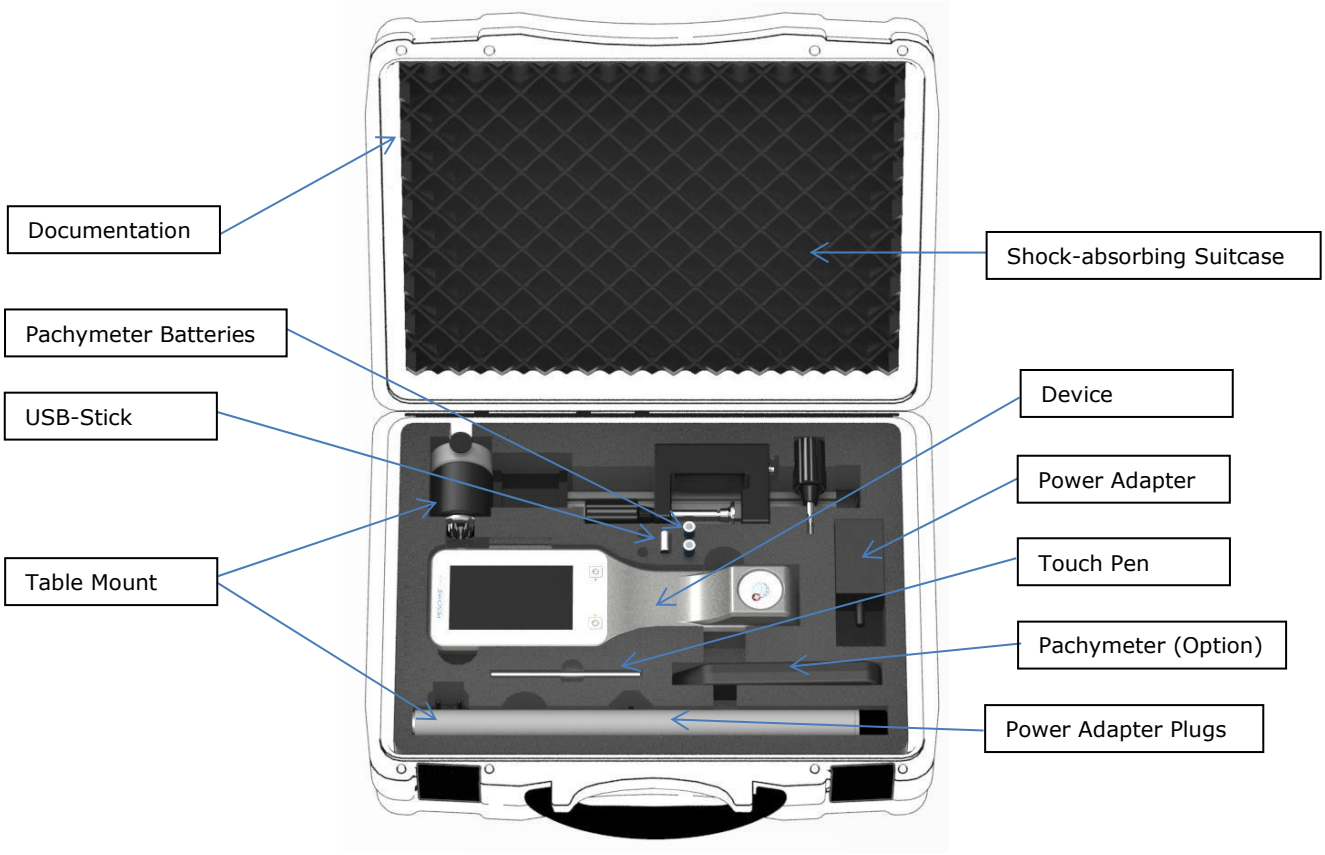


Figure 1: Case with parts

4.2 Table Mount

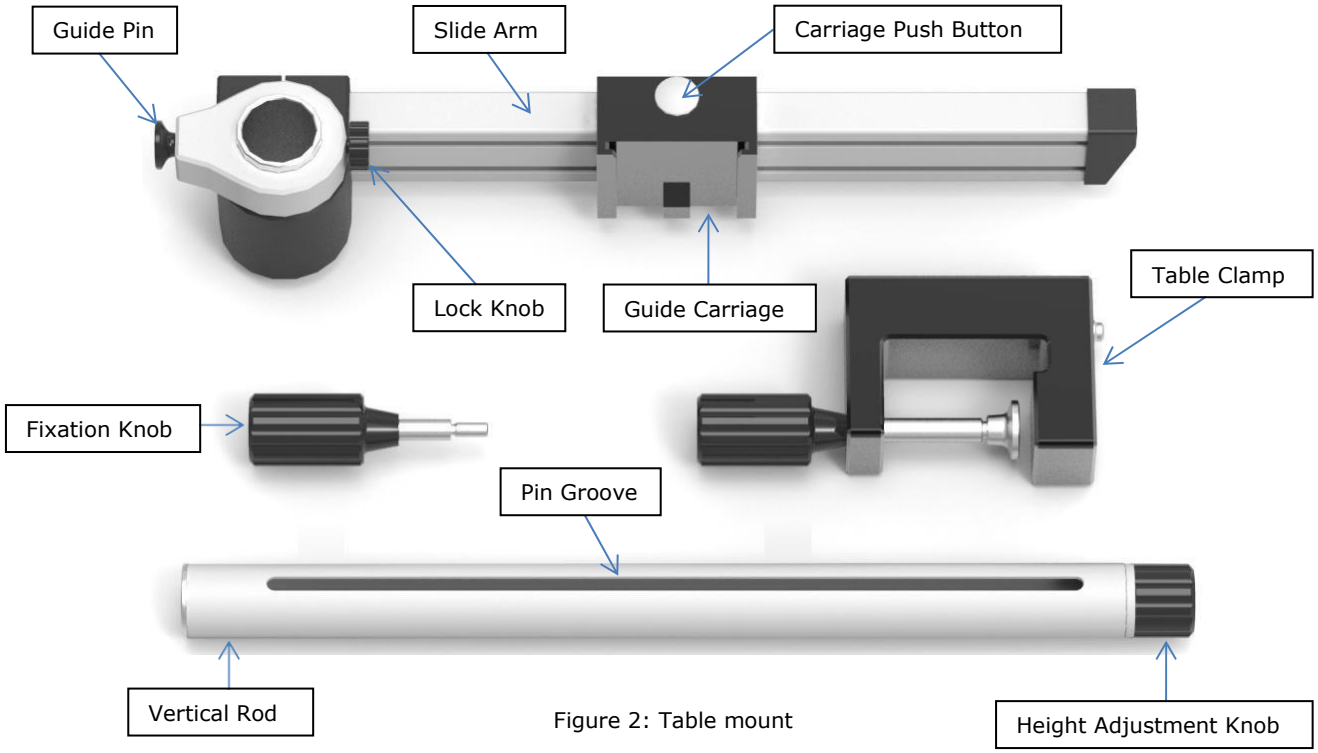


Figure 2: Table mount

4.3 Power Adapter

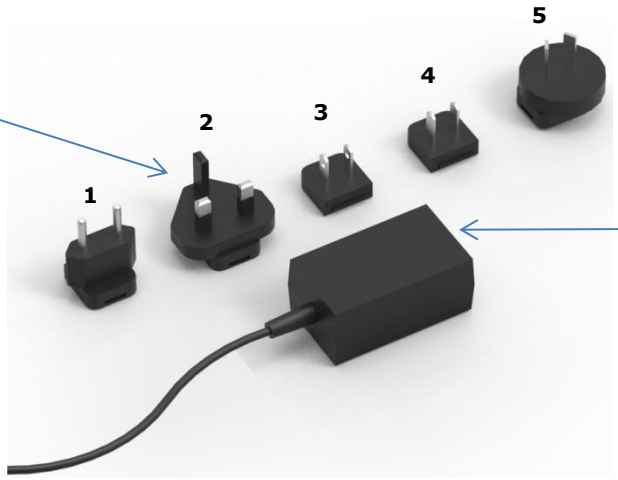


Figure 3: Power adapter with plugs

4.4 Device

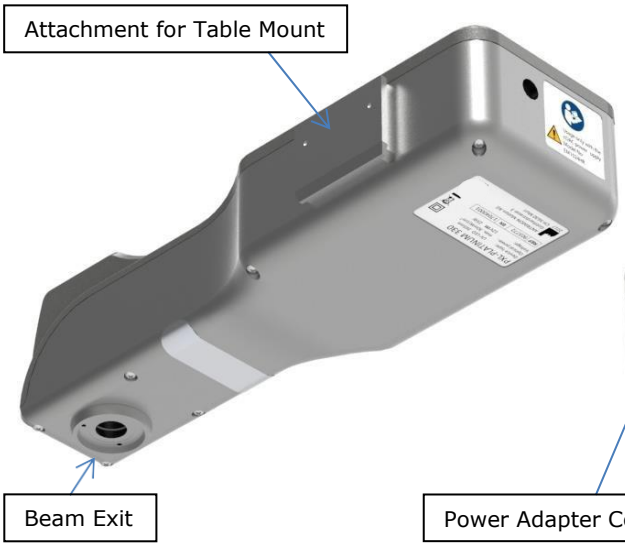


Figure 4: Bottom view

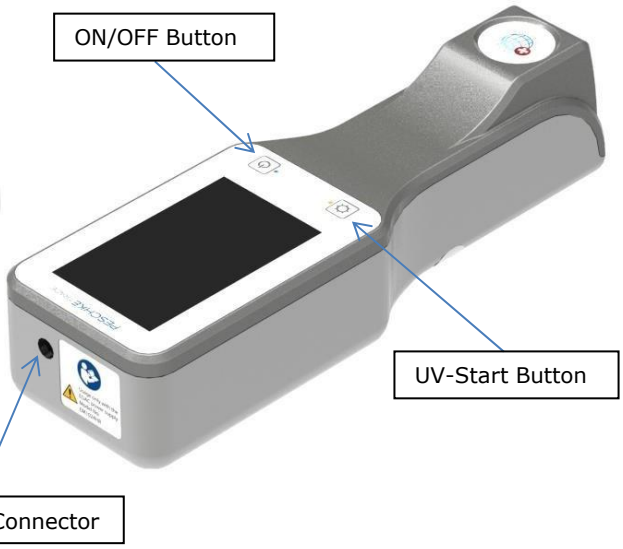


Figure 5: Top view

4.5 Pachymeter (optional)

Figure 6: Pachymeter PACHMATE 2

Detailed information can be found in the Pachymeter manual.

4.6 Labeling

4.6.1 Label on Device

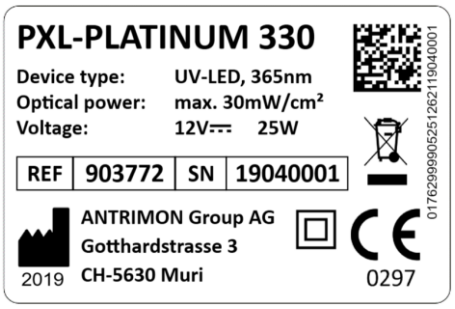


Figure 7: Name plate on rear side of the device

Figure 8: Usage only with the EDAC power supply model number: EM1024HR

4.6.2 Label on Table Mount

Figure 9: Unsafe mounting or fixation might cause physical injury to the patient!

4.6.3 Label on Power Adapter

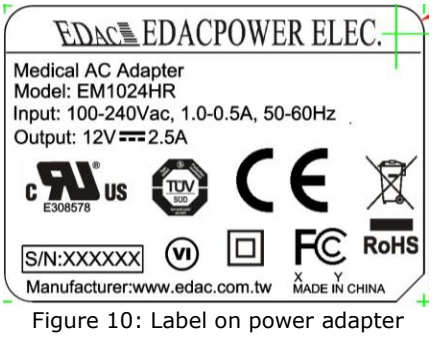


Figure 10: Label on power adapter

4.7 User Interface

4.7.1 Home Screen

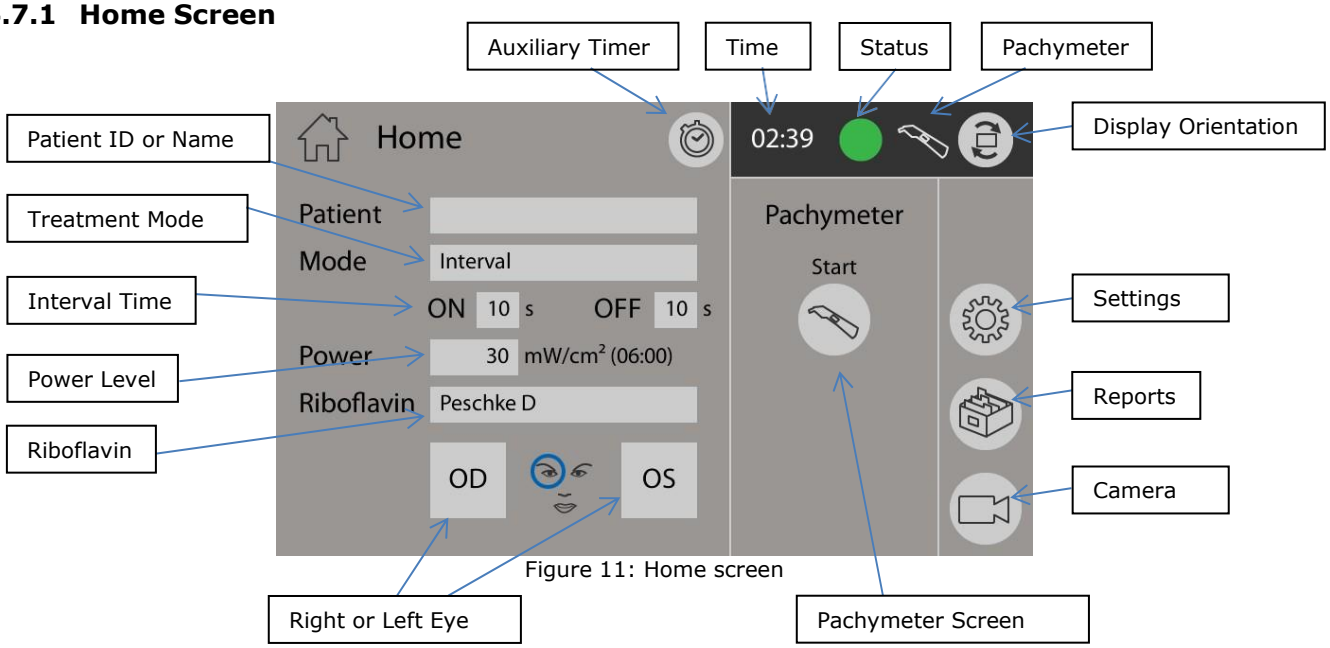


Figure 11: Home screen

Name	Description
Patient ID	Name of patient or ID can be entered with the on-screen keyboard.
Treatment Mode	Continuous, Interval, Lasik continuous and Lasik interval can be set.
Interval Time	Appears when an interval mode is chosen.
Power Level	Standard and accelerated power mode from 3 – 30 mW/cm^2.
Riboflavin	Various PESCHKE vitamin B2 solutions.
OD / OS	Right and left eye can be selected.
Auxiliary Timer	Timer for dispensing the vitamin B2 solution.
Time	Current time which can be set in settings screen.
Status	Shows the device information and possible log messages.
Pachymeter	Status of paired or unpaired Pachymeter displayed.
Display Orientation	The screen can be turned by 180°.
Pachymeter Start	The Pachymeter screen to transmit the measured values opens.
Settings	Physician, clinic and date can be set. Pairing of Pachymeter and custom mode can be activated.
Reports	All saved reports are listed in the screen. Sending and deleting of reports is possible.
Camera	Different settings can be adjusted: Aperture: Diameter of UV beam Threshold: Diameter for eye-tracking area Fix LED: Fixation LED intensity for patient Brightness: IR-Brightness of camera can be adjusted for accurate tracking.

Table 1: Home screen description

4.7.2 Camera Settings

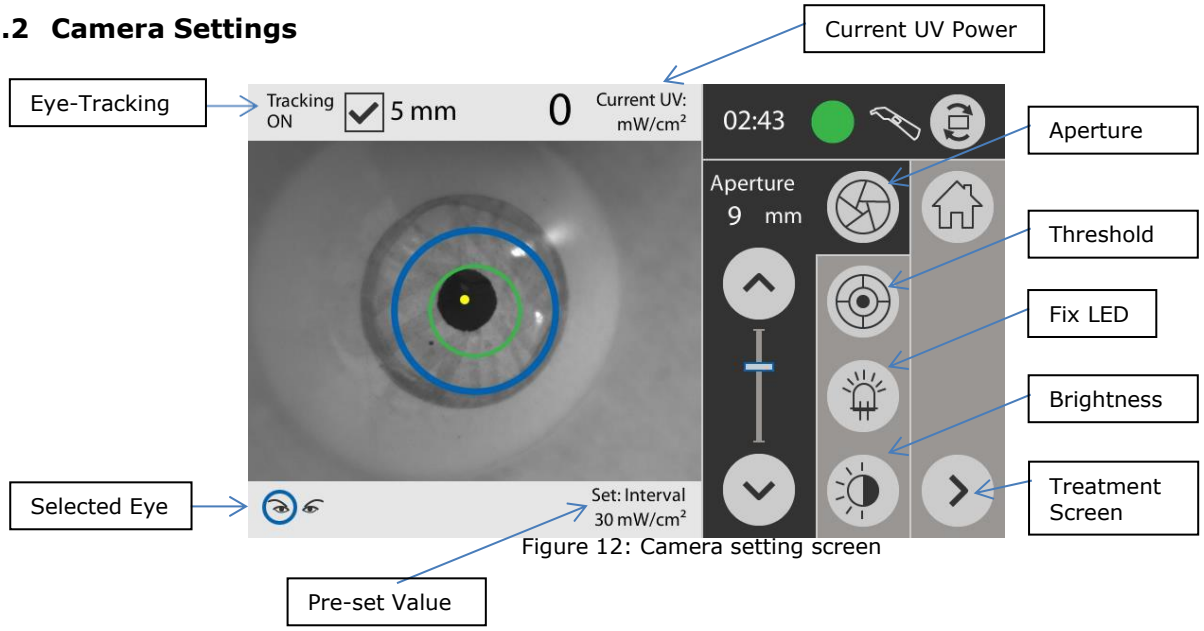


Figure 12: Camera setting screen

Name	Description
Aperture	Diameter of UV beam (blue circle).
Threshold	Diameter for eye tracking area (green / red circle).
Fix LED	Fixation LED intensity for patient.
Brightness	IR-Brightness of camera can be adjusted for accurate tracking.
Eye-Tracking	The tracking function can be enabled and disabled with check-box.
Treatment Screen	Screen with treatment time and UV-status.
Selected Eye	Selected eye is highlighted with a blue frame.
Pre-set Value	Pre-set value mentioned in camera screen.
Current UV Power	Shows current UV power when active.

Table 2: Camera Screen Description

5 How to Use the Device

5.1 Fundamental Operation Procedure

The individual steps are explained in the following sections. The correct positioning and treatment is in the responsibility of the surgeon.

Do not operate the device unattended. Monitor the device during the treatment, monitor the proper functioning of the device and the positioning and spacing of the device to the patient eye!

Detailed operation procedures and configuration of all settings are explained in the following chapters.

Precondition is that the device is already installed with the table mount. The main configuration of the treatment settings is already done.

Connect the power adapter first on the network side and then to the device. The blue LED turns on as soon as there is supply. Start the device by pressing the ON/OFF button.

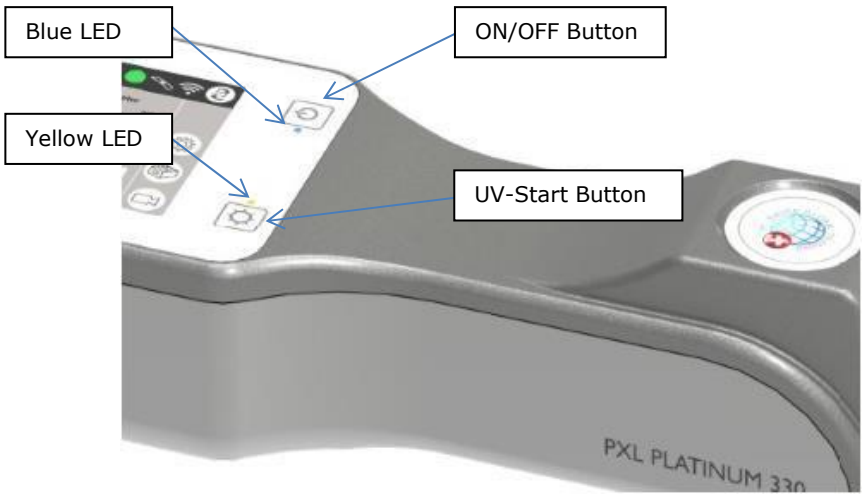


Figure 13: LED's and device buttons

The blue LED will flash while booting the device. Afterwards the home screen appears.

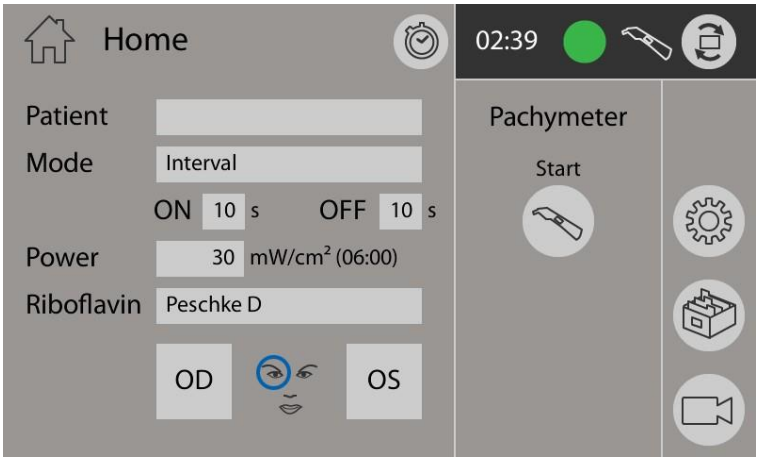
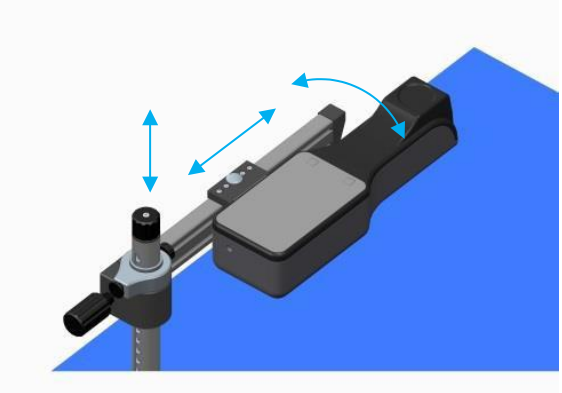


Figure 14: Home screen

Patient ID or Name can be inserted in the corresponding field.
The eye to be treated can be selected pressing "OD" respectively "OS".

The optimal vertical distance is 50 mm from beam exit to the eye. The height of the device can be adjusted by turning the upper black knob on vertical rod. Vertical position has to be fixed by tightening the lock knob. The device can be slided on the guide by pushing the button on guide carriage. The horizontal position can be adjusted rotating the device with respect to the vertical rod. Lock the desired position by turning and tightening the fixation knob clockwise.	 Figure 15

After selecting all settings the treatment can be started by pressing the UV-Start button. The yellow LED will be on during the entire treatment.

The operational distance has to be checked immediately after the start of the treatment.

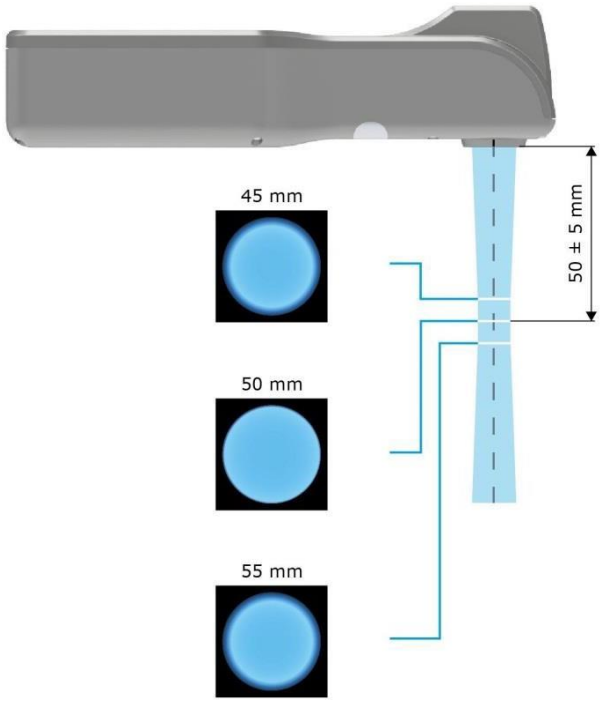


Figure 16: Distance of device to the eye

After treatment the device can be carefully turned away from patient's eye.
An information window appears when the treatment is finished. The treatment report can be viewed by selecting the "View Report" button.

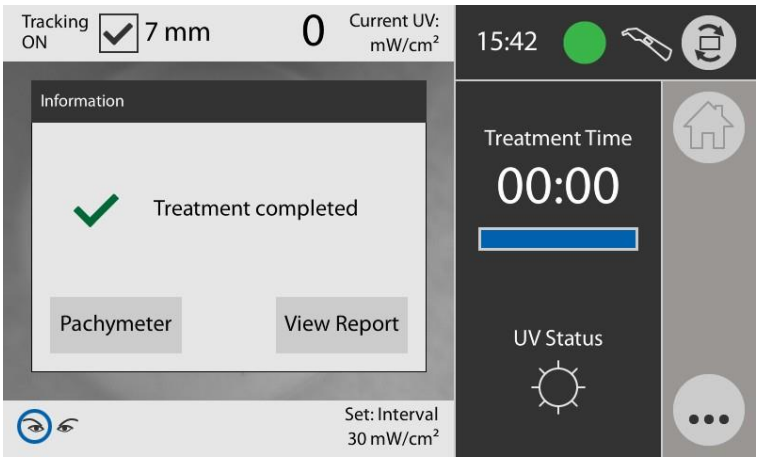


Figure 17: Treatment completed

When the treatment has finished the report viewer appears automatically and must be checked and compared with the configured settings.

Figure 18: Report viewer screen

The device can be switched off by pressing and holding the ON/OFF button for at least 2 seconds. Shutdown has to be confirmed.

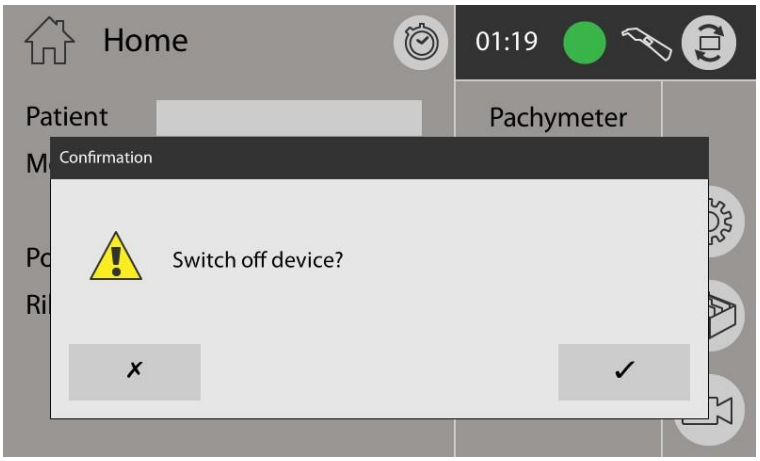
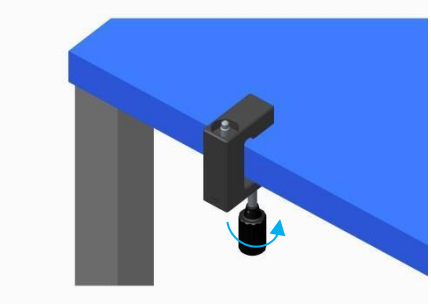
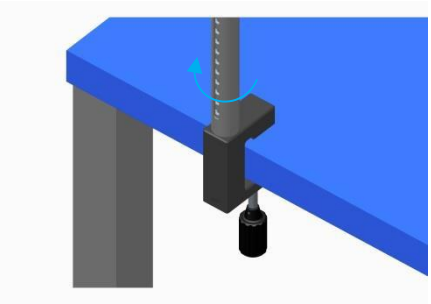
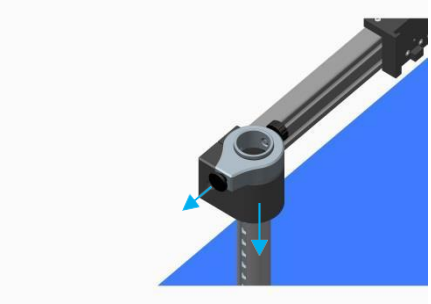
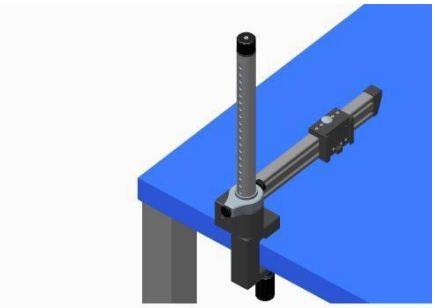
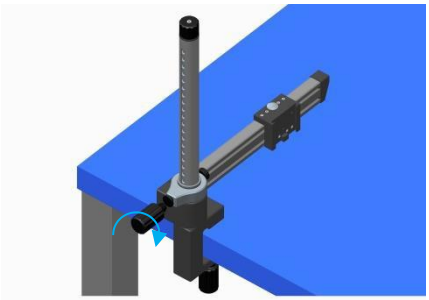
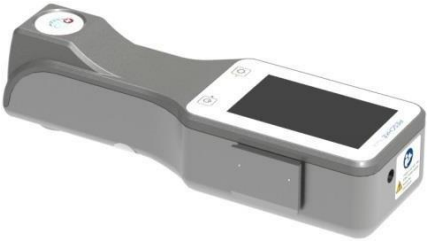
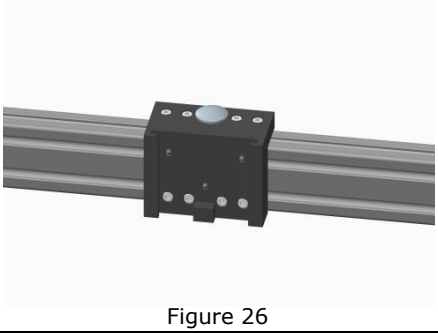
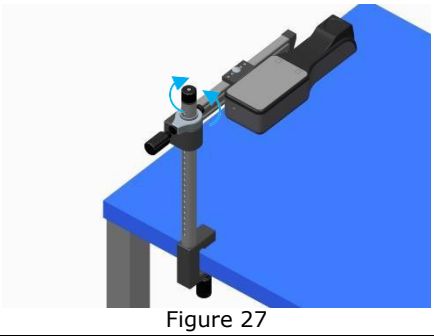
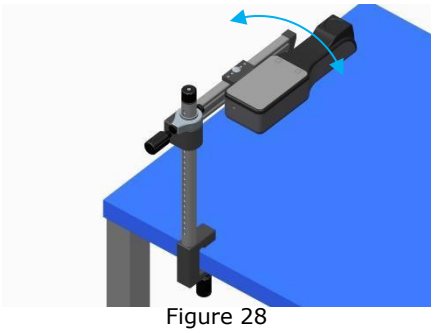


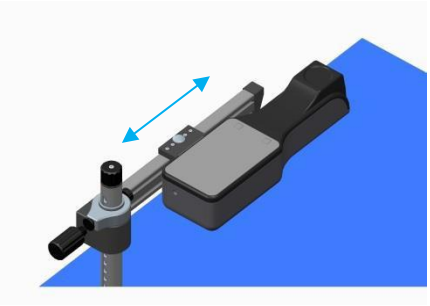
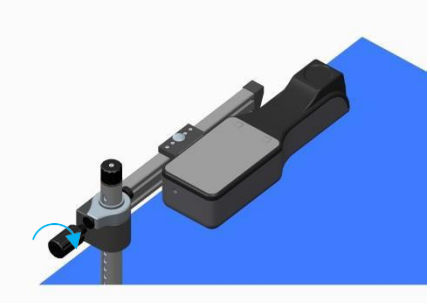
Figure 19: Device shutdown

5.2 Installation of the Table Mount and Device

In order to operate the PXL Platinum 330 system with the table mount, the table mount must first be assembled, and the PXL Platinum 330 system must be attached to it. In the following are the instructions on how to perform this setup without any tools.

Attach the table clamp securely to a flat, stable table as shown.	 Figure 20
Screw in and tighten the vertical rod by turning it clockwise into the table clamp as shown.	 Figure 21
Before sliding the slide arm over the vertical rod by pulling the guide pin, assure that the lock knob is not tightened.	 Figure 22
Release the guide pin in right orientation at lowest position into the provided groove. Make sure the guide pin is locked into the vertical rod guide.	 Figure 23

Screw the fixation knob into the vertical guide. Do not tighten the knob yet.	 Figure 24
On the side of the device an appropriate bracket is already mounted.	 Figure 25
The device can be snapped into the guide carriage.	 Figure 26
The height of the device can be adjusted by turning the upper black knob on vertical rod. Vertical position has to be fixed by tightening the lock knob.	 Figure 27
The horizontal position can be adjusted rotating the device with respect to the vertical rod.	 Figure 28

The device can be slided on the guide by pushing the button on guide carriage.	 Figure 29
Lock the desired position by turning and tightening the fixation knob clockwise.	 Figure 30

5.3 Disassembling of the Table Mount

The disassembling of the table mount is done in reverse order to the installation.

Before sliding the slide arm out of the vertical rod assure to untighten the lock knob.

A detailed view of the arrangement in the transportation case can be found in chapter 4.1.

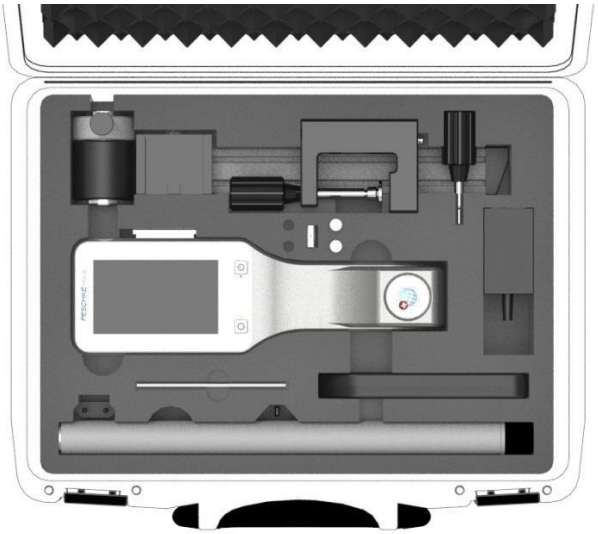


Figure 31: Table mount parts placed in the appropriate space within the transportation case

5.4 General Settings

Connect the power adapter first on the network side and then to the device. The blue LED goes on as soon as there is supply. Start the device by pressing the ON/OFF button.

The supply LED will flash while booting the device. Afterwards the home screen appears.

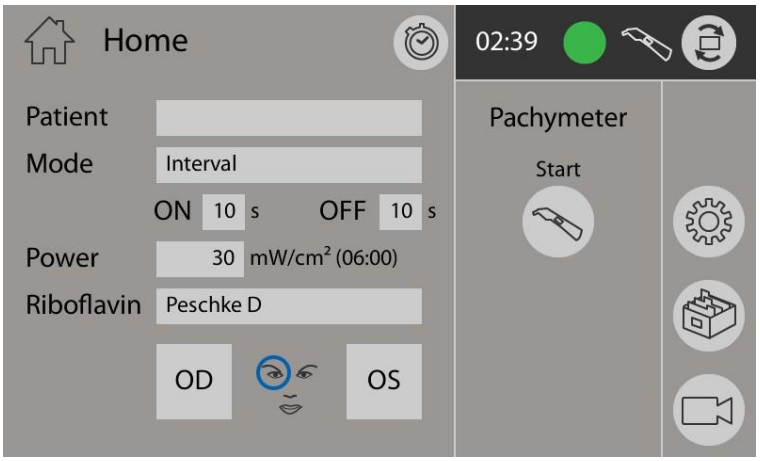


Figure 32: Home screen

Settings have to be done before the first treatment in order to key in the name of the physician, clinic and date.

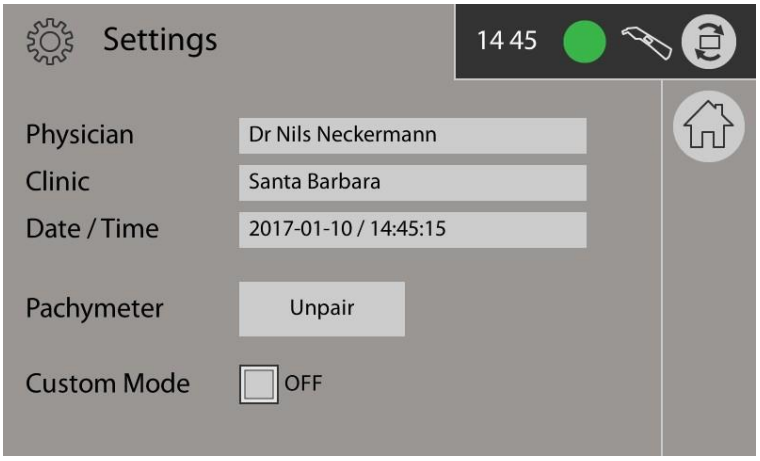


Figure 33: Setting screen

Click into the required field to open online keyboard. Assign name and confirm by pressing the "✓" button.

Figure 34: Keyboard

Date and time can be set in settings screen by pushing on the field. There is also the possibility to choose the format. The set time will be displayed permanently on the screen.

Figure 35: Date and time setting screen

5.5 Pairing Pachymeter (optional)

The Pachymeter is optional and can be paired and unpaired any time in the settings screen. You can turn on the Pachymeter using the PWR button.

Figure 36: Pachymeter PACHMATE 2

	Only registrated and purchased Pachymeter at PESCHKE GmbH can be paired with the device. According to the Pachymeter manual, at least two required settings have to be done (see below hint). 10.3.1 Single Patient Mode 11.2 Mapping Measurement Mode

Extract of Pachymeter Manual:

Manual Point	Description
14.2.2	Turn on the PACHMATE 2 and enter the configuration menu by pressing the "CFG" key.
14.2.3	Press the "ENT" key one time to navigate to the Bluetooth parameters. Check that it is turned 'On'. If not, press the ▲ or ▼ key to enable Bluetooth. (See Section 14.1)
14.2.4	Press the "ENT" key two more times to navigate to 'Add PC/Printer' parameter. Press the "OD" button to initiate a scan. The scan may take up to a minute. 

Table 3: Extract of Pachymeter manual

Open the settings screen on the PXL Platinum and press the "Pair" button. While pairing the Pachymeter info will appear on the screen.

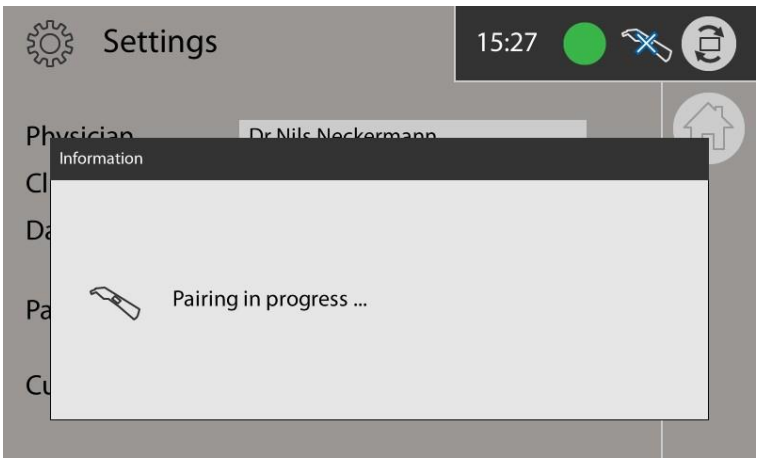


Figure 37: Starting pairing the Pachymeter

As soon as the Pachymeter is paired, on the PXL Platinum a confirmation "Pairing successful!" will appear and the Pachymeter symbol is activated.

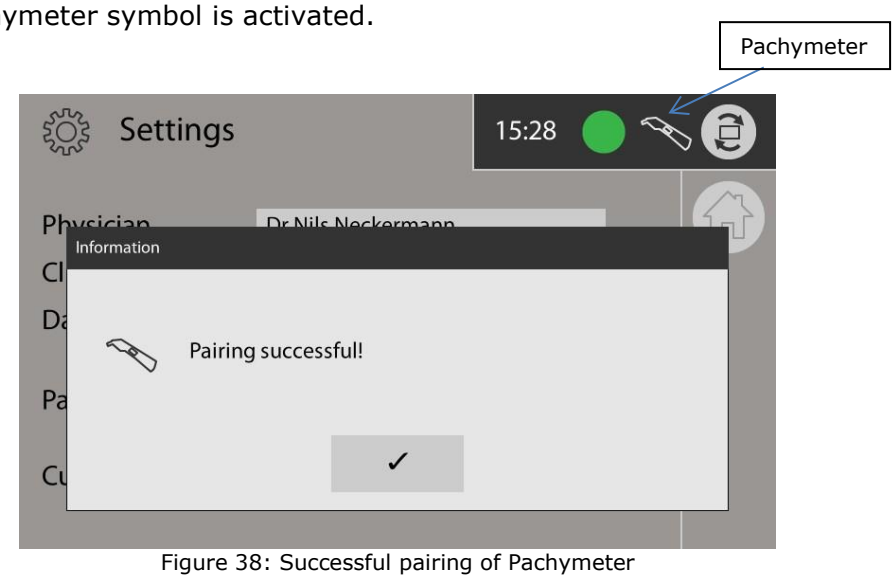


Figure 38: Successful pairing of Pachymeter

	If the PXL Platinum device is paired with the PACHMATE 2, the message 'Paired →' will be displayed. ○ NAME: "PXL_Platinum" is the name of the device discovered. ○ Press CFG key to exit the Configuration Menu.

The device will show "Nothing found" in case there is no Pachymeter available.

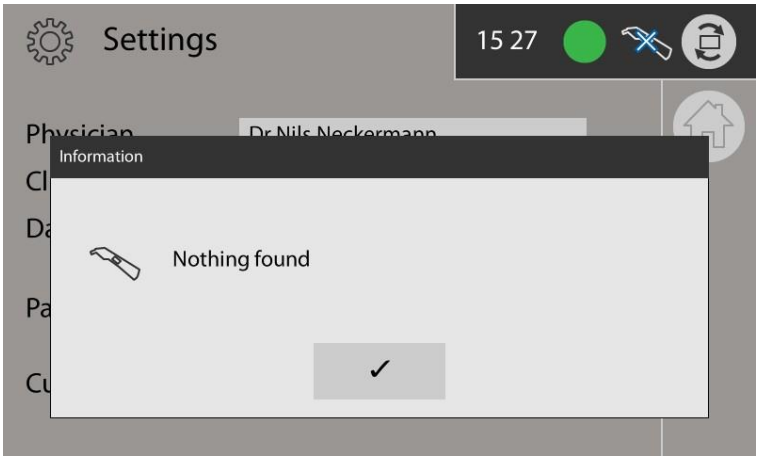


Figure 39: Pachymeter not available

5.6 Unpairing Pachymeter (optional)

Using the button "Unpair" (appears ones the Pachymeter is connected) the Bluetooth connection to the Pachymeter will be disconnected. A warning window will ask if the Pachymeter really should be disconnected.

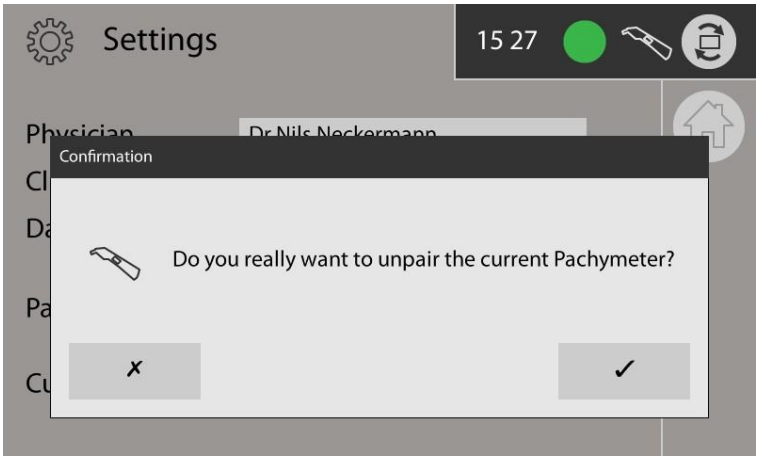


Figure 40: Unpairing Pachymeter

In case the unpairing is successful the information will be displayed.

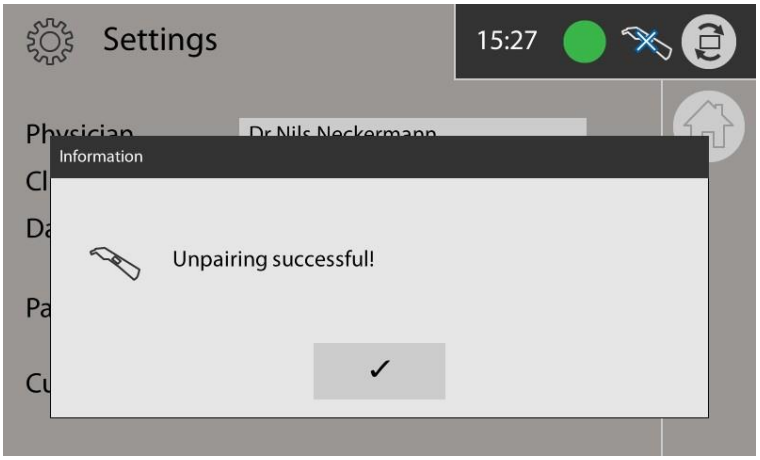


Figure 41: Pachymeter unpaired

	The unpairing of the Pachymeter is only needed in case of a defect or replacement.

5.7 Custom Mode

The custom mode can be activated only with a password.
For more information please contact PESCHKE GmbH directly.

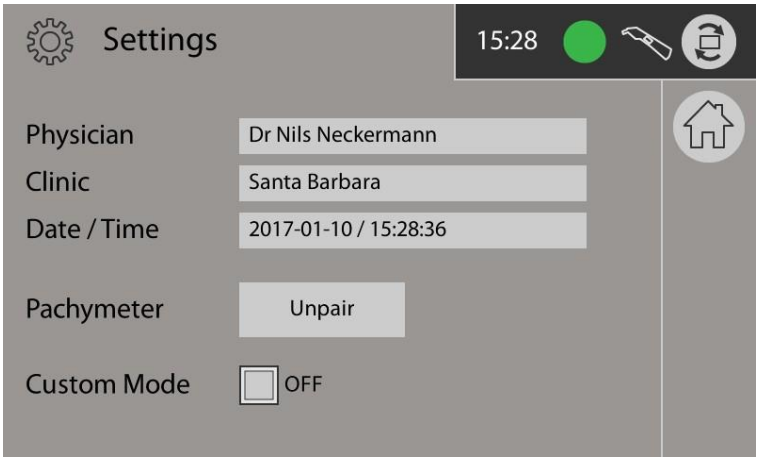


Figure 42: Custom mode on setting screen

5.8 Treatment Settings

5.8.1 Main Settings

By pushing the ON/OFF button once you get directly to the home screen, and you can easily switch to the other screens.
Patient ID or Name can be inserted in the corresponding field.

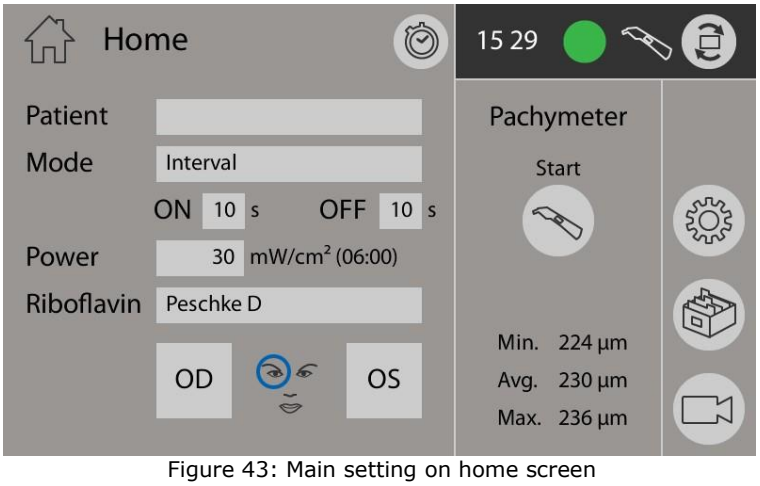


Figure 43: Main setting on home screen

5.8.2 Mode Settings

The preferred treatment mode and power density can be selected. These modes and power densities with corresponding treatment duration are available:

Treatment Mode	Description and Energy Dose
Continuous	Continuous illumination with total energy dose 5400 mJ/cm²
Interval	Intermitted illumination with ON/OFF time from 1 – 10 sec possible. Total energy dose 5400 mJ/cm²
Lasik Continuous	Continuous illumination with total energy dose 2700 mJ/cm²
Lasik interval	Intermitted illumination with ON/OFF time from 1 – 10 sec possible. Total energy dose 2700 mJ/cm²

Table 4: Available treatment modes

Using Interval modes the ON/OFF time can be selected from 1 to 10 seconds.

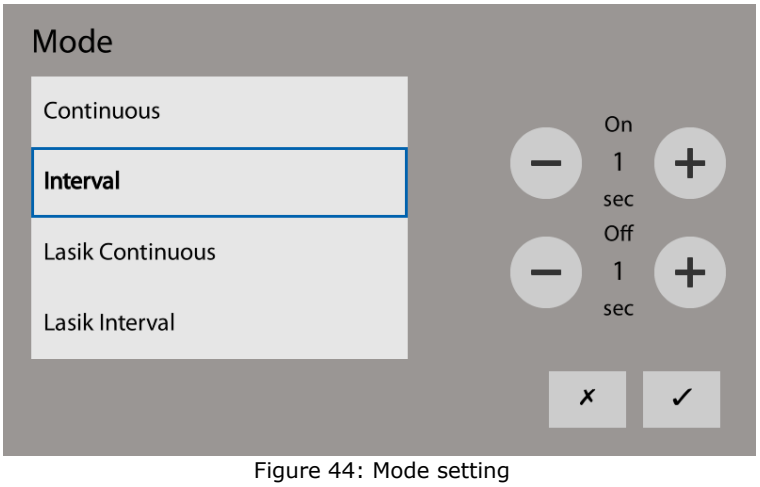


Figure 44: Mode setting

5.8.3 Power Settings

There are two different power modes list available. With active standard power modes check-box, standard power mode protocols are available (see table 5: Power Settings).
With disabled check-box an extended power mode protocol is activated. The power can be selected from 3 – 30 mW/cm^2 increasing by 1 mW/cm^2.

The table shows the duration of the treatment corresponding to the value of power mode using continuous mode and considering a maximum energy dose of 5400 mJ/cm^2.

Standard Power Mode		**Extended Power Modes**	
Power	Duration	Power	Duration
30 mW/cm^2	3 min 00 sec	30 mW/cm^2	3 min 00 sec
18 mW/cm^2	5 min 00 sec	29 mW/cm^2	3 min 06 sec
9 mW/cm^2	10 min 00 sec	28 mW/cm^2	3 min 13 sec
3 mW/cm^2	30 min 00 sec	27 mW/cm^2	3 min 20 sec
		26 mW/cm^2	3 min 28 sec
		25 mW/cm^2	3 min 36 sec
		24 mW/cm^2	3 min 45 sec
		23 mW/cm^2	3 min 55 sec
		22 mW/cm^2	4 min 05 sec
		21 mW/cm^2	4 min 17 sec
		20 mW/cm^2	4 min 30 sec
		19 mW/cm^2	4 min 44 sec
		18 mW/cm^2	5 min 00 sec
		17 mW/cm^2	5 min 17 sec
		16 mW/cm^2	5 min 38 sec
		15 mW/cm^2	6 min 00 sec
		14 mW/cm^2	6 min 26 sec
		13 mW/cm^2	6 min 55 sec
		12 mW/cm^2	7 min 30 sec
		11 mW/cm^2	8 min 11 sec
		10 mW/cm^2	9 min 00 sec
		9 mW/cm^2	10 min 00 sec
		8 mW/cm^2	11 min 15 sec
		7 mW/cm^2	12 min 52 sec
		6 mW/cm^2	15 min 00 sec
		5 mW/cm^2	18 min 00 sec
		4 mW/cm^2	22 min 30 sec
		3 mW/cm^2	30 min 00 sec

Table 5: Power settings

With selected Lasik modes the duration of treatment will be half compared to continuous treatment modes.
Example:
Treatment time with Continuous Mode 30 mW/cm^2 ➔ 3 min 00 sec
Treatment time with Lasik Mode 30 mW/cm^2 ➔ 1 min 30 sec

With selected interval modes, the duration of treatment becomes longer due to the OFF time.
Example:
Treatment time with Continuous Mode 30 mW/cm^2 ➔ 3 min 00 sec
With Interval Mode (2 sec ON/OFF) at 30 mW/cm^2 ➔ 6 min 00 sec

The duration of the treatment with possible interval settings and total energy dose will be displayed in the screen while selecting the power mode on right hand side below.

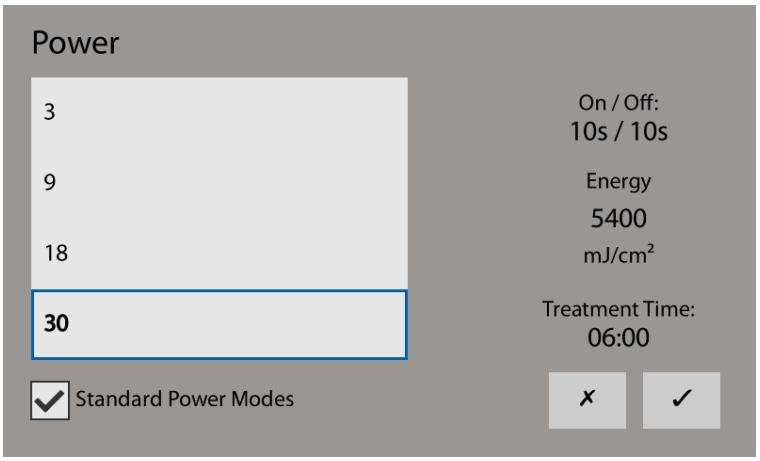


Figure 45: Power mode selection

Once a mode is selected, power and interval ON/OFF time will appear also in the home screen. The eye to be treated can be selected pressing "OD" respectively "OS".

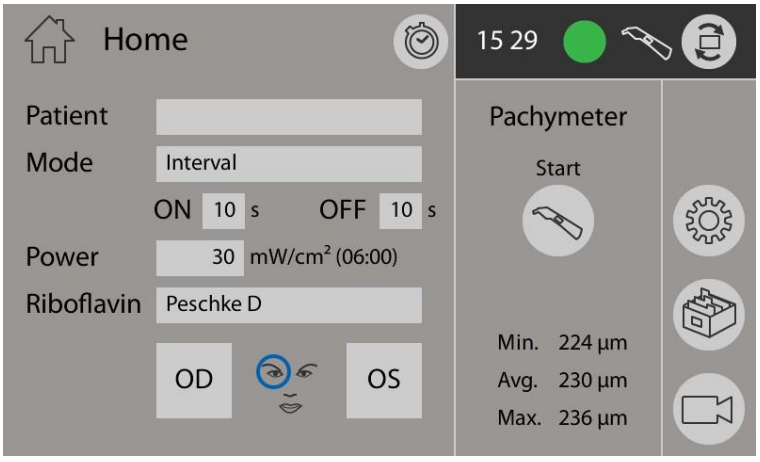


Figure 46: Eye selection

5.8.4 Select Vitamin B2 Solutions

The intended vitamin B2 solution can be chosen by selection.

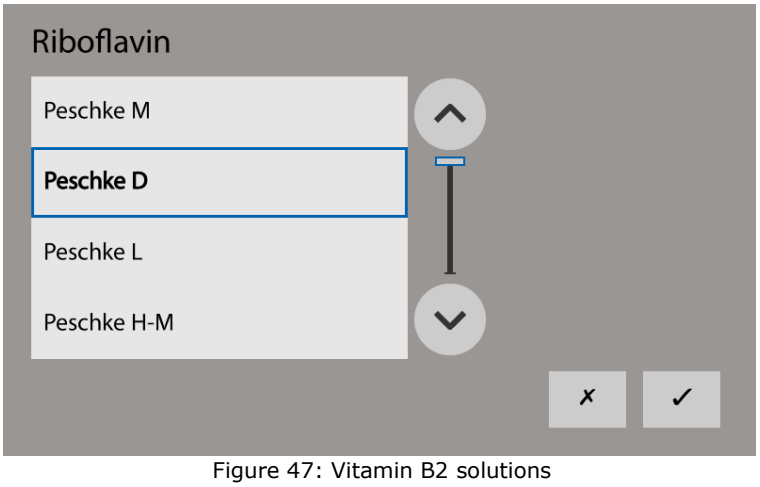


Figure 47: Vitamin B2 solutions

For more information about the vitamin B2 solutions, please contact PESCHKE GmbH.

The auxilary timer which can be selected on home screen can be a help for dispensing the vitamin B2 solution into the patients eye. After interval countdown a short beep sound will be emitted.

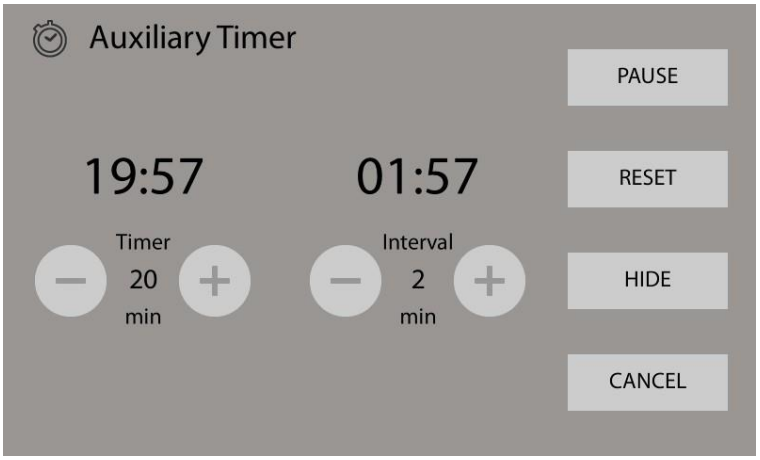


Figure 48: Auxiliary timer

With hidden auxiliary timer window, the active timer will be displayed on the home screen.

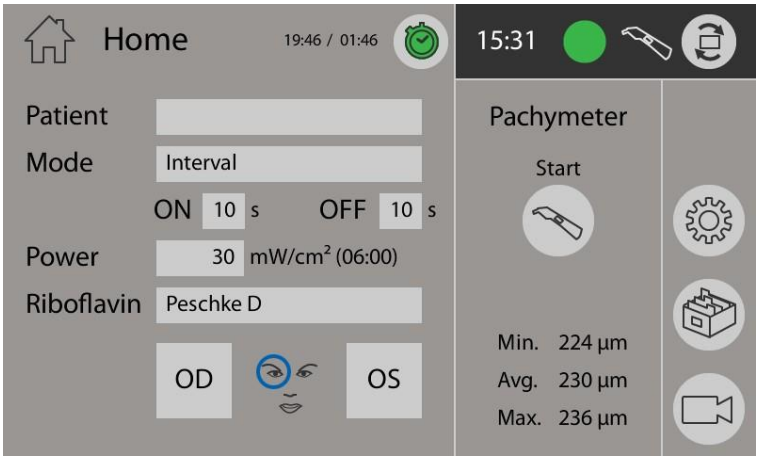


Figure 49: Active auxiliary timer in home screen

5.9 Pachymeter Measurement (optional)

For detailed information about the use of Pachymeter PACHMATE 2 refer to operator's manual of the device.

5.9.1 Proper Applanation for Taking A Measurement

Proper applanation is necessary for obtaining an accurate measurement. Proper applanation occurs when the flat tip of the probe comes into full contact with the cornea perpendicular to the cornea surface. The user must ensure that pressure against the cornea is minimized.

The diagram below illustrates correct and incorrect alignment of the probe tip to the cornea.

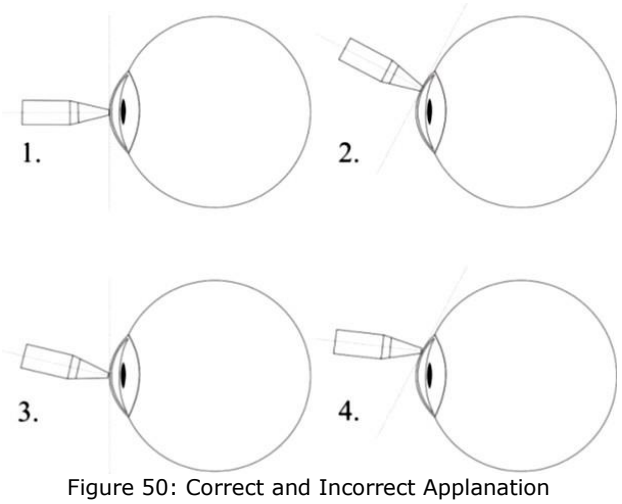


Figure 50: Correct and Incorrect Applanation

1 and 2: CORRECT: The probe IS perpendicular to the corneal surface.
3 and 4: INCORRECT: The probe IS NOT perpendicular to the corneal surface.

While in Measurement Mode, the PACHMATE 2 will automatically take a measurement whenever the tip of the probe is properly applanated to the cornea.

Moving or realigning the probe tip while it is in contact with the cornea or applying pressure while measuring the cornea may cause damage to the cornea. When changing position or alignment of the probe, it is necessary to disengage contact, reorient and then gently re-applanate.

5.9.2 Front View

With paired Pachymeter up to 33 measurements are possible.

Figure 51: Pachymeter PACHMATE 2

Handling of wrong measurements:
Extract of Pachymeter Manual (6.1 Front View)

DEL Key
Used to erase a single measurement from a group of measurements. Also used in conjunction with the "PWR" key to enter the CalBox mode.

CLR Key
This key is used to show the clearing options of the device. The user can clear all measurements, OD measurements, OS measurements, patient information and paired devices. Pressing and holding this key will display the date and time.

CFG Key
Used to enter and exit the configuration mode.

5.9.3 Holding the Device

While handling the device, try to avoid contact with the probe tip (clear plastic cone) so as to avoid contamination. Touching the probe tip with ungloved hands may leave a residue that will cause the device to return an error message when self-testing

Figure 52: Holding Pachymeter

5.9.4 'Check Probe' Error Message

Manual Point	Description
7.3	This message typically indicates an error generated by the probe tip being wet. Dry the tip and cycle the device power off then back on. If drying the tip of the probe does not resolve the error, then the probe may have degraded to the point that it will require replacement. 

Table 6: 'Check Probe' Error Message

5.9.5 'Plug In Probe' Error Message

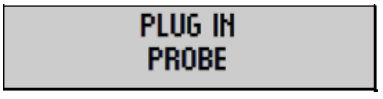
Manual Point	Description
7.4	This message occurs when: (1) the detachable probe is not mated or is improperly mated to the unit, or (2) the probe is defective. If the probe is found to be defective, remove defective probe by holding the probe connector and gently pulling straight out of the unit. 

Table 7: 'Plug In Probe' Error Message

	Do not twist probe as this could damage connectors. Properly align the probe connector and gently push in until properly seated.

5.9.6 Standby Mode

This is when the device is not energizing the probe. The unit automatically goes into Standby Mode if there has been no attempt at measurement for one minute. The device will not be able to detect corneal contact in Standby Mode.

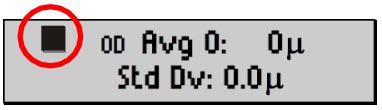
Manual Point	Description
9.2	Standby Mode is indicated by a beep and flashing cursor in the upper left-hand corner of the display. While in Standby Mode, the display will stay on and you will be able to view measurements and access the configuration menu. You will not be able to take a measurement in Standby Mode. 

Table 7: Standby Mode

To exit Standby Mode press the PWR key, this will put the unit back into Measurement Mode. The 1 minute delay can be adjusted from 0.5 to 9.5 minutes by accessing the configuration menu as described in Pachymeter manual section 13.4.1.

5.9.7 Power Up Sequence

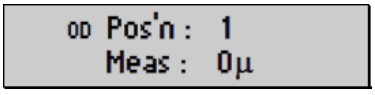
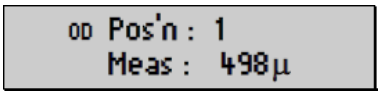
Manual Point	Description
12.1.1	Rotate the probe into the fully open position. It is recommended that the probe be rotated back into the cavity for protection when transporting the PACHMATE 2, or when the unit is not being used.
12.1.2	Turn on the unit.
12.1.3	The PACHMATE 2 performs an internal self-test function.
14.2.4	The unit will briefly display battery status as indicated: 
12.1.5	When the power-up sequence is finished, the device automatically enters Measurement Mode. 
12.1.6	The PACHMATE 2 is now ready to take corneal measurements.

Table 8: Power Up Sequence

5.9.8 Taking Measurements

	For the measurements keep always the eye selection "OD" in the Pachymeter.

	Typically, anesthetizing the patient's eye is necessary for obtaining a measurement.

Manual Point	Description
12.3.1	Perform the Power Up Sequence as described in chapter 5.9.7
12.3.9	Have the patient visualize a fixation point.
12.3.10	Confirm that the device is in Measurement Mode. (The blinking black cursor is not shown in the upper left-hand corner). Described in chapter 5.9.6
12.3.11	Gently position the probe tip on the cornea as described in section 4.4. The PACHMATE 2 will automatically take a single measurement when the probe is properly applanated. ○ For each successful measurement taken the device will emit a quick 'beep'. ○ If the device is not able to obtain a measurement within 3 seconds, the device will emit a long beep and the 'Poor Applanation' message will be displayed.  ○ If the 'Poor Applanation' message is displayed, attempt to reposition the probe tip for proper applanation. Once the probe tip is in proper alignment, the device will continue measurement.
12.3.12	After each successful measurement the device will show the result on the display for a short time (Good Measurement Delay, default 2 seconds).  ○ During this time either wait for two short 'beeps' before re-applanating the probe at the next mapping position or: ○ Re-applanate at the same point to re-measure that mapping position.
12.3.13	The device will emit two short 'beeps' when it is ready to take the measurement at the next mapping position. Reposition the probe and re-applanate at the next position to be mapped.
12.3.14	Continue measuring all positions until all necessary measurements have been taken.

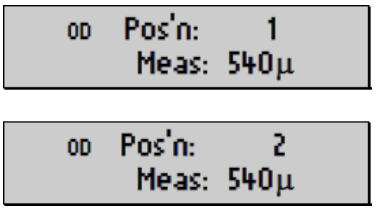
12.3.15	To scroll through each measurement press the ▲ or ▼ key. The device will list the position number and list the thickness measurement below. 
12.3.16	If a questionable measurement is found during review, the operator can delete it. To do this, the operator presses the DEL key while viewing the measurement in question. ○ The operator can take new measurements to replace those that were deleted or choose to accept the remaining measurements.

Table 9: Taking measurements

5.9.9 Pachymeter Measurement Transmission

Open the Pachymeter screen by using the Pachymeter button on the home screen.

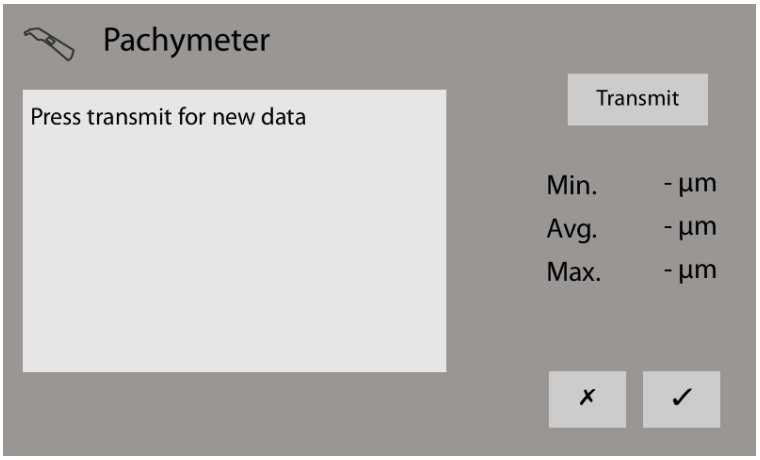


Figure 53: Pachymeter measurement screen

Once the measurements with the Pachymeter are done, press the button "Transmit" to send the measured values to the PXL Platinum 330 device. The minimum, maximum and average thickness will be automatically calculated and shown on the Pachymeter screen.

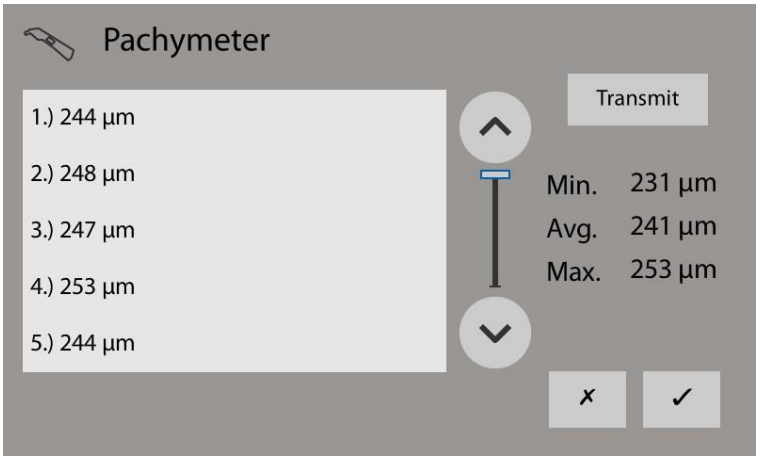


Figure 54: Transmitted Pachymeter measurements

	The Pachmate 2 will display the message ‘Erase Patients Sent?’ Select ‘No’ and make sure that the measurements data in the Pachymeter correspond to the transmitted values in the device. Once compaired the measurements can be cleared as described in chapter 5.9.2.	Erase Patients Sent? ↑=Y ↓=N

A warning window will appear if the measured values are below 400 µm.

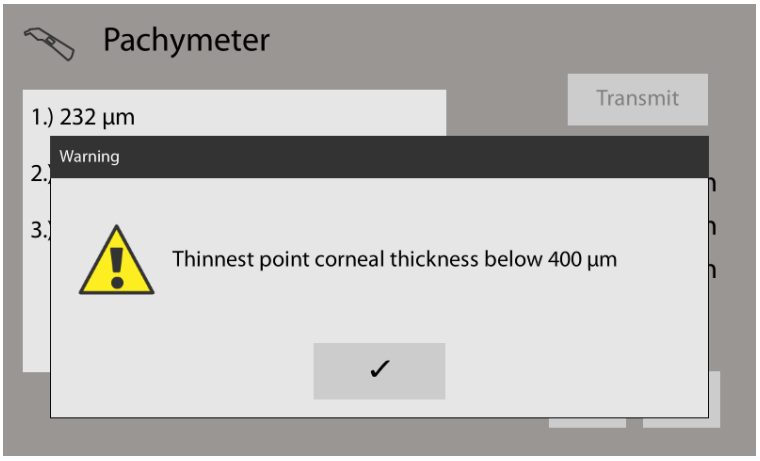


Figure 55: Warning about measurement below 400 µm

For more information about the Pachymeter or the vitamin B2 solutions, please contact PESCHKE GmbH.

5.10 Camera Settings

Pressing the camera button on the home screen, the configuration screen appears.
The aperture for the spot size can be selected from 3 – 12 mm diameter. The diameter appears in the camera picture as a blue circle.

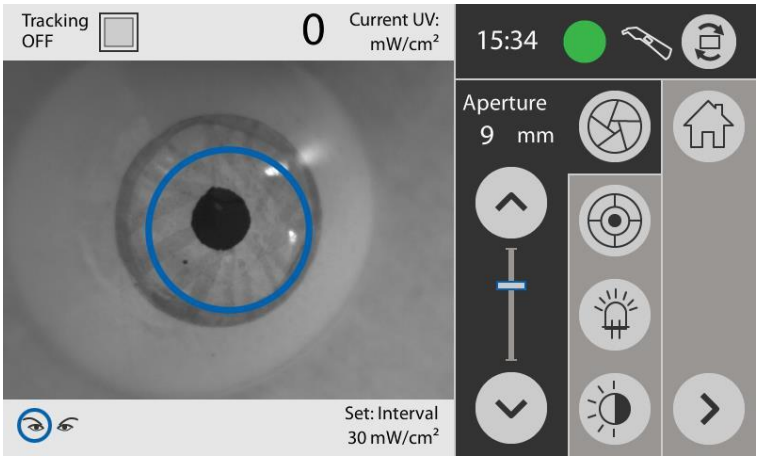


Figure 56: Aperture setting screen

The threshold diameter for eye tracking can be adjusted also from 3 – 12 mm diameter. The diameter appears in the camera picture as a green circle.

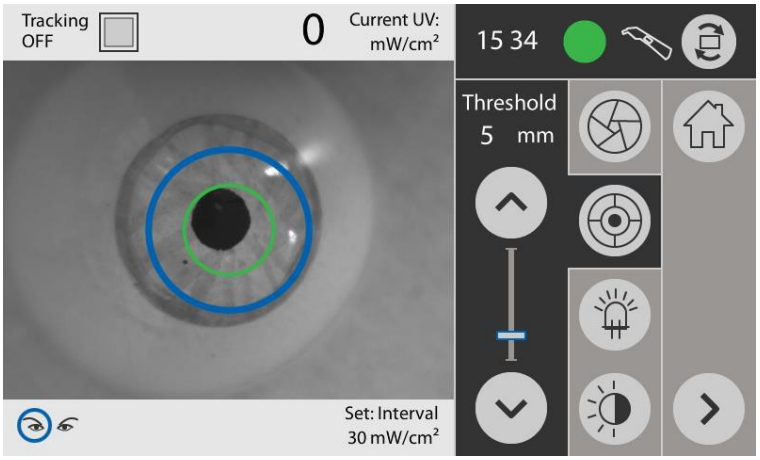


Figure 57: Threshold setting screen

The fixation LED intensity can be changed according to the patients' needs and comfort from 0 – 9.

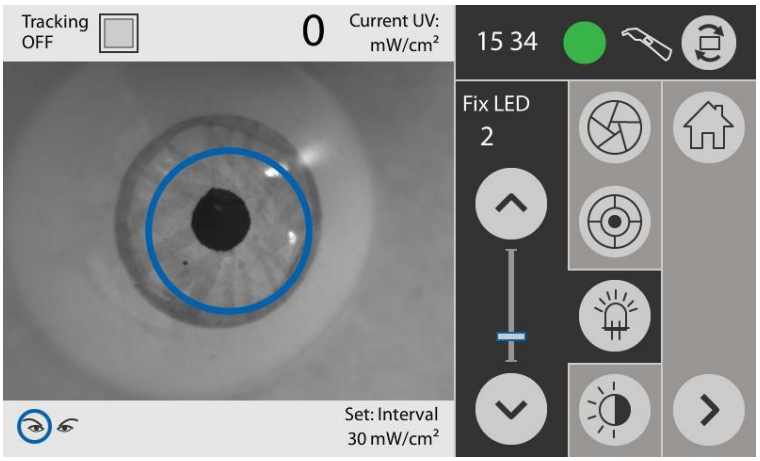


Figure 58: Fix LED setting screen

This selection allows to adjust the brightness of the IR LED's for best view in the camera picture. The brightness can be adjusted from 0 - 9.

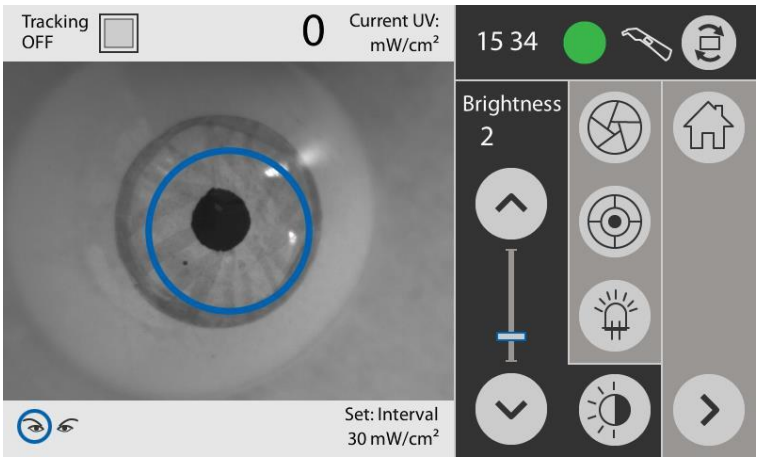


Figure 59: IR-brightness setting screen

After selecting all settings the treatment can be started by pressing the UV-Start button. The yellow LED will be on during the entire treatment.

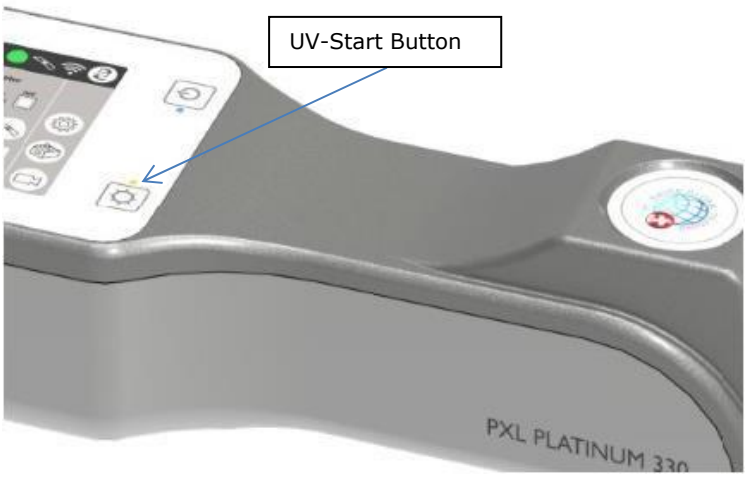


Figure 60: UV-Start button

A pop-up window on the screen shows that the treatment has started. Once the treatment has been initiated, the countdown of the remaining treatment time is running. When the UV light is active, the current power output is displayed on the screen, and the UV status symbol is yellow.

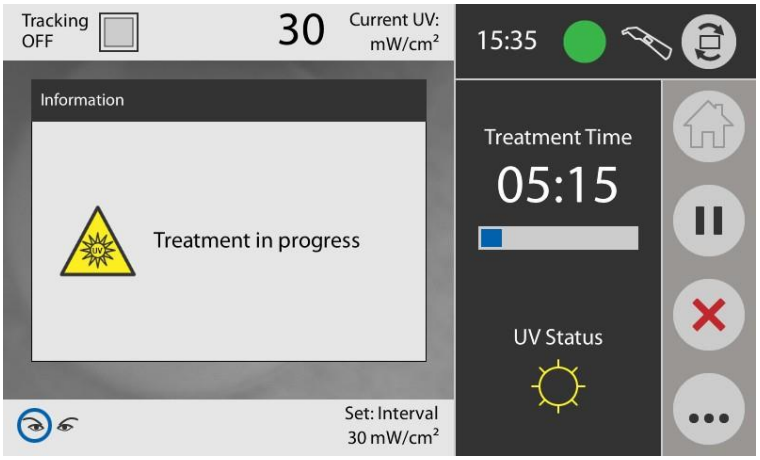


Figure 61: Treatment in progress

The eye tracking mode can be enabled and disabled by using the check-box in the upper left corner on the camera screen.

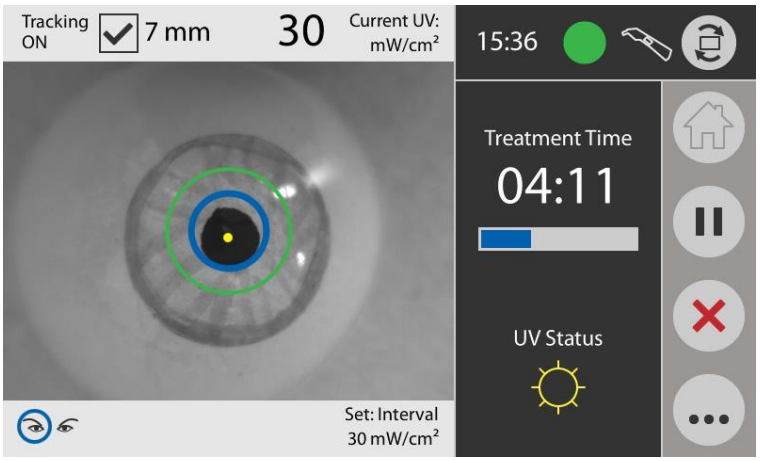


Figure 62: Eye tracking enabled

The UV light emission is interrupted when the eye tracker recognizes that the center of the pupil is outside the tracking zone. In this case a pause symbol is displayed, the treatment timer stops and the illumination break is indicated with a white UV status.

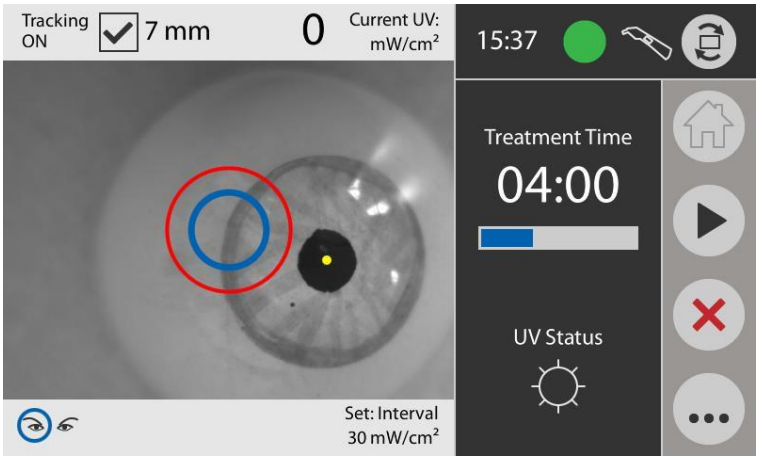


Figure 63: Eye tracking disabled

An information window appears when the treatment is finished. The treatment report can be viewed by selecting the "View Report" button. There is also the possibility to do a Pachymeter measurement after the treatment as long as the device is paired.

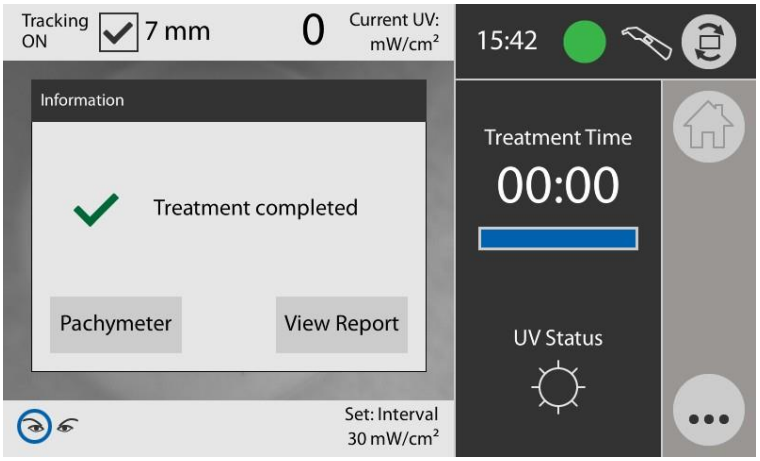


Figure 64: Treatment completed

The active treatment can be stopped any time by using the pause button.

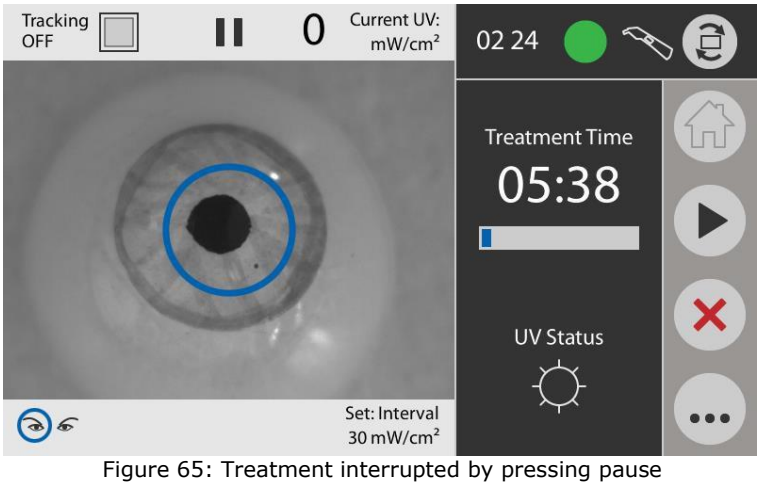


Figure 65: Treatment interrupted by pressing pause

With the stop button the treatment can be aborted completely. A confirmation screen appears.

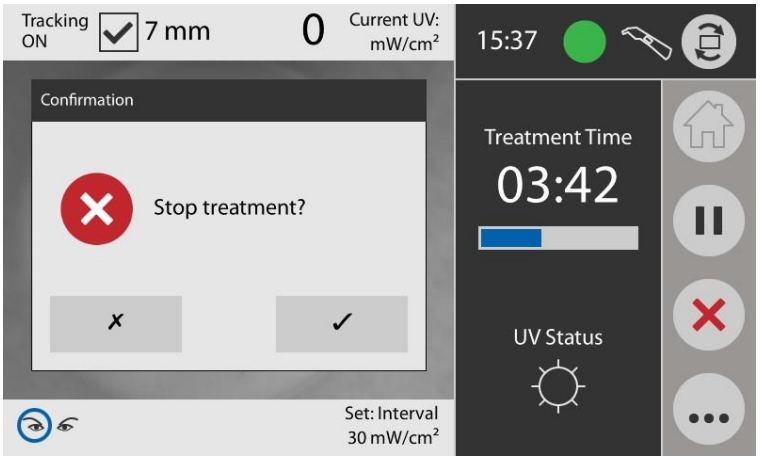


Figure 66: Treatment stop

5.11 Correct Alignment and Positioning of the Eye

The operational distance has to be checked immediately after the start of treatment. As any adjustments only take a few seconds, the treatment can be continued.
The horizontal positioning can be done by sliding and rotating the device on the guide.
The optimal vertical distance is 50 mm from the eye, and then the edge of the beam spot is sharply reproduced on the eye. The adjustment can be done with the upper rotary knob on the vertical rod of the table mount. For correct alignment see also point 5.2 (Installation of the table mount and device).

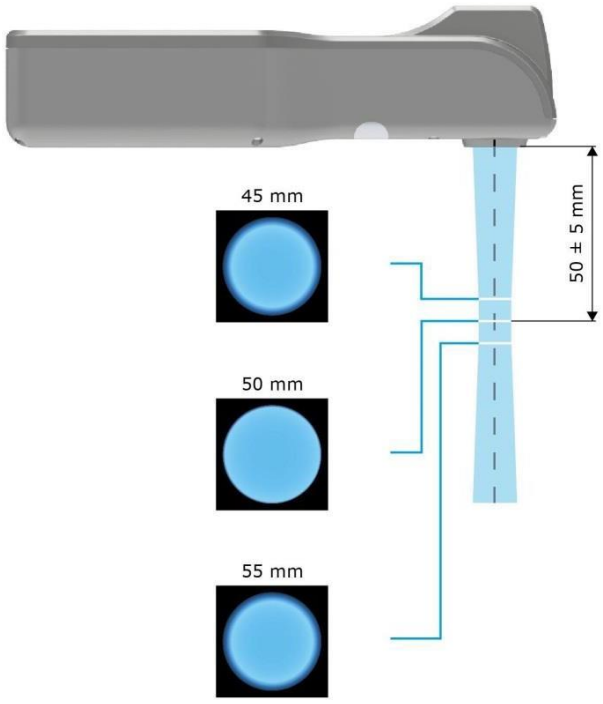


Figure 67: Distance of device to the eye

5.12 Report Viewer

When the treatment has finished or even if the treatment has been aborted with the stop button, the report viewer appears automatically and must be checked and compared with the configured settings. The complete treatment report is saved in the reports folder in the system.

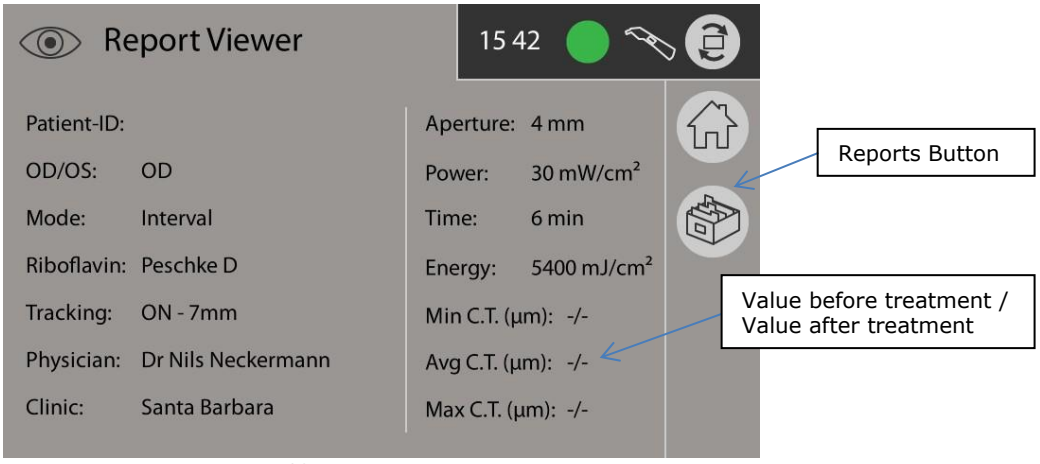


Figure 68: Report viewer screen

5.13 Reports

All reports are automatically stored in the report folder, newest reports appear on top of the list.

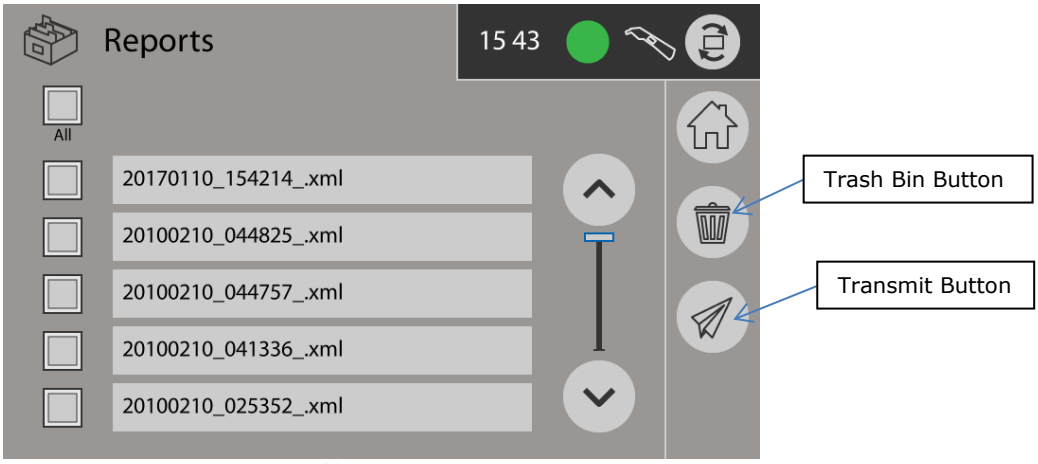


Figure 69: Reports screen

Report file name consists of the treatment date, time and patient name or ID (Format: YYYYMMDD_hhmmss_ID).

5.14 Transmit Reports

The pdf reports can be sent by selecting the corresponding check-box and pressing the transmit button.

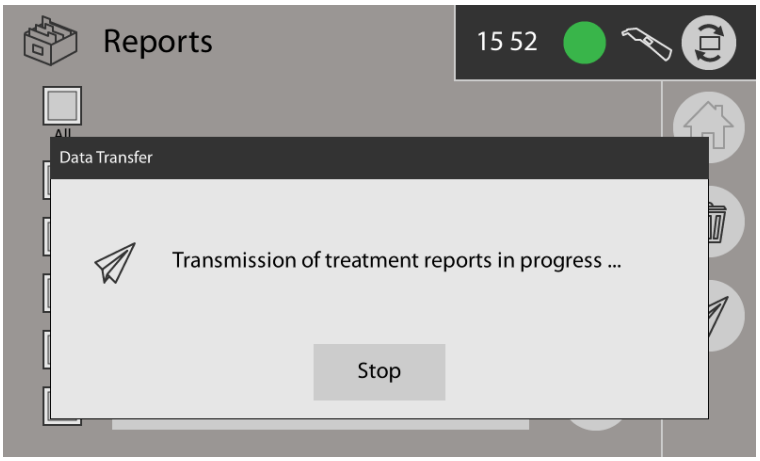


Figure 70: Information for transmit the data to computer

The software and instructions for transmitting the data of the device to a computer is available on the provided USB Stick.

The reports can only be permanently deleted in the PXL Platinum 330 device.

If there are more than 100 reports saved in the system, a warning screen will appear with the information to delete some of them.

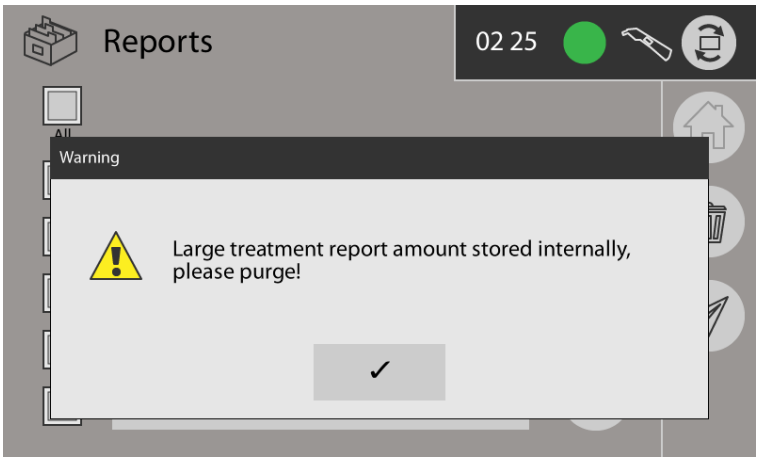


Figure 71: Warning for more than 100 reports saved

Use check-box and trash bin button to delete. Each deletion has to be confirmed.

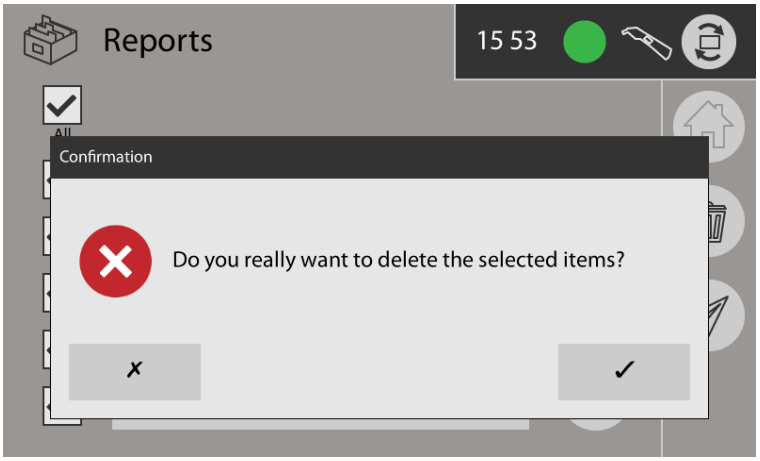


Figure 72: Warning for deleting the reports

5.15 Switch Off Device

The device can be switched off by pressing and holding the ON/OFF button for at least 2 seconds. Shutdown has to be confirmed.

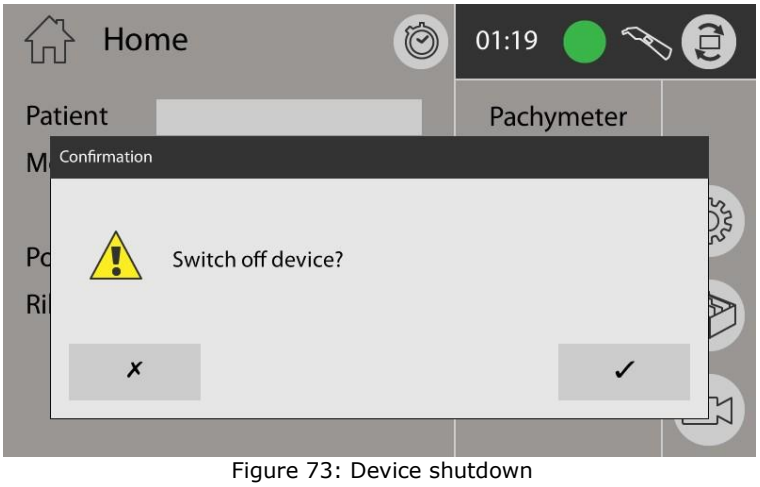


Figure 73: Device shutdown

5.16 Status

When the green status button is pressed, general device information and possible log messages are displayed.
In this screen the display brightness can be adjusted using the corresponding plus and minus buttons on the top of the screen.

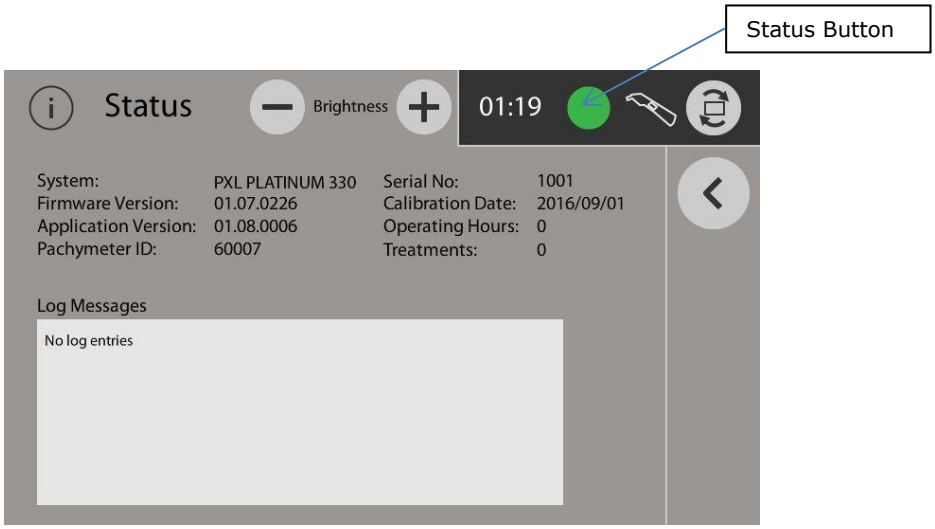


Figure 74: Status screen

6 Troubleshooting Guide

6.1 PXL Platinum 330

Problem / Error Message	Potential Cause	Solution
Blue LED at ON/OFF button stays dark after connection to power supply	Connection to power supply is not correct	Check connection
	Power adapter defect	Check power adapter
	Power adapter plug not inserted correctly	Check power adapter plug
	Device defect	Please contact Peschke for repair
No start of emission after pressing „Start/Stop"-Button	Keystroke was too short	Repeat pressing „Start/Stop" button
Device shows warning "Device temperature out of range! Device needs to be acclimatized"	Device temperature out of range	Device needs to be acclimatized
Device shows message "Device calibration required"	Calibration of device is due	Please contact Peschke for calibration
Power supply was interrupted	Electricity interruption	Restart the treatment by pressing the Start / Stop button at unchanged energy setting. NOTE: New treatment duration must be defined and monitored by the physician, as the treatment timer re-starts. Stop the treatment manually after the end of the new treatment duration. The total treatment time (Table 5: Power Setting) must not be exceeded!
Actual UV-Value shows values +10% or -10% of set value	Device out of calibration	Please contact Peschke for calibration
Device shows error message "Device energy test failure"	Device temperature out of range	The device should be switched on without starting a treatment. After 15 minutes the device has warmed up and should be able to be operated normally.
	The self-test of the internal energy monitoring failed.	Please contact Peschke for repair
Device shows error message with title "Internal Error"	Internal error detected	Please contact Peschke for repair
Spot size varies without operator interaction	Device defect	Please contact Peschke for repair

Table 10: Troubleshooting guide PXL Platinum 330

6.2 Pachymeter

Problem / Error Message	Potential Cause	Solution
'Plug In Probe' Message on screen	The detachable probe is not mated or is improperly mated to the unit	If the probe is found to be defective, remove defective probe by holding the probe connector and gently pulling straight out of the unit.
	The probe is defective	
'Check Probe' message on start up	Probe is wet or has a residue on it	Dry probe
'PQF Failed' Error Message	This message usually indicates a hardware failure occurred within the unit	The unit must be returned for repair.

Table 11: Troubleshooting guide Pachymeter

Decentralized Eye Tracking (optional)

The decentralized eye tracking mode can be enabled before a treatment is started or while a treatment is paused.

The decentralized eye tracking mode can be enabled in the configuration screen.
The eye must be positioned so that the blue circle on the camera picture covers the area to be treated.

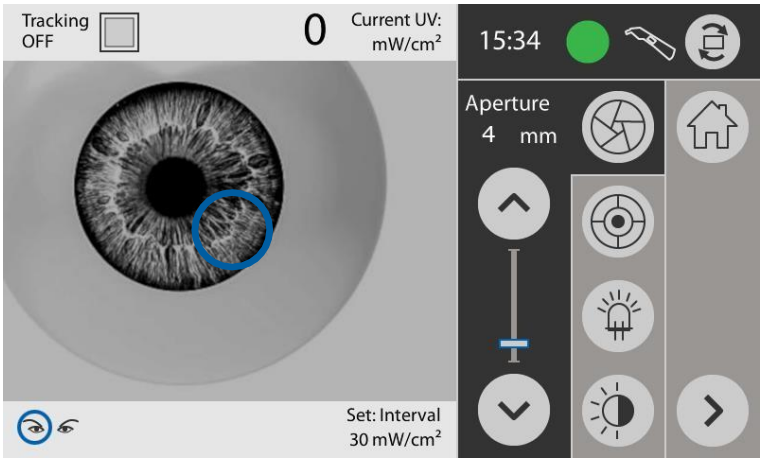


Figure 1: Decentrally positioned patient eye

The eye tracking mode must be enabled by using the check-box in the upper left corner on the camera screen.

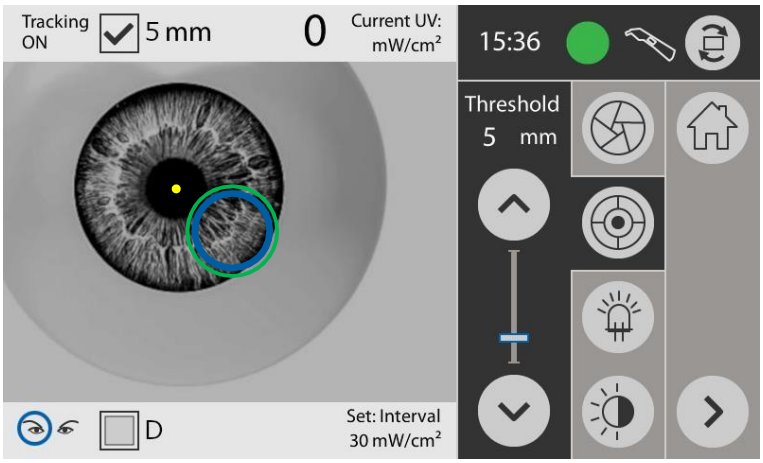


Figure 2: Eye tracking enabled

The decentralized eye tracking mode must be enabled by using the check-box "D" in the lower left corner on the camera screen.
The moment the check-box "D" is enabled, the eye centre is registered as the new tracking centre and the green threshold diameter appears decentraly in the camera picture.

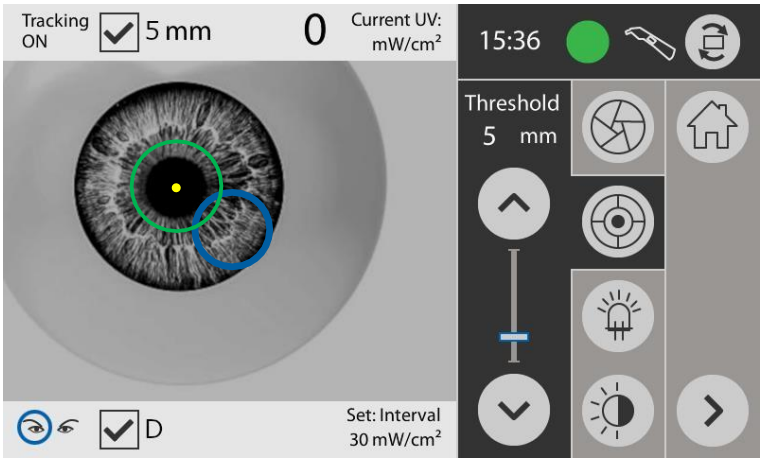


Figure 3: Decentral eye tracking enabled

All treatment parameters can now be changed if necessary, before a decentralized treatment is started. For correct settings see also point 5.10 (Camera Settings).

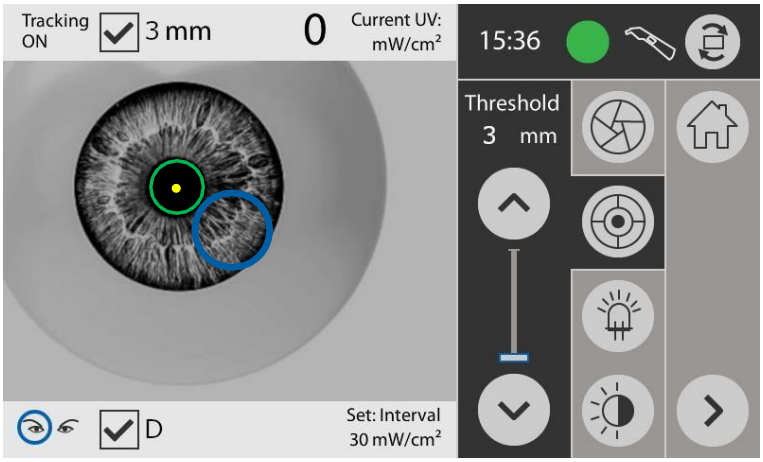


Figure 4: Threshold setting screen

The tracking centre is reset to the centralized position when the configuration screen is left or when a treatment is completed or aborted.

7 Care and Maintenance

Avoid direct contact with the beam exit optics.
Do not flush the device with cleaning liquids to avoid damage from penetration of the liquid into the device.
Do not use aggressive cleaning agents like acetone.

A wipe disinfection should be performed regularly. Use abrasion resistant cloth, moisten it with a disinfectant like Bacillol, and wipe the surface gently.

8 Calibration and Service

The UV illumination system PXL Platinum 330 contains electronic and optical components that are subject to aging. To ensure proper energy delivery, a bi-yearly calibration and service is recommended.

8.1 Repairs and Customer Support

WARNING: Do not modify or attempt to repair this equipment.

WARNING: ELECTRICAL SHOCK HAZARD. Do not open the unit.

Should service be necessary, contact the customer service department at

Peschke GmbH,
Boesch 67,
6331 Huenenberg,
Switzerland
Tel: +41 41 552 47 00
Fax: +41 41 552 47 08
Email: info@peschkeswiss.com

Please clean the device with disinfecting wipes before return.

9 Disposal Information

According to local laws and regulations your product should be disposed of separately from household waste.

10 Technical Data

Parameter	Specification
Wavelength	365 ± 5 nm
Width of spectrum (fwhm)	9 nm
Power density	Depending on energy settings: 3,0 ± 0,3 mW/cm^2 9,0 ± 0,9 mW/cm^2 18,0 ± 1,8 mW/cm^2 30,0 ± 3,0 mW/cm^2
Maximum UV power	30 mW
Mode	Continuous, interval or pulsed wave
Timer	Depending on energy settings: 30 minutes at 3 mW/cm^2 10 minutes at 9 mW/cm^2 5 minutes at 18 mW/cm^2 3 minutes at 30 mW/cm^2
Treatment distance	50 ± 5 mm
Beam diameter in application area	3 – 12 mm
Power input	30 VA
Operating conditions	18 – 28 °C Max. 70% rel. humidity, non-condensing Max. 3000 m
Storage conditions	18 – 28 °C Max. 70% rel. humidity, non-condensing
Transport conditions	-10 – 50°C < 80% rel. humidity
Power supply	EDAC Model no.: EM1024HR Input: 100–240 Vac; 50–60 Hz; 1.0–0,5 A Output: +12V DC center positive; 2,5 A Cable: 1.8m
Dimension (L x B x H)	Case: 46 x 36 x 16 cm
Weight	< 9 kg incl. packaging
EMV	Professional healthcare facility environment according to EN 60601-1-2:2014 4th Edition CISPR 11, EN 55011 Class B
RF Module	Bluetooth V4.0+EDR Frequency Range: 2402~2480 MHz Output power: 3 mW
Safety	Protection class II, EN 60601-1
Medical device class	IIa according to 93/42/EWG

Table 12: Technical data of device

10.1 Warranty

PESCHKE GmbH warrants each new PXL Platinum 330 and its accompanying accessories (hereinafter called "Equipment") to be free from defects in material and workmanship for two (2) years from the date of delivery to the original purchaser. This warranty is not applicable to any defect that is the result of an accident, misuse, mishandling, neglect, improper installation, improper repair or improper modification by persons other than the manufacturer. This warranty does not apply if the equipment has not been operated and maintained in accordance with the operating and maintenance manuals and instructions or bulletins issued in respect thereof by the manufacturer. It is further understood that the cost of servicing replaceable and expandable items including parts and labor made in connection with the routine maintenance services as described in the operator's manual is not covered under this warranty and is the responsibility of the purchaser. This warranty is strictly limited to replacement or repair of the part that is found to be defective in material and workmanship.

PESCHKE GmbH reserves the right to make changes in the design and material of equipment without incurring any obligations to incorporate such changes in equipment already completed on the effective date of any such change or changes.

This is the only warranty of this product and is expressly in lieu of all other warranties, expressed or implied by law or otherwise, including any implied warranties of merchantability and of fitness for a particular purpose. Without regard to the alleged defect, PESCHKE GmbH does not, under any circumstances, assume any responsibility for the loss of time, inconvenience or other consequential damages, including but not limited to, loss or damage of personal property, or loss of revenue.

11 Regulatory Compliance

The PXL Platinum 330 is EMC-tested in conformity with the requirements of IEC 60601-1-2:2007 3th and IEC 60601-1-2:2014 4th Edition (according clause 7 and 8.9, tables 4 to 9). The PXL Platinum 330 is a medical device that requires special safety precautions and must be installed and placed in operation in accordance with the attached EMC information.

Guidance and manufacturer's declaration – electromagnetic emissions		
The PXL Platinum 330 is intended for use in the electromagnetic environment specified below. The customer or the user of the PXL Platinum 330 should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 1	The PXL Platinum 330 uses RF energy for its internal function. Additionally the EUT contains a Radio Bluetooth module, which complies with the national regulations. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. However, a separation distance of 30 cm shall be maintained.
RF emissions CISPR 11	Class B	The PXL Platinum 330 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Table 13: Emission table for IEC 60601-1-2 3th and 4th edition

The following tables are guidelines according to the 3th edition of the medical standard IEC 60601-1-2.

Guidance and manufacturer's declaration – electromagnetic immunity			
The PXL Platinum 330 is intended for use in the electromagnetic environment specified below. The customer or the user of PXL Platinum 330 should assure that it is used in such an environment.			
Immunity test standard	**IEC 60601 test level**	**Compliance level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±8 kV contact ±15 kV air	/
Electrical fast transient / burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines	Mean power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line	±1 kV line to line	Mean power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	<5% U_T (0,5 cycle) 40% U_T (5 cycles) 70% U_T (25 cycles) <5% U_T for 5 s	<5% U_T (0,5 cycle) 40% U_T (5 cycles) 70% U_T (25 cycles) <5% U_T for 5 s	Mean power quality should be that of a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	100 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity			
The PXL Platinum 330 is intended for use in the electromagnetic environment specified below. The customer or the user of the PXL Platinum 330 should assure that it is used in such an environment.			
Immunity test standard	**IEC 60601 test level**	**Compliance level**	**Recommended separation distance** [c]
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	10 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the PXL Platinum 330, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 0.35\sqrt{P}$ 150 kHz to 80 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m 80 MHz to 3.0 GHz	$d = 0.35\sqrt{P}$ 80 MHz to 800 MHz $d = 0.7\sqrt{P}$ 800 MHz bis 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PXL Platinum 330 is used exceeds the applicable RF compliance level above, the PXL Platinum 330 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the PXL Platinum 330 b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than **3 V/m**.			

Table 14: Immunity

Recommended separation distances between portable and mobile RF communications equipment and the PXL Platinum 330

The PXL Platinum 330 is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PXL Platinum 330 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PXL Platinum 330 as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 0.35\sqrt{P}$	80 MHz to 800 MHz $d = 0.35\sqrt{P}$	800 MHz to 2500 MHz $d = 0.7\sqrt{P}$
0.01	0.04 m	0.04 m	0.07 m
0.1	0.11 m	0.11 m	0.22 m
1	0.35 m	0.35 m	0.7 m
10	1.1 m	1.1 m	2.2 m
100	3.5 m	3.5 m	7 m

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Note 3: An additional factor of 10/3 is used in calculating the recommended separation distance to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

Table 15: Recommended Separation Distances

12 Forms and Templates

Please make a copy of the following forms in order to use.

12.1 Documentation of Repair and Maintenance

Documentation of Repair and Maintenance

Serial number: _____

Date	Maintenance	Repair	Comment	Name/Signature
	☐	☐		
	☐	☐		
	☐	☐		
	☐	☐		
	☐	☐		
	☐	☐		
	☐	☐		
	☐	☐		
	☐	☐		
	☐	☐		

Please use a copy!

12.2 Information on Incidents

Information on Incidents Occurring after Marketing

According to 93/42/EWG article 10 all incidents with medical devices have to be reported. Any occurrence, problem or change in performance or output, which causes death or injury at the patient, has to be reported.

Date: _____

Serial number: _____

Occurrence; failure description, potential hazard:

_____

_____

_____

_____

_____

_____

_____

_____

_____

Clinic: _____

Reported through name / signature: _____

Send to: **Peschke GmbH**,
Boesch 67,
6331 Huenenberg,
Switzerland
Tel: +41 41 552 47 00
Fax: +41 41 552 47 08
Email: info@peschkeswiss.com

Please use a copy!