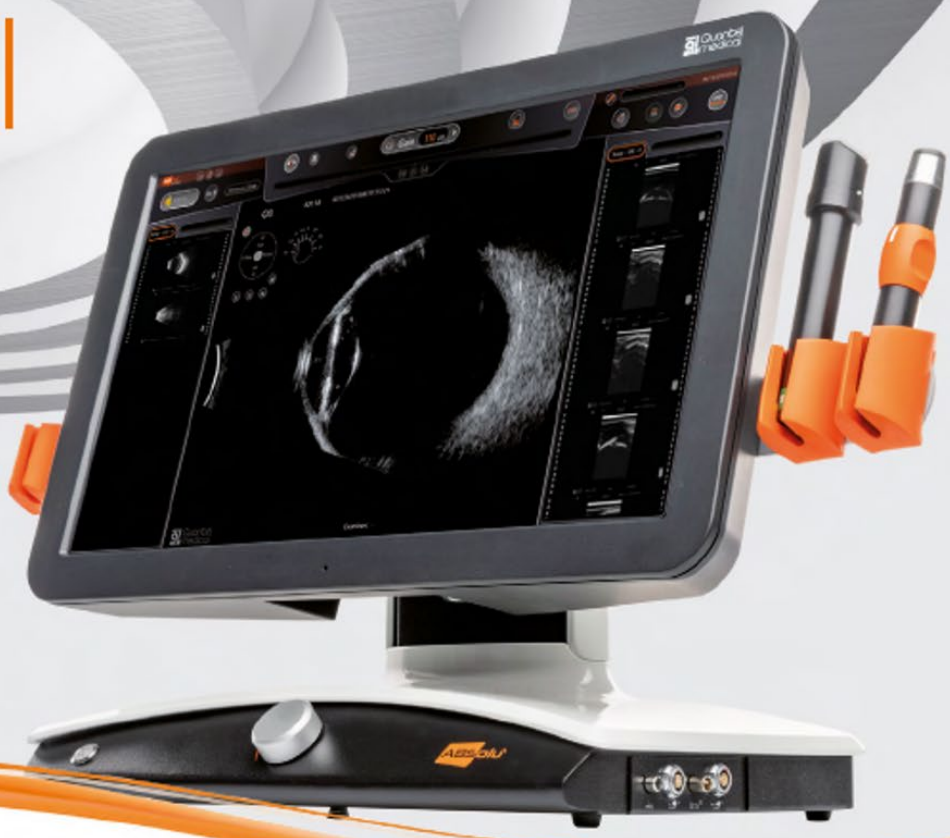
USER MANUAL

Select a chapter

IMAGING
EXCELLENCE



OCTOBER 2024

Quantel medical
BY LUMIBIRD MEDICAL

A/B/S/UBM Ultrasound Platform

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2024 CE 0459

Regulation (EU) 2017/745

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QUANTEL MEDICAL
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ABSolu® User Manual
Software Version 1.0.5 and over
International version (Ref.: ME00437C)
October 7, 2024

Introduction

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TABLE OF CONTENTS

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1. INTRODUCTION

The ABSolu® is an ultrasonic system intended to be used for diagnostic and biometry purposes using A-scan and dynamic examination of the anterior and posterior segment of the eye and orbit using conventional B-scan or ultrasound biomicroscopy according to the configuration of the device (specifical probes/transducers).
The device is indicated for:

- Examination of eye (orbit and ocular annexes) in presence of clear or opaque media.
- Determination of normality or pathological status in the previous described organs/areas by means of scanning with available probes.
- Measurement of different parameters including biometry and other (related to classify different types of pathologies).

The ABSolu® is a high-definition multifunction ophthalmic ultrasound system used for:

- Axial Length measurement of the eye by ultrasonic means.
- Implanted IOL power calculation, using the axial length measurement.
- Visualization of the interior of the eye and the orbit by A and B scans.
- ABSolu® S only: Advanced diagnostic - Standardized echography provides detailed information about the internal reflectivity of tissues and allows optimal tissues differentiation, localization, and measurement of structures in the eye and orbit.

  The ABSolu® is a user-friendly system that includes a high resolution 21,5" LCD screen mounted onto a stable base on which probes can be connected. The device can be delivered with different basic configurations (see figure below).

Single Emitter-Receiver board		Combined Emitter-Receiver board	
ABSolu B modes: Biometry A-Probe 15MHz Probe (B1) LIN 50MHz Probe (BHF-50LIN)	**ABSolu S modes:** Standardized A-Probe 15MHz Probe (B1) LIN 50MHz Probe (BHF-50LIN)	**ABSolu B modes when B 20MHz annular option:** Biometry A-Probe 15MHz Probe (B1) LIN 50MHz Probe (BHF-50LIN) 20MHz-5A Probe (B20-5A)	**ABSolu S modes when B 20MHz annular option:** Standardized A-Probe 15MHz Probe (B1) LIN 50MHz Probe (BHF-50LIN) 20MHz-5A Probe (B20-5A)

The table below shows in which configuration a probe is compatible.

Probe	ABSolu® B	ABSolu® S	ABSolu® B with B 20 Annular option	ABSolu® S with B 20 Annular option
Biometry A-probe	Yes	Yes	Yes	Yes
Biometry A-probe with a laser aiming beam	Yes	Yes	Yes	Yes
Standardized A-probe	No	Yes	No	Yes
15MHz Probe (B1)	Yes	Yes	Yes	Yes
LIN 50MHz Probe (BHF-50LIN)	Yes	Yes	Yes	Yes
20MHz-5A Probe (B20-5A)	No	No	Yes	Yes

2. USER MANUAL DESCRIPTION

This user manual is provided in electronic format (PDF) with the ABSolu® device. It is organized into the following chapters:

3. USER MANUAL TERMS AND SAFETY SYMBOLS

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. ABSOLU® DESCRIPTION

The ABSolu® is a complete Ophthalmic Ultrasound system with these features:

- The ABSolu® Welcome screen allows to select a Physician name and an Examiner name. Each user gets a user file that can be customized with personal data such as:
  - Physician's name.
  - Address and the clinic name as well as other characteristics common to all users.
- The ABSolu® Welcome screen allows the Physician to select or to create a Patient file. The Patient file can be filled in with name, date of birth, keratometry, etc.
- When a Patient is selected in the Welcome screen, the Examiner can start a new session in the Exam screen and perform:

  Regular A-scan Echography for AXIAL BIOMETRY

  - The biometry probe is specially designed to be mounted on a tonometer in place of the optical cone. This allows the Examiner to easily position the probe on the optical axis of the patient and to control the indentation of the probe on the eye.
  - A special Prager Shell may be used to perform the immersion technique. The probe can be fitted inside the shell and thus fixed on the visual axis.
  - In automatic mode, the Examiner can easily perform up to ten scans in a row for each eye.
    - Each scan is stored with the following segment measurements: Cornea (for axial length in S mode only), Anterior chamber, Lens, Vitreous and total Axial Length.
    - The RESULTS table shows the average value of the 10 measurements and calculates the Standard Deviation for each segment.
  - The acquisition program is adaptable to all commonly found cases:
    - Phakic, Aphakic or Pseudo-phakic eyes (PMMA, Acrylic or Silicone), Vitreous material.
    - Manual or automatic image-freezing.
    - Manual or automatic storage of the ten scans.

  IOL calculations

  The calculation screen uses:

  - The Patient file Keratometry.
  - The Axial Length coming from:
    - one specific scan.
    - Stat-2 result.
    - the average of several scans.
    - a value entered by the operator.

  These 4 IOL calculations can simultaneously be displayed on the screen:

  - Value for emmetropia.
  - Refraction for 9 implants separated by 1/2 or 1/4 Diopter, the centered value corresponding to the desired post-operative ametropia.
  - Implants pre-selected in the ABSolu® General Setup Screen.
  - Several formulae:
    - For normal eyes calculations:
      - IOL Formulae: Binkhorst II; SRK-II; SRK-T; Holladay; Hoffer-Q; Haigis.
    - For Post-Refractive surgery eyes:
      - Two other IOL formulae are available
        - Double-K / SRK-T from Dr Aramberri and the Shammas formula.
      - Five Keratometry evaluation methods:
        - History Derived, Refraction Derived, Rosa regression, Shammas regression, and Contact Lens.

Echography in B mode

The ABSolu® allows the user to display a high-definition image on the 21,5'' LED screen.

- Using mechanical sector scanning probes.
- The definition is: 256 lines of 2133 points with a sector angle of 50° for the 15MHz probe (B1) and 450 lines of 2000 points for the 20MHz-5A probe (B20-5A).
- Using linear motion scanning probes:
- The definition is: 384 lines of 2048 points.
- Post processing measurement tools can be used to measure distances on a saved exam.
- Biometry guided by B mode.
- 1 image to 400 images Cineloop sequence.

Echography in A-Standardized mode

The ABSolu® system with the Standardized option is optimally designed for advanced diagnosis:

- An "S" shape amplifier provides adequate acoustic acuity and perfect acoustic field.
- The A Standardized scan probe uses a specific frequency and specific ultrasound beam.
- A tissue model helps determine tissue sensitivity.
- The ABSolu® system with the Standardized option allows the user to differentiate and measure a wide variety of ocular tissues. It has unique differential diagnosis capabilities:
  - To detect intraocular and orbital lesions using the **Lesion QI** (Bio 2 QI K mode measurement of mass lesions, automatic calculation of internal reflectivity, calculation of angle Kappa attenuation).
  - To differentiate unique tissues using the **Retina A (A1)** mode or **Retina QII (Quantitative II)** mode (differentiation of retinal detachment vs intraocular membranes).
  - To automatically give diagnosis support (recognition of specific levels of reflectivity for retina and membranes).
  - To calculate muscle profile (for characterization of orbitopathy) in **Musc. Profile** mode.

Data transfer

- EMR (Electronic Medical Record).
- Option: DICOM (Digital Imaging and COmmunication in Medicine).

Customized reports (adjustable number of images & font)

Reports can be customized with different fonts and a flexible number of images.

Automatic database backup

Automatic backup of the database.

5. 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 it on may cause serious damage. Unpack the instrument and leave it at normal temperature for at least half a day to ensure that the internal components warm up gradually.

6. PACKING LIST

6.1 Packing list configuration

Before beginning the installation, check the received configuration against the following list in the table below.

Configuration code	Probes included	Other
PCBX0037A1B	15MHz probe (B1)	• Power cord • Footswitch • 2 probe holders (+hex key) • Azerty/Qwerty Keyboard (optional) • Mouse and mouse pad • Documentation • Probe parameters USB key(s) • ABSOLU® cover
PCBX0037A1AB	Biometry A-probe and 15MHz probe (B1)	
PCBX0037A1LAB	ProBeam A-probe and 15MHz probe (B1)	
PCBX0037A2V	20MHz-5A probe (B20-5A)	
PCBX0037A2AV	Biometry A-probe and 20MHz-5A probe (B20-5A)	
PCBX0037A2LAV	ProBeam A-probe and 20MHz-5A probe (B20-5A)	
PCBX0037S1S	Standardized A-probe	
PCBX0037S1A	Standardized A-probe and Biometry A-probe	
PCBX0037S1LA	Standardized A-probe and ProBeam A-probe	
PCBX0037S1B	Standardized A-probe and 15MHz probe (B1)	
PCBX0037S1AB	Standardized A-probe, 15MHz probe (B1) and Biometry probe	
PCBX0037S1LAB	Standardized A-probe, 15MHz probe (B1) and ProBeam A-probe	
PCBX0037S2V	Standardized A-probe and 20MHz-5A probe (B20-5A)	
PCBX0037S2AV	Standardized A-probe, Biometry A-probe and 20MHz-5A probe (B20-5A)	
PCBX0037S2LAV	Standardized A-probe, ProBeam A-probe and 20MHz-5A probe (B20-5A)	

6.2 Items sold independently

Other items may be sold independently from the ABSolu® packing list configuration.

6.2.1 Probes and options

Configuration code	Description
PCEX0009	Biometry probe + accessories
PCEX0010	ProBeam probe (Biometry probe with a laser aiming beam) + accessories
PCSX0005	15MHz probe (B1) + accessories
PCSX0007	LIN 50MHz probe (BHF-50LIN) + accessories
PCBX0056	20 MHz option (20MHz probe + accessories + ERM board)
PCBX0037SUP	Standardized mode option (Standardized A-probe + accessories + ERM board)
PCEX0007	DICOM option
PCEX0016	STS option
PCEX0017	XML Worklist option
PCBX0037ABS	ABSolu® console for connection with 15MHz, 50MHz and Biometry probes + accessories

6.2.2 Accessories and consumables

Configuration code	Description
XEAAACOQLIN14	14mm scleral shell for Linear Probe
XEAAACOQLIN16	16mm scleral shell for Linear Probe
XEAAACOQLIN18	18mm scleral shell for Linear Probe
XEAAACOQPRAEG15	15mm Präger shell for children
XEAAACOQPRAEG17	17mm Präger shell for adults
XEPRBFEN2	Filmed windows for 50Mhz Linear Probe (box of 10 pcs)
XEPRBFS	ClearScan for Linear 50MHz probe – diam. 25mm (10 units)

6.2.3 Other parts

Configuration code	Description
RM150292	Probe holder for B probes (B15MHz or B20MHz)
SC010128	Wireless Azerty keyboard + mouse
SC010129	Wireless Qwerty keyboard + mouse
SC010047	Finger grip sleeve for 15MHz probe
SC010122	Finger grip sleeve for 20MHz probe
XEAAAPAM	Biometry handpiece
XEAAAPEDALE4RF	Wireless 4 position footswitch
XEHUBUSB	HUB for multiple HUB connections
XEIMPUSBLASER	USB laser printer
XEIMPUSBSONY	Sony Video USB printer
SC010130	Test Block for ABSolu®
RP120119	Dust Cover for ABSolu®

I – Regulatory & safety information

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1. INTENDED USE

The ABSolu® is an ultrasonic system intended to be used for diagnostic and biometry purposes using A-scan and dynamic examination of the anterior and posterior segment of the eye and orbit using conventional B-scan or ultrasound biomicroscopy according to the configuration of the device (specifical probes/transducers).

This user manual 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.

1.1 Indications for use

The ABSolu® is a high-definition multifunction ophthalmic ultrasound system (used) for:

- Examination of eye (orbit and ocular annexes) in presence of clear or opaque media.
- Determination of normality or pathological status in the previous described organs/areas by means of scanning with available probes.
- Measurement of different parameters including biometry and other (related to classify different types of pathologies) by ultrasonic means.
- Through the right transducer it is possible to have high-definition images of the anterior segment (UBM 50 MHz) or the posterior pole of the eye (20MHz 5-Annular)
- 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.
- By means of the standardized echography module, is possible to achieve tissue differentiation of different structures like tumors, retinal detachment vs PVD, grave diseases and other conditions.
- Automatic sulcus to sulcus (STS) measurement allows to obtain the real distance and space for intraocular contact lens (ICL) implantation.
- Axial Length measurement of the eye by ultrasonic means.
- Implanted IOL power calculation, using the axial length measurement.
- Visualization of the interior of the eye and the orbit by A and B scans.
- ABSolu® S only: Advanced diagnostic - Standardized echography provides detailed information about the internal reflectivity of tissues and allows optimal tissues differentiation, localization, and measurement of structures in the eye and orbit.

1.2 Contraindications

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

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

1.3 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

1.4 Targeted population

The patient population includes people of any age, sex or ethnic origin, where an examination of the internal structures of the eye is required for the monitoring or diagnosis of an ocular pathology.

2. SAFETY INFORMATION AND PRECAUTIONS

2.1 General warning and cautions information

Tissue exposure to ultrasound energy: the ABSolu® unit is designed for use in ophthalmology only. While QUANTEL MEDICAL is not aware of any reports of adverse effects from using ophthalmologic ultrasound unit, even at FDA pre-enactment levels, no other use is intended or implied. 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.

WARNINGS
Before using the device, read these warnings carefully:

- USA Federal Law requires that this device be sold only by on the prescription of a physician.
- This device is not intended for fetal 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
- To avoid risk of electric shock, this equipment must only be connected to supply mains with protective earth.
- The ABSolu® is categorized as a device having a B type applied part. It is mandatory to connect the ABSolu® unit to the protective earth so that the B type applied part ensures an appropriate degree of protection against electric shocks.
- While using the unit, mains plug must be easily accessible.
- The ABSolu® 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: ABSolu® User Manual: Chapter II - Technical information Chapter 5 – Installation: technical information
- Do not open and/ or 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 unit has to be disconnected from the telecom, IT network and/or USB accessories during examination, if the connected accessories are not separated with a network isolator and/or USB isolator (that complies with IEC 60601-1 and IEC 60950 standards, moreover the installation of accessories / isolators have to be performed or checked by the responsible organizations: IEC 60601-1).
- 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: IEC 60601-1.
- Do not use flammable anesthetics product.
- Do not use in oxygen rich atmosphere.
- Some persons are extremely allergic to isopropyl alcohol.
- Do not place any other electrical/electronic device within a 15cm radius of the ABSolu®, to avoid near-field magnetic interference.

- 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.
- The part of devices in contact the with patient's and user's skin must to de cleaned and disinfected before and after use. Chapter I Regulatory & Safety, section 2.4 Cleaning and High Disinfection Procedure.

CAUTIONS

Before using the device, read these cautions carefully:

- 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 ABSolu® 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 ABSolu® 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 ABSolu® to the Internet.
- The installation of an antivirus may use computer resources that are necessary to the normal functioning of the ABSolu® unit and thus reduce the system performances. The image acquisition in real time by the ABSolu® 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 ABSolu® system (especially concerning the image acquisition).
- When cleaning the screen: the device must be switched off and no abrasive cleaner should be used.

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

2.2 CLEANING AND DISINFECTION PROCEDURE

The cleaning, disinfection or high disinfection of ophthalmic ultrasound medical devices 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 disinfection and high disinfection.

 WARNING

Carefully read these warnings about cleaning and disinfection instructions:

- The probes must be cleaned and high disinfected before using them for the first time.
- The probes in contact with the patients and the users must be cleaned and high disinfected for each patient to prevent the transmission of infection (refer to the procedure “PR00172”);
- The other parts of device in contact with the users must also be cleaned and disinfected before and after use (refer to the procedure “PR00172”);
- 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. To determine which product to use, refer to the procedure “PR00172”);
- The device must be cleaned and disinfected after each maintenance (Chapter V_General_Setup_&_Maintenance).
- Ensure that the device switched off, and then disconnect the power supply before cleaning and disinfection the device.

RESPONSIBILITY

The medical department where the instrument is used must:

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

2.3 Probes care

 WARNINGS

Carefully read these warnings for probes care:

- When cleaning and high disinfection the probes (following the Cleaning and High Disinfection Procedure PR00172, Chapter I Regulatory & Safety, section 2.4), or in “normal” use, or for performance evaluation purposes, the tip of the 15MHz Probe (B1), 20MHz-5A Probe (B20-5A) and LIN 50MHz (BHF-50LIN) probe must be immersed on 1,5cm length maximum in the high disinfection / exam liquid.
- After each cleaning and disinfecting cycle (and/or at least once a week), check that:
  - The 15MHz (B1) and 20MHz-5A (B20-5A) probes membrane or the front part of the LIN 50MHz (BHF-50LIN) probe opened (visible transducer) is not damaged (signs of impact) and that the connecting cable is not stripped and/or damaged.
  - Regularly check the probe body and cord aspect to detect any crack that could allow penetration of liquid or to detect any damage that could alter the probe performance.
- Linear probes calibration must be checked periodically. If the probe is used for sizing: the probe calibration should systematically be checked.
- The ultrasound unit must be imperatively turned off before disconnecting the probes. Avoid splashing liquids onto the probe connectors.

- Do not immerse the connector.
  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
Carefully read these cautions for probes care:

- 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.
- Do not use any abrasive cleaning products or solvents that may alter the probe's body aspect. If possible, clean off stains immediately (refer to the Cleaning and High Disinfection Procedure "PR00172").
- The LIN 50MHz probe (BHF-50LIN) transducer is very fragile: do not touch it.

2.4 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.

2.5 Precautions concerning wastes and elimination of device and accessories

This product complies with the WEEE Directive (2012/19/EU) marking requirements. The ABSolu® 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, contact QUANTEL MEDICAL.

3. HIPAA COMPLIANCE

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

3.1 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 must 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).

3.2 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, on DVD or external hard drive, by using the dedicated function, which is 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 must be only done by IT person. Third party software may be installed to fill this function.

3.3 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.

3.4 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).

3.5 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.

3.6 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.

3.7 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.