AXIalis

PRECISION AT YOUR FINGERTIPS

Quantel medical
BY LUMIBIRD MEDICAL

Biometry and pachymetry

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E-mail: contact@lumibirdmedical.com Web site: www.lumibirdmedical.com

2024 CE 0459
Regulation (EU) 2017/745

Any questions about the installation, operation, use or maintenance of this device, please contact the QUANTEL MEDICAL after-sales service or your local distributor.

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Representative Offices

Thailand, Chiang Mai
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QUANTEL MEDICAL
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AXIalis® User Manual
Software Version 1.0.1 and over
International version
(Ref: ME00432C)
September 27, 2024

INTRODUCTION

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1. INTRODUCTION

The AXIALIS® is an ultrasonic echography system intended to be used for biometry purposes using ocular A-scan biometry. This Ophthalmic Ultrasound System and the probes that are used with it are indicated for:

- Measurement of different parameters including biometry and other (related to classify different types of pathologies)
- Using data obtained by biometry and manage it by the included formulas, is possible to calculate the intraocular lens power to be used during cataract surgery.

The AXIALIS Ophthalmic Ultrasound System and the probes that are used with it are indicated for diagnostic imaging and biometric measurement of the eye including:

- Axial Length measurement of the eye by ultrasonic means.
- Implanted IOL power calculation, using the Axial Length measurement.
- Measurement of corneal thickness by ultrasonic means.

The AXIALIS® Ophthalmic Ultrasound System is a user-friendly system that includes a touchscreen for user interface. All image acquisition is controlled via the touch-screen.

Setup of the AXIALIS® is simple. Built on a PC board, the software is ready to use.

The device can be delivered with the following configurations:

- AXIALIS® Ophthalmic Ultrasound System A: with Biometry A probe only
- AXIALIS® Ophthalmic Ultrasound System LA: with ProBeam A probe only

An optional pachymetry probe can be delivered with all configurations.

2. USER MANUAL DESCRIPTION

The user manual is organized into the following chapters:

3. TERMS AND SYMBOLS

This manual uses symbols and terms that draw the attention of the reader to additional security information.
Their signification is described below:

WARNING

Potential hazards which, if not avoided, could result in serious injury or death

CAUTION

Potential hazards which, if not avoided, could result in minor or moderate injury and/or product damage

NOTE

Significant additional information or explanation.

4. UNPACKING THE INSTRUMENT

The instrument is delivered in a special shockproof casing. If the instrument has been subjected to low temperature during transportation, it should not be turned on immediately after unpacking.

WARNING:

If the instrument is at a temperature below 10°C (50°F): 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.

5. PACKING LIST

5.1. PACKING LIST: BASIC CONFIGURATIONS

Before beginning the installation, check the contents of the package against the following list:

Configuration code	Probes included	Other accessories
PCBX0066A	Biometry A-probe	• AXIALIS® ultrasound device • Power supply block and cable • Footswitch • Test block for biometry probe • Mouse and mouse pad • Documentation
PCBX0066LA	ProBeam A-probe (Probe with Laser Aiming Beam)	

5.2. OTHER ITEMS

Other items may be sold independently from the device packing list configurations such as:

5.2.1. ARTICLES

Configuration code	Description
PCEX0011	Pachymetry option including: pachymetry probe, keycode, pachymetry probe holder and an Allen key to fix the probe holder
XEAX2PRBBIO	Biometry Probe
XEPRBBIOL	Biometry Probe with Laser Aiming Beam
XEAAACOQPRAEG15	15mm Prager shell for biometry (accessory)
XEAAACOQPRAEG17	17mm Prager shell for biometry (accessory)

5.2.2. OTHER ARTICLES

Configuration code	Description
PCEX0012	DICOM option
XEAAAPAM	Biometry probe hand piece
RP160027	USB Laser Printer
XEIMPUSBSONY	USB Video Printer

I – REGULATORY & SAFETY INFORMATION

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CONTENTS rev. 27/09/2024

1. INTENDED USE

1.1. INTENDED PURPOSE

The Axialis® is an ultrasound system intended to be used for biometry purposes using ocular A-scan biometry.

1.2. INDICATIONS FOR USE

- Measurement of different parameters including biometry and other (related to classify different types of pathologies)
- Using data obtained by biometry and manage it by the included formulas, is possible to calculate the intraocular lens power to be used during cataract surgery

1.3. CONTRAINDICATIONS

There are no absolute contraindications to the use of the Axialis for ultrasound examination of the eye.

Be cautious when exercising on patients with active ocular infections, ocular trauma or recent surgery.

1.4. ADVERSE EFFECTS

Ophthalmic ultrasound is a safe procedure with no major side effects. However, on rare occasions, the following side effects may occur:

- Discomfort
- Eye irritation
- Eye infection

1.5. INTENDED USERS

This device is intended to be used in health institutions by:

- Ophthalmologists.
- Ophthalmic technicians.
- Any other healthcare professional trained in the use of medical ultrasound in ophthalmology

1.6. TARGETED POPULATION

The patient population includes people of any age, sex or ethnic origin, where a measure of the internal structures of the eye is required. The device is not intended for fetal use.

NOTE: QUANTEL MEDICAL is not aware of any report of adverse effects from using ophthalmologic ultrasound systems.

2. SAFETY INFORMATION AND PRECAUTIONS

2.1. GENERAL WARNINGS AND SAFETY INFORMATION

Tissue exposure to ultrasound energy:
AXIALIS® OPHTHALMIC ULTRASOUND SYSTEM unit is designed for use in ophthalmology only. The system controls limit the output energy to within the parameters specified for its intended purpose. No control of ultrasound energy is available to the user other than the duration of exposure. The system controls limit the energy to the specified values for its use.

WARNINGS

- This device is not intended for foetal use.
- This device is not intended to operate with an ultrasonic (HF) chirurgical device.
- Disconnect AC power before cleaning the case.
- AC power should be disconnected every time after turning the system OFF
- While using the unit, mains plug must be easily accessible.
- The AXIALIS® OPHTHALMIC ULTRASOUND SYSTEM IOL calculator will calculate negative IOL values if such is predicted by the entered data. These are displayed with a minus sign (-). Do not ignore this sign!
- Be careful not to compress the cornea when measuring axial length.
- No modification of this equipment is allowed.
- Before adding any other equipment to the basic configuration, please refer to the:
  AXIALIS® User Manual: Chapter II - Technical information
  Section – Installation: technical information
- Do not modify the equipment without authorization of the manufacturer.
- In case the equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.
- Only connect Medical Electrical Equipment which has been specified as some parts of the equipment or as compatible with the equipment.
- The AXIALIS® OPHTHALMIC ULTRASOUND SYSTEM has to be disconnected from the telecom, IT network and/or USB accessories during examination.
- Only use a network device or USB accessories that comply with IEC 60601-1 and IEC 60950 standards.
- When new equipment (not delivered by QUANTEL MEDICAL) is connected to the equipment (via USB, network...), the leakage current measurements and checks have to be performed by the responsible organization with the new equipment installation: clause 16 IEC 60601-1 third edition.
- Connect only power supply module provided by QUANTEL MEDICAL.
- To avoid the electrical choc risk, the device must be only connected to a grounded power supply.
- Do not use flammable anesthetics product.
- Do not use in oxygen rich atmosphere.
- Some persons are extremely allergic to isopropyl alcohol.
- Should a malfunction occur, that could lead to an adverse event, inform QUANTEL MEDICAL as soon as possible at the following email address: materiovigilance@quantelmedical.fr or fax the incident report to **+33 (0) 473 745 700**. In case of an adverse event, severe or not severe, involving one (or more) human being(s), inform QUANTEL MEDICAL as soon as possible at the following email address: materiovigilance@quantelmedical.fr or fax the incident report to **+33 (0) 473 745 700**. If none of the possibilities for contacting QUANTEL MEDICAL are suitable for your system, contact the legal representative of QUANTEL MEDICAL who sold you the device.

CAUTIONS

- Federal law restricts this device to sale by or on the order of a physician.
- Considering the current concern for possible unknown hazards, and despite the extremely low output intensities used in ultrasound biometry, QUANTEL MEDICAL recommends that patient exposure time during measurement be minimized.
- To preserve the finish of the case, avoid the use of abrasive cleaners. If possible, clean spots before they dry.
- Do not install non QUANTEL MEDICAL software onto the unit, as it may compromise the AXIALIS® OPHTHALMIC ULTRASOUND SYSTEM software. Installing non QUANTEL MEDICAL software will cause the warranty to be void. QUANTEL MEDICAL is not responsible for any errors caused by additional programs on the unit's hard drive.
- Do not connect the unit to the Internet. The AXIALIS® OPHTHALMIC ULTRASOUND SYSTEM does not have antivirus protection. Connecting the unit to the Internet will cause the warranty to be void. QUANTEL MEDICAL is not responsible for any errors caused by connecting the AXIALIS® OPHTHALMIC ULTRASOUND SYSTEM to the Internet.
- The installation of an antivirus may use computer resources that are necessary to the normal functioning of the AXIALIS® OPHTHALMIC ULTRASOUND SYSTEM unit and thus reduce the system performances. The image acquisition in real time by the AXIALIS® OPHTHALMIC ULTRASOUND SYSTEM might be altered: risk of delays, saccades, image interruption… It is up to the person who would install this type of software to set the appropriate parameters and validate that the software does not disrupt the normal functioning of the AXIALIS® OPHTHALMIC ULTRASOUND SYSTEM (especially concerning the image acquisition).
- When cleaning the screen: the device must be switched off and no abrasive cleaner should be used.

2.2. ESSENTIAL PERFORMANCES

According to the risk analysis table, the essential performances identified for the device are the following:

Essential performance
Display of correct, non-ambiguous numerical values, clearly identifiable and in known units of measurement
Non-excessive or purely intentional surface temperature generation
Continuous display of correct values
Energy delivery adapted to the intended use and not excessive
Non-excessive or purely intentional acoustic pressure
Display of correct values, images and waveforms in an electromagnetic environment

2.3. PROBES CARE / WARNINGS AND CAUTIONS

WARNING

- If you notice a change in the probe efficiency or have any doubt about the probe integrity: contact QUANTEL MEDICAL Service Department or your local distributor.

CAUTIONS

- The probes are fragile and must be handled with care. They will be damaged if dropped onto a hard surface.
- The probes should never be autoclaved or subjected to excessive heat.
- The ultrasound unit must be imperatively turned off before disconnecting the probes. Avoid splashing liquids onto the probe connectors.
- Do not immerse the connector.

3. CLEANING AND DISINFECTION PROCEDURE

The cleaning and disinfection of the ultrasound medical device, probes and accessories before and after use, is described in the Quantel Medical procedure “PR00172”. Before and after the use of the device refer to the procedure “PR00172” for cleaning and disinfection.

NOTE

This document is available in electronic format (PDF) on the desktop of the AXIALIS® OPHTHALMIC ULTRASOUND SYSTEM: "Quantel Medical_eManual" directory.

WARNING Carefully read these warnings about cleaning and disinfection instructions:

- The parts of device in contact with the patients and the users must be cleaned and disinfected for each patient to prevent the transmission of infection;
- The parts of device in contact with the patients and the users must also be cleaned before and after use;
- If the device is used in the operating room, all the surfaces of the device should be cleaned and disinfected before and after use. The internal hospital procedures should also be followed regarding the cleaning and disinfection of electromedical devices when they are used in the operating room;
- The device must be cleaned and disinfected after each maintenance (the routine cleaning for the maintenance of parts which are not described in the Quantel Medical procedure “PR00172”;
- Ensure that the ultrasound system is switched off, and then disconnect the power supply before cleaning and disinfection the device.

RESPONSIBILITY

The medical department where the device is used must:

- Follow Quantel Medical’s procedure “PR00172” for cleaning and disinfection of ultrasound medical devices before and after use;
- Train appropriately the staff who carry out the cleaning and disinfection;
- Ensure that the methods of disinfection used in departmental cleaning routines are compatible with those used for the device.
- Ensure that the entire system is routinely cleaned and disinfected.

4. BIOLOGICAL EVALUATION, REACH AND ROHS COMPLIANCE

QUANTEL MEDICAL is committed to providing safe products consistent with the improvement and protection of human health and the environment through improved and earlier identification of chemical substances.
Biological evaluation is done of the materials that come into direct contact with the human body and which are used in the fabrication of QUANTEL MEDICAL devices.
REACH compliance of chemical materials (mixtures for onwards sale, articles, materials into direct contact with the human body) used in the fabrication of QUANTEL MEDICAL devices is updated frequently in order to improve the protection of human health and the environment from the risks related to chemicals.
RoHS compliance of electrical and electronic equipment (EEE) used in the fabrication of QUANTEL MEDICAL devices is evaluated in view of contributing to the protection of human health and the environment, including the environmentally disposal of waste EEE.

4.1. PRECAUTIONS TO TAKE CONCERNING WASTES AND ELIMINATION OF DEVICE AND ACCESSORIES

This product complies with the WEEE Directive (2012/19/EU) marking requirements. The AXIALIS® OPHTHALMIC ULTRASOUND SYSTEM is an electrical / electronic product and must not be discarded with 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 completely of the device and its accessories, please contact QUANTEL MEDICAL at contact@lumibirdmedical.com

5. HIPAA COMLIANCE

The Health Insurance Portability and Accountability Act (HIPAA) regulations include elements that focus on securing medical records in order to ensure patient privacy. QUANTEL MEDICAL has implemented the following technical measures to be compliant with the HIPAA regulations:

5.1. SECURITY AWARENESS AND TRAINING

Regulation	Implementation specification	Specification	Features implemented
164.308(a)(5)(ii)(A)	Security reminders	The covered entity must "implement periodic security updates".	Security updates are controlled by Windows Operating System (Windows Operating System control panel/ Windows update menu). When a new software is released; the unit can be updated by authorized people only (who have previously been trained by Quantel Medical).
164.308(a)(5)(ii)(B)	Protection from malicious software	The covered entity must "implement procedures for guarding against, detecting, and reporting malicious software."	- Windows Firewall parameters may be adjusted from the Control Panel of the Windows session; - UAC may be adjusted to the correct level (Medium Level). - A third party antivirus may be installed, but the IT person who installs this kind of software has to adjust the appropriate parameters and validate that the software does not disrupt the normal functioning of the Quantel Medical software. - Via Windows OS settings, it is possible to lock the access of the memory stick on the USB connectors (the files of the memory stick cannot be read and cannot be accessible).
164.308(a)(5)(ii)(C)	Log in monitoring	The covered entity must "implement procedures for monitoring log-in attempts and reporting discrepancies."	The Log-in monitoring is controlled by Windows Operating System (audit account login).
164.308(a)(5)(ii)(D)	Password management	The covered entity must "implement procedures for creating, changing, and safeguarding passwords."	This function is controlled by Windows Operating System (User Accounts window / password management).

5.2. CONTINGENCY PLAN

Regulation	Implementation specification	Specification	Features implemented
164.308(a)(7)(ii)(A)	Data Backup Plan	The covered entity must "establish and implement procedures to create and maintain retrievable exact copies of electronic protected health information."	A backup of the Quantel Medical device can be done on network or external hard drive, by using the dedicated function; which is located in the software. Third party software may be installed to fill this function.
164.308(a)(7)(ii)(B)	Disaster Recovery Plan	The covered entity must "establish (and implement as needed) procedures to restore any loss of data."	The procedure is established in the Service Manual of the unit to restore the software data; this procedure has to be only done by IT person. Third party software may be installed to fill this function.

5.3. ACCESS CONTROLS

Regulation	Implementation specification	Specification	Features implemented
164.312(a)(2)(i)	Unique User Identification	The covered entity must "assign a unique name and/or number for identifying and tracking user identity."	This function may be controlled by the account session of the Windows Operating System.
164.312(a)(2)(ii)	Emergency Access Procedure	The covered entity must "establish (and implement as needed) procedures for obtaining necessary electronic protected health information during an emergency."	A dedicated user account may be created and set by the IT person; when the Quantel Medical unit is installed and set. This is the responsibility of the IT person to decide the emergency access procedure: refer to the dedicated chapter of the HIPAA for more details and refer to the authentication policy of the hospital.
164.312(a)(2)(iii)	Automatic Logoff	The covered entity must "implement electronic procedures that terminate an electronic session after a predetermined time of inactivity."	This function may be controlled by the Windows operating system and set by the IT person.
164.312(a)(2)(iv)	Encryption and Decryption	The covered entity must "implement a mechanism to encrypt and decrypt electronic protected health information."	Third party software may be installed to fill in this function.

5.4. AUDIT CONTROLS

Regulation	Implementation specification	Specification	Features implemented
164.312(b)	Requires auditing of information system	The covered entity must "implement hardware, software, and/or procedural mechanisms that record and examine activity in information systems that contain or use electronic protected health information."	This function may be controlled by the Windows Operating System and set by the IT person (by using the Windows Audit Policies).

5.5. INTEGRITY

Regulation	Implementation specification	Specification	Features implemented
164.312(c)(2)	Mechanism to Authenticate Electronic Protected Health Information	The covered entity must "implement electronic mechanisms to corroborate that electronic protected health information has not been altered or destroyed in an unauthorized manner."	A checksum is used to check that the data and images are not corrupted, modified, altered or destroyed. If one image is in the above situation, this one is not displayed.

5.6. PERSON OR ENTITY AUTHENTICATION

Regulation	Implementation specification	Specification	Features implemented
164.312(d)	-	The covered entity must "implement procedures to verify that a person or entity seeking access to electronic protected health information is the one claimed."	This is the responsibility of the IT person to decide the level of protection (by using password, token...): refer to the dedicated chapter of the HIPAA for more details and refer to the authentication policy of the hospital.

5.7. TRANSMISSION SECURITY

Regulation	Implementation specification	Specification	Features implemented
164.312(e)(2)(i)	Integrity Controls	The covered entity must "implement security measures to ensure that electronically transmitted electronic protected health information is not improperly modified without detection until disposed of."	The Integrity Controls depend upon the network configuration and to the authentication policy of the hospital. Third party software may be used to fill in this function.
164.312(e)(2)(ii)	Encryption	The covered entity must "implement a mechanism to encrypt electronic protected health information whenever deemed appropriate."	Third party software may be installed to fill in this function.

II – TECHNICAL INFORMATION

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CONTENTS REV. 27/09/2024

1. LABELS

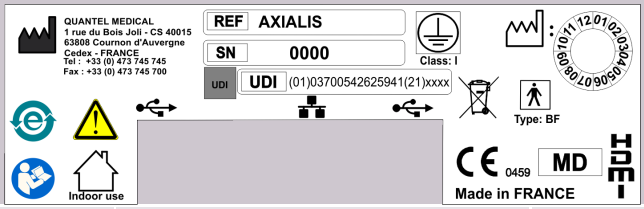
NOTE

Photos and diagrams are not contractual.

1.1. BACK PANEL

Ref.	Label & Description

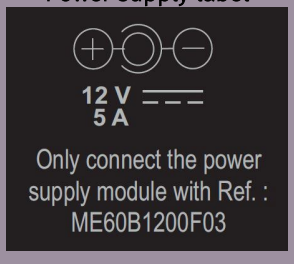
Identification label



①	SDO-established symbol	Standard containing the label	Title of the symbol & reference number	Explanatory text for the symbol
		ISO 15223-1	Manufacturer N°ISO 7000-3082	Indicates the medical device manufacturer.
	REF	ISO 15223-1	Catalogue reference N°ISO 7000-2493	Indicates the manufacturer's catalogue reference so as to formally identify the medical device.
	SN	ISO 15223-1	Serial Number N° ISO 7000-2498	Indicates the manufacturer's serial number for the medical device.
	MD	ISO 15223-1	Medical device No. 5.7.7	Indicates that the product is a medical device.
	UDI	ISO 15223-1	UDI: Unique Device Identification No. 5.7.10	
		IEC 60601-1	Type BF applied part Ref.: IEC 60417-5333	-
		IEC 60601-1	Earth of protection (ground) Ref.: IEC 60417-5019	-
		IEC 60601-1	Refer to instruction manual/brochure Ref.: ISO 7010-M002	-
	CE		CE conformity marking	-
		In accordance with the directive 2002/95/EC (WEEE)	China ROHS	Restriction Of the use Of certain Hazardous Substances

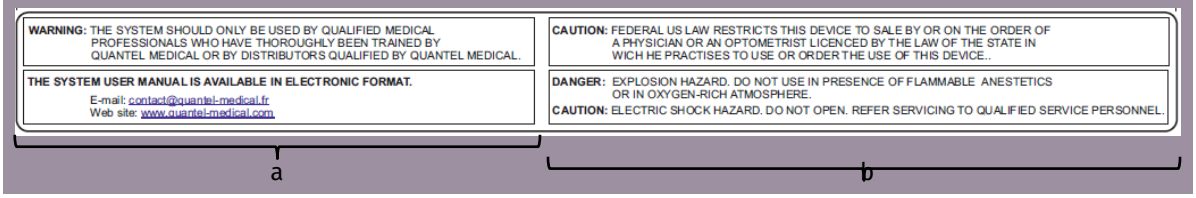
	ISO 15223-1	Manufacturing date N°ISO 7000-2497	-
	IEC 60601-1	General security sign N° ISO 7010-W001	-
	EN 50419	WEEE symbol	Do not dispose with domestic household wastes.
	ISO 15223-1	For indoor use only Ref.: CEI 60417-5957	-
	Non recognized symbol	-	HDMI port
	Non recognized symbol	-	USB port
	Non recognized symbol	-	Network port

② Power supply label



SDO-established symbol	Standard containing the label	Title of the symbol & reference number	Explanatory text for the symbol
	IEC 60617	-	Graphical symbols for use in electro technical diagrams.
	IEC 60601	Continuous current IEC 60417-5031	-

③ Electronic user manual & Federal Law label



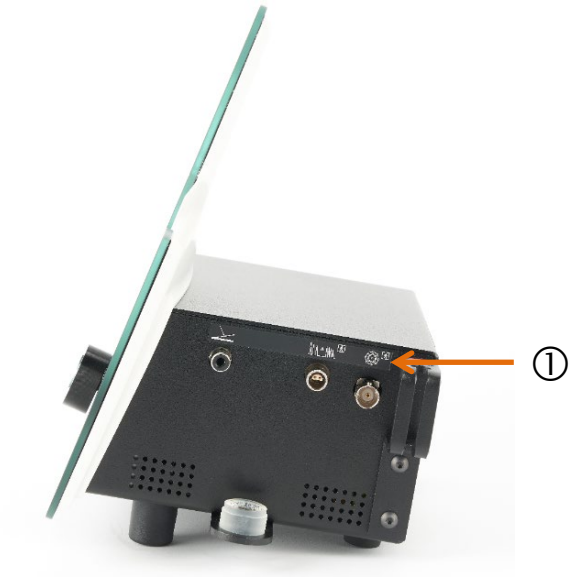
a. Label which indicates that the User Manual is available in electronic format (Commission Regulation (EU) No 2021/2226 of December 2021 on electronic instructions for use of medical devices

b. FDA Sales Restriction US label

④ Magnetic Resonance Unsafe label

Label which indicates that there is a danger of magnetic resonance when using this device in a MR environment.

1.2. RIGHT PANEL



Ref.	Label & Description

① 

SDO-established symbol	Standard containing the label	Title of the symbol & reference number	Explanatory text for the symbol
	IEC 60601-1	BF type applied part Ref.: IEC 60417-5333	-
	Non recognized symbol	-	Pachymetry probe connector
	Non recognized symbol	-	Biometry probe connector
	Non recognized symbol	-	Footswitch connector

CAUTIONS

- Do not install non QUANTEL MEDICAL software onto the unit, as it may compromise the AXIALIS® software. Installing non QUANTEL MEDICAL software will cause the warranty to be void. QUANTEL MEDICAL is not responsible for any errors caused by additional programs on the unit's hard drive.
- Do not connect the unit to the Internet. The AXIALIS® does not have antivirus protection. Connecting the unit to the Internet will cause the warranty to be void. QUANTEL MEDICAL is not responsible for any errors caused by connecting the AXIALIS® to the Internet.
- The installation of an antivirus may use computer resources that are necessary to the normal functioning of the AXIALIS® unit and thus reduce the system performances. The image acquisition in real time by the AXIALIS® system might be altered: risk of delays, saccades, image interruption... It is up to the person who would install this type of software to set the appropriate parameters and validate that the software does not disrupt the normal functioning of the AXIALIS® system (especially concerning the image acquisition).

Security awareness and training

Regulation	Implementation specification	Specification	Features implemented
164.308(a)(5)(ii)(A)	Security reminders	The covered entity must "implement periodic security updates".	Security updates are controlled by Windows Operating System (Windows Operating System control panel/ Windows update menu). When a new software is released; the unit can be updated by authorized people only (who have previously been trained by Quantel Medical).
164.308(a)(5)(ii)(B)	Protection from malicious software	The covered entity must "implement procedures for guarding against, detecting, and reporting malicious software."	- Windows Firewall parameters may be adjusted from the Control Panel of the Windows session; - UAC may be adjusted to the correct level (Medium Level). - A third party antivirus may be installed, but the IT person who installs this kind of software has to adjust the appropriate parameters and validate that the software does not disrupt the normal functioning of the Quantel Medical software. - Via Windows OS settings, it is possible to lock the access of the memory stick on the USB connectors (the files of the memory stick cannot be read and cannot be accessible).
164.308(a)(5)(ii)(C)	Log in monitoring	The covered entity must "implement procedures for monitoring log-in attempts and reporting discrepancies."	The Log-in monitoring is controlled by Windows Operating System (audit account login).
164.308(a)(5)(ii)(D)	Password management	The covered entity must "implement procedures for creating, changing, and safeguarding passwords."	This function is controlled by Windows Operating System (User Accounts window / password management).

Access controls

Regulation	Implementation specification	Specification	Features implemented
164.312(a)(2)(i)	Unique User Identification	The covered entity must "assign a unique name and/or number for identifying and tracking user identity."	This function may be controlled by the account session of the Windows Operating System.
164.312(a)(2)(ii)	Emergency Access Procedure	The covered entity must "establish (and implement as needed) procedures for obtaining necessary electronic protected health information during an emergency."	A dedicated user account may be created and set by the IT person; when the Quantel Medical unit is installed and set. This is the responsibility of the IT person to decide the emergency access procedure: refer to the dedicated chapter of the HIPAA for more details and refer to the authentication policy of the hospital.
164.312(a)(2)(iii)	Automatic Logoff	The covered entity must "implement electronic procedures that terminate an electronic session after a predetermined time of inactivity."	This function may be controlled by the Windows operating system and set by the IT person.
164.312(a)(2)(iv)	Encryption and Decryption	The covered entity must "implement a mechanism to encrypt and decrypt electronic protected health information."	Third party software may be installed to fill in this function.

Person or entity authentication

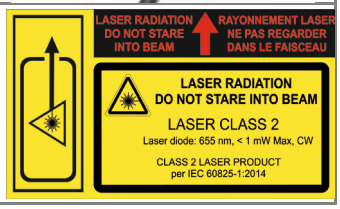
Regulation	Implementation specification	Specification	Features implemented
164.312(d)	-	The covered entity must "implement procedures to verify that a person or entity seeking access to electronic protected health information is the one claimed."	This is the responsibility of the IT person to decide the level of protection (by using password, token…): refer to the dedicated chapter of the HIPAA for more details and refer to the authentication policy of the hospital.

1.3. FOOTSWITCH

① Footswitch label: [redacted]

SDO-established symbol	Standard containing the label	Title of the symbol & reference number	Explanatory text for the symbol
IP44	IEC 60529	-	- Protection against the penetration of foreign solid bodies of diameter Ø ≥ 1 mm. - Protection against splashing water.
	EN 50419	WEEE symbol	Do not dispose with domestic household wastes.

1.4. PROBE LABELS AND MARKS

Probe type	Probe name	Labels	Pictures
PACHYMETRY PROBE	Pachymerty Probe P1	*Cable information:* Unique Device Identification (GTIN = 03700542625125) QUANTEL MEDICAL - FRAGILE IPX7 Ref: P1- 20MHz	
BIOMETRY PROBE	Biometry Probe 11MHz (Tp-01-b)	*Cable information:* Unique Device Identification (GTIN = 03700542625095) QUANTEL MEDICAL - FRAGILE IPX7 Ref: TP-01-b- 11MHz	
PROBEAM BIOMETRY PROBE	ProBeam Probe 11MHz (Tp-02-las)	*Cable information:* Unique Device Identification (GTIN = 03700542625101) QUANTEL MEDICAL – FRAGILE - IPX7 PROBEAM - Ref: TP-02-las - 11MHz	
		Laser radiation danger label	

2. TECHNICAL SPECIFICATIONS

2.1. CLASSIFICATION

The system is intended for continuous operation and has the following classification:

Electric security class	EN 60 601-1 Standard
Protective class	I
Type	BF (protection against electrical shocks)
Protection degree	IP20 (protection from solid substances > 12.5mm)

2.2. ELECTRICAL REQUIREMENTS

WARNING
Only connect the power supply module provided by QUANTEL MEDICAL.

WARNING
To avoid the electrical choc risk, the device must be only connected to a grounded power supply.

Power supply	External module with automatic voltage adaptor: no selection is needed
Input voltage	100-240 Vac 1.5A/0.7A
Frequency	50-60 Hz
Mains consumption	60 W MAX
AXIALIS® consumption	12 Vcc 5A
Reference	ME60B1200F03
Trade Mark	SL Power Electronics

2.3. TRANSMITTER RF SPECIFICATIONS

RF transmitter	
Type	WiFi + Bluetooth combo Module
Frequency	2.4GHz, 5 GHz
Frequency bandwidth	2.412 to 2.484GHz, 5.150 to 5.850 GHz
Standards	Wifi: IEEE 802.11ac, IEEE 802.11a, IEEE 802.11b, IEEE 802.11g, IEEE 802.11n Bluetooth: V5.0, V4.2, V4.1, V4.0 LE, V3.0+HS, V2.1+EDR
Modulation	Wi-Fi: 802.11b: DSSS (DBPSK, DQPSK, CCK) 802.11g: OFDM (BPSK, QPSK, 16-QAM, 64-QAM) 802.11n: OFDM (BPSK, QPSK, 16-QAM, 64-QAM) 802.11a: OFDM (BPSK, QPSK, 16-QAM, 64-QAM) 802.11ac: OFDM (BPSK, QPSK, 16-QAM, 64-QAM, 256-QAM) Bluetooth: Header: GFSK Payload 2M: π/4-DQPSK Payload 3M: 8-DPSK
Effective radiated power (Tolerance: ±2.0dBm)	Wifi: 802.11a/g@54Mbps 10.5 dBm 802.11b@11Mbps 18 dBm 802.11g/g@54Mbps 16 dBm 802.11n 2.4 GHz 16 dBm (1Tx) 19 dBm (2Tx) (MCS7_HT20 et MCS7_HT40) 802.11n 5 GHz 10 dBm (1Tx) 13 dBm (2Tx) (MCS7_HT20 et MCS7_HT40) 802.11ac 6 dBm (1Tx) 9 dBm (2Tx) (MCS9_VTH80)

2.4. DIMENSIONS

Width	22.6 cm (8.9 in)
Depth	15.8 cm (6.23 in)
Height	22.9 cm (9.02 in)
Weight	2.5 kg (5.51 lbs)

2.5. COMPLIANCE

STANDARD	SUBJECT
IEC 60 601-1	**Medical electrical equipment-Part 1:** General requirements for basic safety and essential performance
IEC 60 601-1-2	**Medical electrical equipment-Part 1:** General requirements for basic safety and essential performance – Amendment electromagnetic compatibility – requirements and testing
IEC 60 601-1-6	**Medical electrical equipment-Part 1-6**: General requirements for basic safety and essential performance – Amendment: usability
IEC 62 304	**Medical device software –** Software life-cycle process (IEC 62A/474/CDV)
ISO 14 971	**Medical devices –** Application of risk management to medical devices (ISO/DIS 14971)
Regulation (EU) 2017/745	European Medical Device Regulation

2.6. ENVIRONMENTAL CONDITIONS

The temperature of the room where the device is operated must be within the following range:

10 °C < T° < 35 °C (50 °F < T° < 95 °F)

The relative humidity must not exceed **95 %** without condensation
The Device storage and transportation temperature must be within the following range:

-20 °C < T° < 70 °C (- 4 °F < T° < 158 °F)

The atmospheric pressure must be within the following range:

70 kPa < P < 106 kPa

Maximum operating altitude: **2000 m** (about 7000 ft.)

2.7. ENVIRONMENTAL CONDITIONS WHEN STORAGE > 1 MONTH

If the medical device, including the probes, is stored for more than one month, the temperature of the storage location must be within the following range:

10 °C < T° < 35 °C (50 °F < T° < 95 °F).

The relative humidity must not exceed **95 %** without condensation.

2.8. ULTRASOUND SPECIFICATIONS

2.8.1. BIOMETRY PROBE

Probe Reference	TP-01-b (Tono-Probe) or TP-02-las (ProBeam)
Frequency	11 MHz
Focal Length	20 to 25 mm
Emission running mode	Pulsed
Emission Repetition Rate	67 Hz
Active diameter	5 mm
Active surface	20 mm^2
Axial resolution	0.15 mm (at – 6 dB)

2.8.2. PACHYMETRY PROBE (OPTION)

Probe Reference	P1
Type	A
Ceramic Frequency	20 MHz
Material	PZT ceramic
Emission Repetition Rate	5882 Hz

2.8.3. ACQUISITION ECHOGRAMS

Points in X axis	1536
Points in Y axis	256
Electronic resolution	0.03 mm at 1550 m/s

2.8.4. MEASUREMENTS ACCURACY

The accuracy is achieved by the electronic resolution: ± 0.03 mm

CAUTION

The global accuracy of the A-Scan is dependent upon:

- A good alignment with the visual axis
- A low pressure on cornea, especially when using the Contact Technique

2.8.5. ACCURACY ON IOL CALCULATION

Display resolution on IOL power: ± 0.1 Diopter.

NOTE

Using the SRK II formula, a ± 0.2 mm accuracy in measurement results in an IOL difference of 0.5 diopter.
Using the other 4 formulae, a ± 0.15 mm accuracy in measurement results in an IOL difference of 0.5 diopter.

2.8.6. PHYSIOLOGICAL LIMITS OF MEASUREMENTS

Physiological limits of measurements (auto)		Minimum (mm)	Maximum (mm)
Phakic	Anterior chamber at: 1532 m/s	1.5	7
	Lens thickness at 1641 m/s	2.5	7
	Total length = AC+L+V	14	45
Pseudo-phakic	Anterior chamber at: 1532 m/s	1.5	7
	Lens thickness at 1641 m/s	0.5	7
	Total length = AC+L+V	14	45
Aphakic	Total length at 1532 m/s	14	45

NOTE

These values correspond to the Automatic freezing control criteria.
On a manually frozen image, the markers being set manually there are no limits within the acquisition depth of 60mm.

2.8.7. DATA ENTRY LIMITS

The AXIALIS® will accept values within the ranges listed below as valid data entries.

NOTE

Some of these are outside the range of normal ophthalmic physiological values.

Parameters	Allowable range	
	Minimum	Maximum
Anterior chamber, lens and vitreous velocities	500 m/s	5000 m/s
Dense cataract velocity	500 m/s	5000 m/s
PMMA, acrylic and silicon IOL velocity	500 m/s	5000 m/s
Keratometry in millimeters	5 mm	13 mm
Keratometry in diopter	25.0 D	68.0 D
Sphere value	-40.0D	+20.0D
Cylinder value	-40.0D	+20.0D
Cylinder axis value	0°	+180°
Axis value for keratometry	0°	+180°
Total length in IOL calculation screen	15 mm	40 mm
Anterior chamber in IOL calculation screen	0 mm	9.9 mm
Post-operative ametropia	-20.0 D	+20.0 D
SRK A constant	113.00	120.59
Holladay surgeon factor calculated from A	-1.61	+2.69
Hoffer-Q ACD	2.05	6.48
Binkhorst II post-op. anterior chamber depth: ACDb	1 mm	8 mm
Constant for Haigis formula: a_0	-10	+10
Constant for Haigis formula: a_1, a_2	-1	+1
Haigis constants: combined limits for a (1.16 to 7mm) ACD range	$-2 < a_0 + 3.37\ a_1 + 23.39\ a_2 < 12$ $-2 < a_0 + 2.53\ a_1 + 20.00\ a_2 < 12$ $-2 < a_0 + 3.50\ a_1 + 27.00\ a_2 < 12$	
Measurement in Pachy mode	200 µm	999 µm
Speed in Pachy mode	500 m/s	4000 m/s

2.9. TISSUE EXPOSURE TO ULTRASOUND ENERGY

The AXIALIS® unit is designed for use in ophthalmology only.

WARNING
This device is not intended for foetal use.

2.9.1. ALARA SECTION (ALARA: AS LOW AS REASONABLY POSSIBLE)

Ultrasound energy will always be attenuated by the tissue between the transducer and the focus when used as recommended. The values presented here are the values at the focal point, the point of maximum intensity.

It is not possible to vary the output energy of the transducer. However, to minimize exposure, measurements should be kept as short as possible.

If more accuracy is desired, the intensity in the body at any transducer point may be calculated according to the formula recommended by the FDA:

$$I_t = I_w \exp(-0.069fz)$$

Where:

- I_t = is the estimated *in situ* intensity
- I_w is the measured intensity in water at the focus of the transducer
- **f** is the ultrasonic frequency in megahertz
- **z** is the distance from the face of the probe to the transducer focus in centimeters, which is the point of measurement

This formula was also used to calculate the derated values shown above.

2.9.2. SONIC VALUES

Transducer parameters show considerable variation from transducer to transducer. The measured and calculated values given in the sections below (2.8.2.1 / 2.8.2.2) were those for 3 actual transducers, whose values deviated slightly from the values in the specification above, and whose values are likely to be different from the transducer of the user's system. However, the values in the specification should give results that are accurate enough for any practical purpose, since the intensities are very low.

CAUTION:

It is always recommended to minimize exposure by limiting the ultrasonic transmission to as short periods as possible.

Symbols used in the following tables are described below:	
$I_{SPTA.3}$	The derated spatial-peak temporal-average intensity (milliwatts per square centimeter).
$I_{SPPA.3}$	The derated spatial-peak pulse-average intensity (watts per square centimeter). The value of $I_{PA.3}$ at the position of global maximum MI ($I_{PA.3}$@MI) may be reported instead of $I_{SPPA.3}$ if the global maximum MI is reported.
MI	The Mechanical Index. The value of MI at the position of $I_{SPPA\ 3}$, (MI@$I_{SPPA.3}$) may be reported instead of MI (global maximum value) if $I_{SPPA.3}$ is $\leq$ 190W/cm^2.
$P_{R.3}$	The derated peak rarefactional pressure (megapascals) associated with the transmit pattern giving rise to the value reported under MI.
W_o	The ultrasonic power (milliwatts). For the operating condition giving rise to $I_{SPTA.3}$, W_o is the total time-average power; for the operating condition subject to reporting under $I_{SPPA.3}$, W_0 is the ultrasonic power associated with the transmit pattern giving rise to the value reported under $I_{SPPA.3}$.
f_c	The center frequency (MHz). For MI and $I_{SPPA.3}$, f_c is the center frequency associated with the transmit pattern giving rise to the global maximum value of the respective parameter. For $I_{SPTA.3}$, for combined modes involving beam types of unequal center frequency, f_c is defined as the overall range of center frequencies of the respective transmit patterns.
z_{SP}	The axial distance at which the reported parameter is measured (centimeters).
x_{-6}, y_{-6}	Are respectively the in-plane (azimuthal) and out-of-plane (elevational) -6dB dimensions in the x-y plane where z_{sp} is found (centimeters).
PD	Pulse duration (microseconds) associated with the transmit pattern giving rise to the reported value of the respective parameter.
PRF	Pulse repetition frequency (Hz) associated with the transmit pattern giving rise to the reported value of the respective parameter.
EBD	Entrance beam dimensions for the azimuthal and elevational planes (centimeters).
EDS	Entrance dimensions of the scan for the azimuthal and elevational planes (centimeters).

2.9.2.1. A-SCAN PROBE

Probe reference	TP-01-b / TP-02-las (ProBeam)
Type	A-Scan
Material	PZT ceramic
Frequency	11 MHz
Application	Ophthalmic biometer
Thermal Index (T.I.)	< 1

Ultrasonic intensities in tissue at measured transducer focus (about 22 mm from probe tip)

Acoustic output			MI	$I_{SPTA.3}$ (mW/ cm^2)	$I_{SPPA.3}$ (W/ cm^2)
Associated Acoustic Parameters	Maximum Value		0.16	0.140	
	$P_{r.3}$	(Mpa)			
	W_0	(mW)			
	f_c	(MHz)			
	Z_{sp}	(cm)			
	Beam Dimension	X_{-6} (cm)			
		Y_{-6} (cm)			
	PD	(µm)			
	PRF	(Hz)			
	EBD	Az (cm)			
		E1 (cm)			

NOTE

All acoustical values can be provided upon request: please contact QUANTEL MEDICAL customer service or your local distributor.

2.9.2.2. PACHYMETRY PROBE

Probe reference	P1
Type	A
Tip diameter	1.2 mm
Active tip diameter	1.5 mm
Focal point	0.5 mm from the tip
Material	PZT ceramic
Ceramic frequency	20 MHz
Angle	45 degrees
Application	Ophthalmic Pachymetry
Thermal Index (T.I.)	< 1

Ultrasonic intensities in tissue at measured transducer focus (2 mm from probe tip):

Acoustic output			MI	$I_{SPTA.3}$ (mW/ cm^2)	$I_{SPPA.3}$ (W/ cm^2)
Maximum Value			0.04	0.097	
Associated Acoustic Parameters	$P_{r.3}$	(Mpa)			
	W_0	(mW)			
	f_c	(MHz)			
	Z_{sp}	(cm)			
	Beam Dimension	X_{-6} (cm)			
		Y_{-6} (cm)			
	PD	(µs)			
	PRF	(Hz)			
	EBD	Az (cm)			
		E1 (cm)			

NOTE: All acoustical values can be provided upon request: please contact QUANTEL MEDICAL customer service or your local distributor.

<u>Accuracy in pachymetry mode:</u>

The least-significant digit of the display is one micron. However, the accuracy of the measurements is ± 5 microns, over a range of corneal thicknesses from 200 to 999 microns. The maximum acoustic resolution (the ability to distinguish two separate echos) is 81 microns, and is limited by the central frequency of the imaging transducer. For structures larger than 200 microns, the reproducibility of the measurements is actually ± 5 microns. It does not include errors caused by operation or uncertainty in the velocity of sound.

The operator should minimize errors by keeping the probe perpendicular to the cornea and applying as little pressure as possible.

The default value of sound velocity, 1620 m/s, is considered to be the most standard value of velocity in the cornea. Other values can only be used if they are specifically documented for the type of eye under treatment.

NOTE: It is not recommended to modify the value of velocity in cornea.

The accuracy of the emissions given in the table above is: Power 29 %, Pressure 14.6 %, Intensities 29 %, Center frequency 2 %, as defined by the spectrum of the pulse.

3. EMC DATA AND GUIDELINES

WARNING: The electro-medical device requires special precautions as regards electromagnetic compatibility. The following EMC Directives must be followed when installing and using the device.

WARNING: Portable and mobile devices using RF communication may affect the electro-medical device.

The device is suitable for use in all premises other than domestic premises and those directly connected to the public low-voltage power supply network supplying buildings for domestic use.
The performance of the device is validated so that the device can be used in this electromagnetic environment.
In the event of electromagnetic disturbances, the device may cause errors or stop.

WARNING: This device should not be used next to or stacked with other devices because it may cause incorrect operation.
If such use is necessary, this device and other equipment should be observed to check for normal operation.

The use of accessories, transducers and cables other than those specified or provided by the manufacturer of this device may result in increased electromagnetic emissions or decreased immunity of this device and cause incorrect operation.

WARNING: Portable RF communications equipment should not be used close to any part of the device (maximum 30 cm/12 inches), including peripherals such as antenna cables and external antennas specified by the manufacturer. Otherwise, the performance of these devices could be impaired.

NOTE: Depending on the emission characteristics of this device, it is permitted for use in industrial and hospital areas (Class A defined in the CISPR 11).
When used in a residential environment (for which class B defined in CISPR 11 is normally required), this device cannot guarantee adequate protection for radio frequency communication services.
The user may need to take corrective measures, such as re-implanting or reorienting the device.

EMC COMPLIANCE:

Emission test	Compliance
Radiated emissions EN 55032	**Enclosure port:** Group 1, Class A at 10 m 30 MHz _ 230 MHz = 40 dBµV/m 230 MHz _ 1 GHz = 47 dBµV/m 1 GHz to 3 GHz – Limits at 3 m 76 dBµV/m (peak), 56 dBµV/m (average) 3 GHz to 6 GHz – Limits at 3 m 80 dBµV/m (peak), 60 dBµV/m (average)
Conducted emissions EN 55032	**Input a.c. power PORT:** 230 Vac/50 Hz Limits: Group 1 Class **A**
Harmonic emissions 50 Hz IEC 61000-3-2	230 Vac 50 Hz access: Limit Class **A**
Voltage changes (Flickers) IEC 61000-3-3	230 Vac 50 Hz access: PST < 1 PLT < 0.65

Supply voltage: 230 Vac 50 Hz

Immunity test	Compliance
Electrostatic discharges IEC 61000-4-2	**Enclosure port & PATIENT coupling PORT:** ± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Radiated RF EM Fields Electromagnetic field IEC 61000-4-3	**Enclosure port:** 80 MHz to 2.7 GHz: 3 V/m 80% AM at 1 kHz, 1%, 2 sec
Proximity fields from RF Wireless communications equipment IEC 61000-4-3 (Ch 8.10)	**Enclosure port :** **Frequency spots:** Table 9 of standard and part 3.2 Pulse modulation or MF as band
Electrical Fast transients/bursts IEC 61000-4-4	**Input a.c. power PORT:** ± 2 kV (100 kHz)/230 Vac @ 50 Hz **Signal Input/output parts PORT:** ± 1 kV (100 kHz)
Surge IEC 61000-4-5	**Input a.c. power PORT:** 230 Vac @ 50 Hz ± 0.5 kV, ± 1 kV, ± 2 kV line-to-ground ± 0.5 kV, ± 1 kV line-to-line
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V – AM 80%, at 1 kHz, 1%, 0.5 sec **Frequency band 150kHz - 80MHz** 6 V in ISM bands **Frequency band 0.15 MHz - 80MHz** **Input a.c. power PORT:** 230 Vac @ 50 Hz **Signal input/output parts PORT**
RATED Power frequency magnetic fields IEC 61000-4-8	**Enclosure port:** **Level:** 30 A/m (50 Hz)
Voltage dips and interruptions IEC 61000-4-11	**Input a.c. power PORT:** 240 Vac @ 50 Hz • 0% U_T; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° • 0% U_T; 1 cycle – Single phase: at 0° • 70% U_T; 25 cycles – Single phase: at 0° • % U_T; 250 cycles
Proximity fields in the frequency range 9 kHz to 13.56 MHz IEC 61000-4-39	• 30 kHz: 8 A/m • 134.2 kHz: 64 A/m • 13.56 MHz: 7.5 A/m

Recommended separation distances between portable and mobile RF communications equipment and the AXIALIS®

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

Maximum transmitter power output (W)	Separation distance according to the transmitter's frequency (m)		
	150 kHz to 80 MHz $d=0.35\sqrt{P}$	**80 MHz to 800 MHz** $d=0.35\sqrt{P}$	**800 MHz to 2.7 GHz** $d=0.7\sqrt{P}$
0,01	0.035	0.035	0.07
0,1	0.11	0.11	0.22
1	0.35	0.35	0.70
10	1.1	1.1	2.2
100	3.5	3.5	7.0

Where *P* is the maximum emission output power of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m).
Field strength 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: 

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

NOTE 1: Between 80 MHz and 800 MHz, separation distance for the highest 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 strength from fixed transmitters, such as base stations for radio (Cellular / cordless) 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 device AXIALIS® is used exceeds the applicable RF compliance level above, additional measures may be necessary, such as reorientation or relocating the AXIALIS®. In case unusual performance is witnessed, additional measures may be required such as change of orientation or location of the AXIALIS®.

[b] Field strength should be less than 3 V/m in the range between 150 kHz and 80 MHz

4. UNIT DESCRIPTION

The connectors have different shape to avoid installation errors.

WARNING

Do not force on the connectors

4.1. BACK PANEL

The user must switch the main switch to "I" to power the unit, or to "0" to turn off main power to the unit

CAUTION:
In order to avoid an unfortunate loss of data in the database, you must stop the device by using the Windows 10 closing process or by pressing the "Start / Stop" button on the left side of the device.

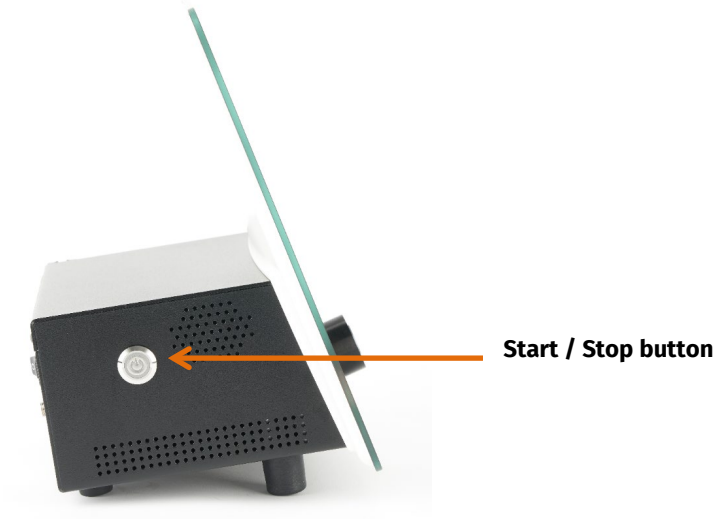
When the Windows shutdown process is completed, the button LED turns orange:

You can then toggle the main switch to the "0" position to turn off the main power supply.

Do not perform this operation until the Windows shutdown process is completed (green LED).

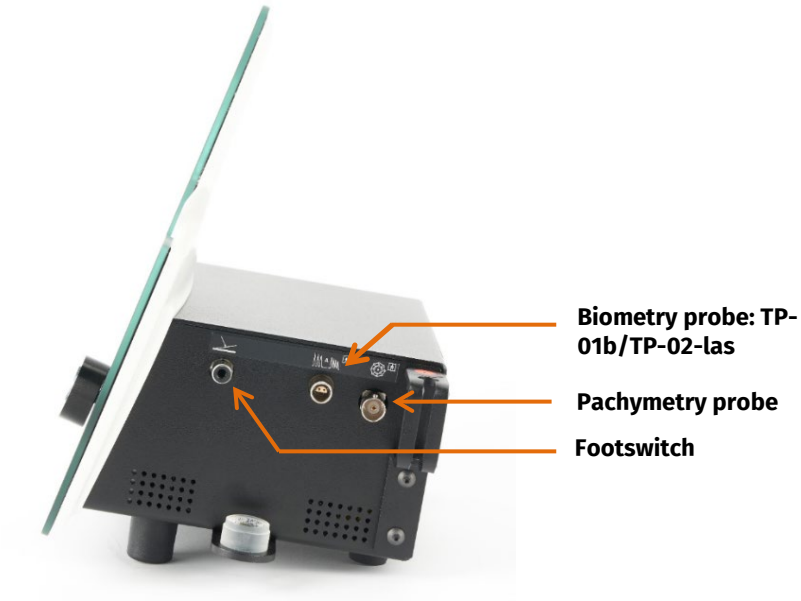
USB 3.0 and 2.0 ports	There are 3 USB connectors which can be used to connect a printer, a data storage key or an external keyboard.
Network port (RJ-45)	This connector can be used to connect the AXIALIS® to a network.
HDMI port	This connector can be used to connect the AXIALIS® to a High-Definition Multimedia Interface.
Power supply	2.1 mm connector for connecting the 12 Vdc external power supply.

4.2. LEFT PANEL



"Start / Stop" button	When the main switch is in position "1", pressing the **"Start / Stop"** button starts / closes the Windows operating system. The LED color of the **"Start / Stop"** button indicates:  Green: the AXIALIS® is powered and Windows operating system is started.  Orange: the AXIALIS® is powered, but Windows operating system is not started.

4.3. RIGHT PANEL



Biometry probe connector	The biometry probe has a LEMO four-pin connector. It is a push-pull type connector with a locking system
Pachymetry probe connector	A pachymetry probe can be plugged into this rotative BNC connector
Footswitch connector	The footswitch connector is the Audio type connector

4.4. FRONT PANEL

Ref.	Description
1	Color LCD LED touchscreen
2	Probe holder: Biometry
3	The front knob may be used: - to increase / decrease values - to move the markers - to move from one field to another one in specific screen

5. INSTALLATION: TECHNICAL INFORMATION

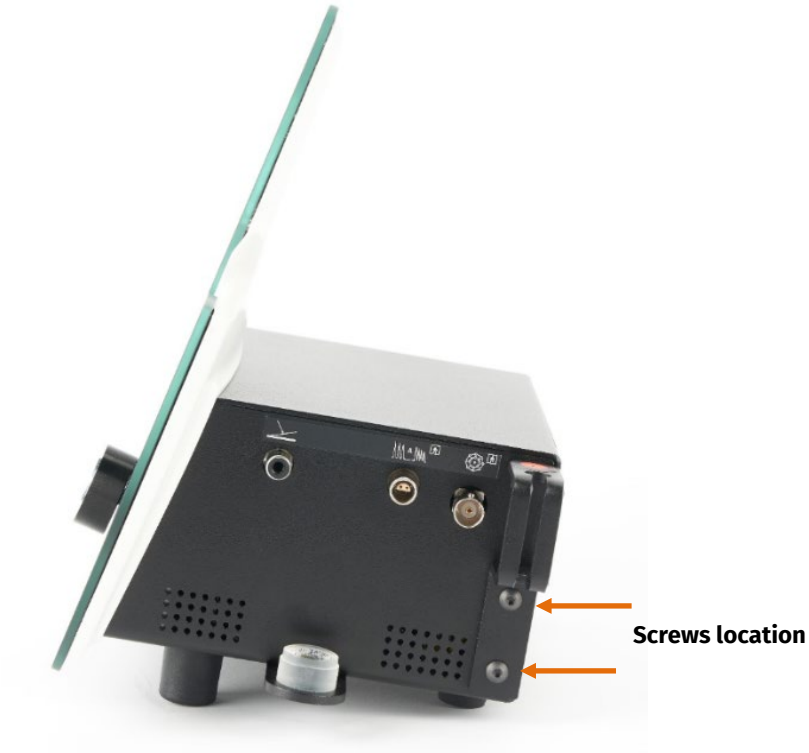
5.1. PACHYMETRY PROBE HOLDER ASSEMBLING

CAUTION

Before any intervention on the device, unplug the mains cord on the left side. Disconnect all probe connectors, footswitch and remove the probes from their holder.

- Take the probe holder delivered with the probe.

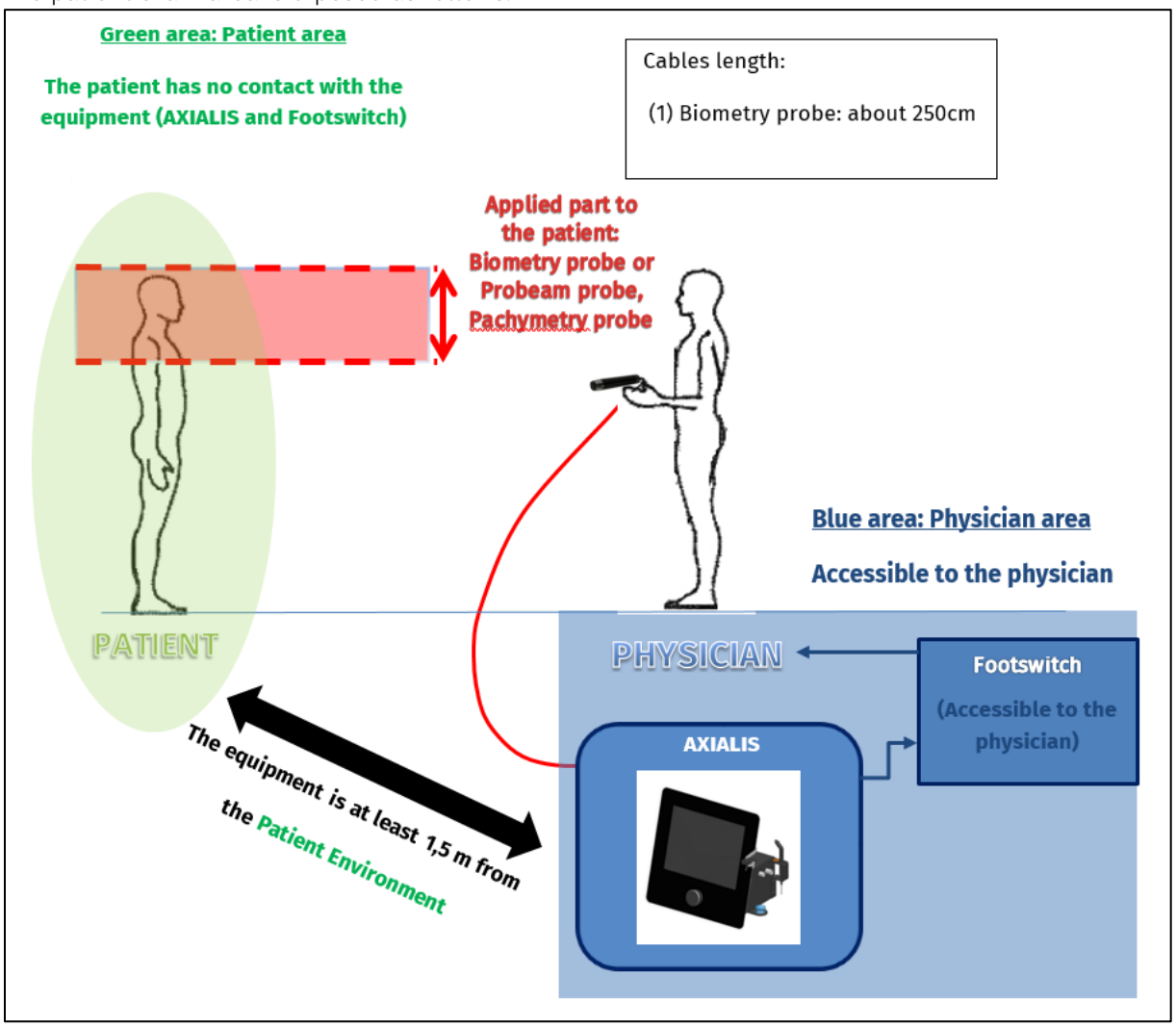
Pachymetry probe holder for AXIALIS®



- Unscrew both hexagon socket screws placed on the probe holder location;
- Position the probe holder on the right panel as indicated above;
- Screw on the hexagon socket screws with an Allen key to fix the probe holder.

5.2. PATIENT EXAM AREA

The patient exam area is diposed as follows:



Applied part to the patient:
The probes area corresponding to the applied part is indicated with the blue color mark underneath:

PACHYMETRY PROBE :

BIOMETRY PROBE :

PROBEAM BIOMETRY PROBE :

5.3. POWER SUPPLY

The power supply is an external module with an automatic voltage adaptation. No selection is necessary. For more information, refer to the:

AXIALIS® User Manual: Chapter II- Technical information
Section 2.2: Electrical requirements

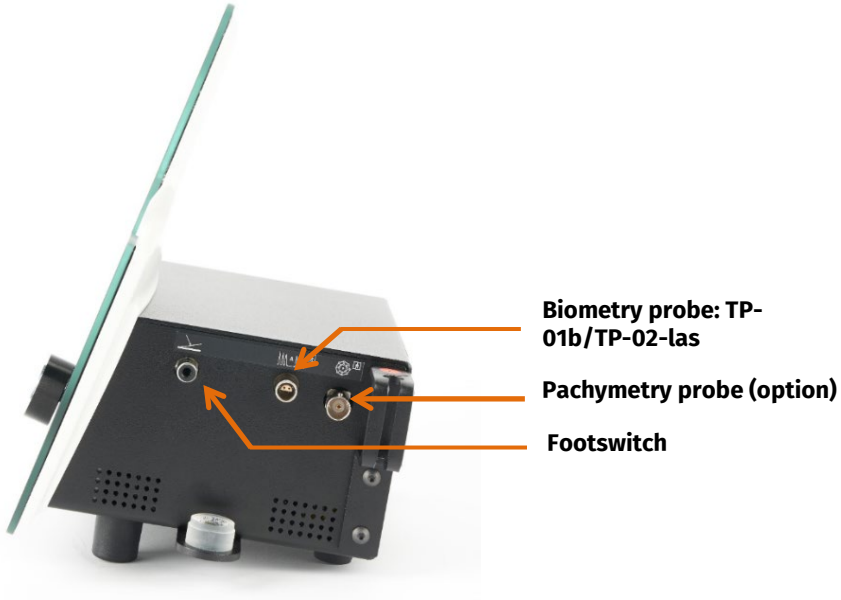
CAUTION:
Only connect the power supply provided by QUANTEL MEDICAL.

WARNING
To avoid the electrical choc risk, the device must be only connected to a grounded power supply.

5.4. CONNECTIONS TO THE RIGHT AND LEFT PANELS

All connectors are located on the back and right panels of the unit. To avoid wrong connections, the connectors have different shapes.

WARNING
Do not force on connectors



CAUTION:
Only connect to devices complying with the international standard: IEC 60950 for Input and Output signals.

CAUTION:
Do not connect USB unit (printer, mouse, keyboard…) during acquisition.

CAUTION:
Be cautious when connecting devices other than the ones provided with the AXIALIS® by QUANTEL MEDICAL:

1. To comply with the IEC 60601-1-1 Standard for “Medical Systems”, the configuration must respect the following regulations:

   a. Accessories installed in the “Patient Environment” are considered medical devices and must comply with the IEC 60601-1 standard.
   The “Patient Environment” is defined as the area in which medical diagnosis, monitoring, or treatment is carried out, as well as the area in which intentional or unintentional contact can occur between the patient or other persons present and parts of the system.

   b. Non-medical electrical equipment may be connected to AXIALIS® in the following conditions:
      - the equipment is at least 1.5 m from the “Patient Environment”;
      - the equipment is not touched by any person in close proximity of the patient.

2. Only connect to devices complying with these international standards:
   - IEC 60 601-1 Medical Electrical equipment
   - Or IEC 60 950-1 Safety of Information Technology equipment including electrical business equipment.

5.4.1. PROBE CONNECTIONS

The biometry probe holder is integrated to the screen.

The pachymetry probe holder is fixed on the right side of the device.

5.4.1.1. BIOMETRY PROBE

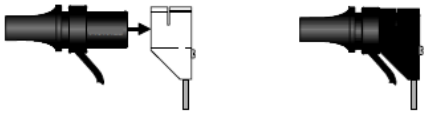
The Biometry probe is equipped with a push-pull type connector with a locking system. Before inserting the connector, rotate it slightly to find the good position.

CAUTION:

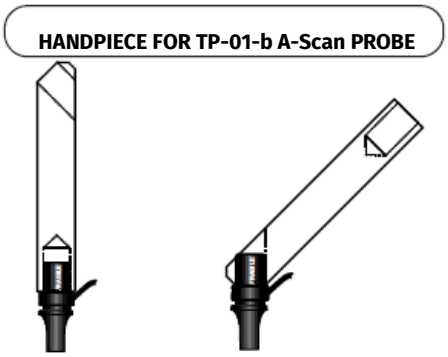
Do not pull the cable to disconnect the probe. Pull the connector body to unlock it.

a) Standard probe (TP-01-b: Tono-PROBE)

The Biometry probe is uni-directional. Its small size allows it to be mounted on the Goldman tonometer in place of the optical cone. The cable outlet along the tonometer stem does not disturb the balance of the instrument, and the pressure regulation of the tonometer remains easily adjustable.



A hand-piece may be used to handle it more easily, either at 45 degrees or vertically



The probe hand-piece can be ordered through your local distributor or to QUANTEL MEDICAL. The ordering code is XEAAAPAM.

b) ProBeam Probe (TP-02-las)

The ProBeam is a probe with a laser aiming beam.

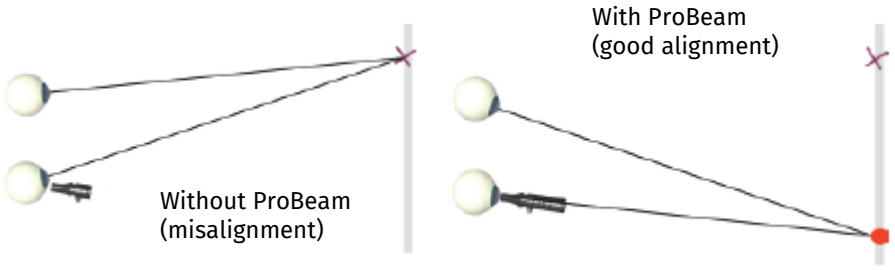
WARNING:

A laser radiation is emitted from the ProBeam probe, so avoid direct eye exposure.

Sticker on the ProBeam:

Use of the probe:

In the acquisition screen, the probe is activated by pressing on the footswitch. When the footswitch is pressed to get an unfrozen image (with the emission echo), the ProBeam laser aiming beam is turned ON. The patient should then fix the red point projected on the wall (or on the ceiling) so that the patient's eye to be measured and the ProBeam are in good alignment.



5.4.1.2. PACHYMETRY PROBE

The pachymetry connector is located on the right panel. The pachymetry probe must be plugged into this BNC connector.

5.4.2. OTHER CONNECTIONS

5.4.2.1. FOOTSWITCH

The footswitch connector is located on the right panel.

5.4.2.2. USB PORTS

The USB ports (located on the back panel) are used to connect the following peripherals:

- USB data storage device
- External printer with a USB cable
- Additional USB keyboard

5.4.2.3. NETWORK & HDMI PORTS

Those ports are located on the back panel.

III – USE

AXIalis

PRECISION AT YOUR FINGERTIPS

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Biometry and pachymetry

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