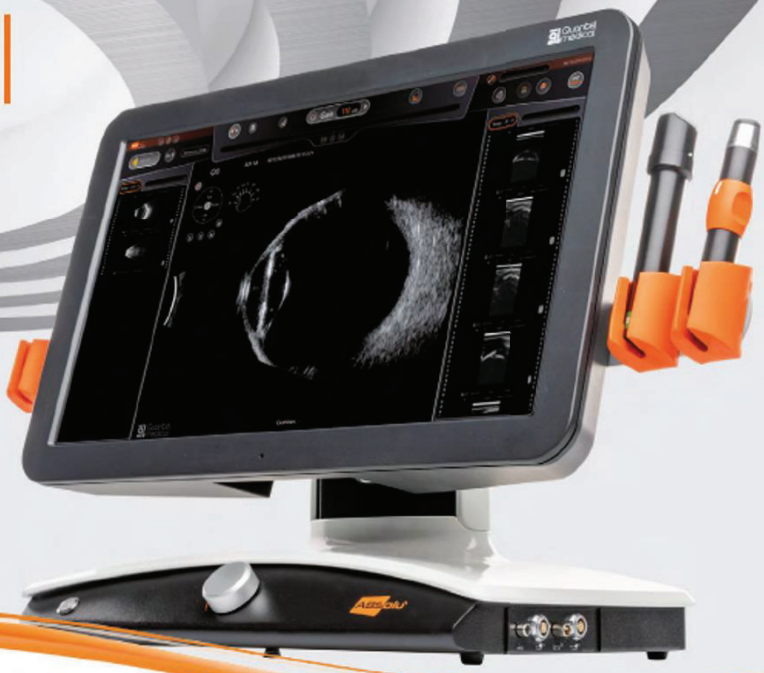
USER MANUAL
MAY 2023

Select a chapter

ABSolu®

IMAGING
EXCELLENCE



Quantel medical
BY LUMIBIRD MEDICAL

A/B/S/UBM Ultrasound Platform

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2018 CE 0459
Directive 93/42/EEC

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ABSolu User Manual
Software Version 1.0.5 and over
International version (Ref.: ME00437B)
May 26, 2023

Introduction

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TABLE OF CONTENTS

1. INTRODUCTION

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

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)

Combined Emitter-Receiver board

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
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
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
XEAAAPAM	Biometry handpiece
XEPRBFEN2	Filmed windows for 50Mhz Linear Probe (box of 10 pcs)
XEPRBFS	ClearScan for Linear 50MHz probe – diam. 25mm (10 units)
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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TABLE OF CONTENTS

1. INDICATIONS FOR USE AND CONTRAINDICATIONS

The ABSolu Ophthalmic Ultrasound System is indicated to be used on children, young adults, adults, and elderly people with the exceptions listed in the contraindications.

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.

This user manual is intended to be used in health institutions by:

- Ophthalmologists.
- Ophthalmic technicians.
- Any other personnel engaged in the diagnosis and treatment of eye diseases.

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

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.
- 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

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.

2.2 Probes care

WARNINGS

Carefully read these warnings for probes care:

- When cleaning the probes, 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 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.
- The LIN 50MHz probe (BHF-50LIN) transducer is very fragile: do not touch it.

2.3 How to prevent a transfer of infection

WARNINGS
Read these warnings carefully regarding prevention of infection transfer:

- Probes must be disinfected before using them for the first time.
- Probes must be disinfected before each using with a disinfectant wipe.
- The LIN 50 MHz probe should be prepared / cleaned and disinfected / used according to the procedure provided with the LIN 50 MHz probe:
  Procedure for Linear 50MHz probes: Preparation - Cleaning and disinfection - Usability (Documentation code NI00045).

2.3.1 Pre-disinfection and disinfection procedures / Europe

WARNING
Between two patients, the probes and scleral shells must be cleaned and disinfected to prevent patient-to-patient transfer of infection. QUANTEL MEDICAL recommends cleaning procedures:

QUANTEL MEDICAL devices pre-disinfection and disinfection procedures.
(Documentation code XE_SDE_PR_AN).

This document is available in electronic format (PDF) in the ABSolu software.

2.3.2 Pre-disinfection and disinfection procedures / USA only

WARNING
Between two patients, the probes and scleral shells must be cleaned and disinfected to prevent patient-to-patient transfer of infection. QUANTEL MEDICAL recommends cleaning procedures:

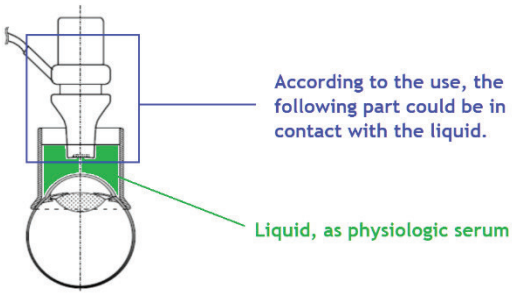
QUANTEL MEDICAL devices pre-disinfection and disinfection procedures.
(Documentation code XE_SDE_PR_AN).

This document is available in electronic format (PDF) in the ABSolu software.

CAUTIONS
Biometry (TP-01) / ProBeam (TP-02-Las) probes disinfection:

- When using the probe (with the "contact" technique), only the front face of the probe is in contact with the patient.
- When using the probe with a scleral shell, the physiological serum (or other liquid) is in contact with the front part of the probe: it is thus advised to disinfect the probe on the whole front part (or the entire probe).
- See the example below: the probe is used with a scleral shell (called immersion technique because the probe is not in direct contact with the patient but via a liquid):

Immersion Technique



- Protection against liquids: The probe is IPX7 except for the connector.

2.4 Probes storage after disinfection

After disinfection, probes must be stored in their probe holder, device must be stored in a dry and clean place and according to the Chapter II - Technical information Section 2.6 Environmental conditions.

After disinfection, shells must be stored in a dry and clean space device must be stored in a dry and clean place and according to the Chapter II - Technical information Section 2.6 Environmental conditions.

2.5 Finger cots for B probe

Finger cots are a simple way to prevent probe contamination.

WARNING
Finger cots are for single use only and must be replaced after each patient.

To use finger cots:

• Place a small amount of ultrasound gel on the B probe membrane.	
• Place the finger cot. The gel must ensure a good contact without air bubble.	
• Add gel to the probe tip before starting the examination.	

2.6 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.

2.7 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.

II – Technical information

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2018 CE 0459

Directive 93/42/EEC

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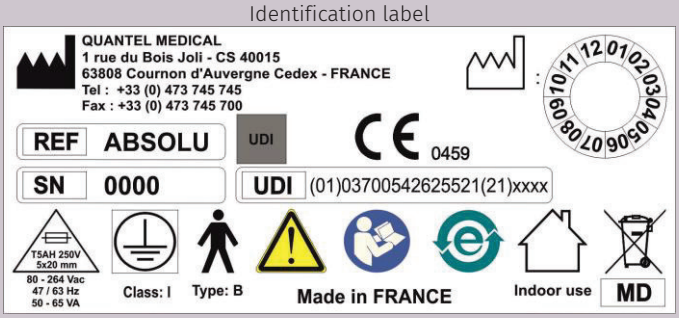
1. LABELS

NOTE
Images and diagrams are not contractual.

1.1 Back panel

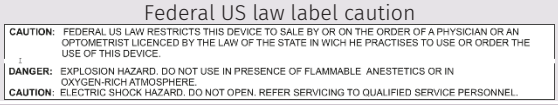
The table below provides a description to each label on the back panel.

Ref.	Label & Description
1	Identification label 

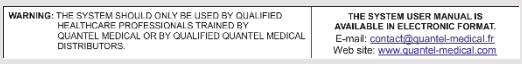
SDO established symbol	Standard containing the label	Title of the symbol & reference number	Explanatory text for the symbol
UDI	ISO 15223-1	Unique Device Identifier	Indicates the manufacturer's UDI for the medical device.
REF	ISO 15223-1	Catalogue reference N° ISO 7000-2493	Indicates the manufacturer's catalogue reference 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.
CE	93/42/EEC directive	CE conformity marking	-
	ISO 15223-1	Manufacturer N° ISO 7000-3082	Indicates the manufacturer of the medical device, as defined in European Directives 90/385/EEC, 93/42/EEC, and 98/79/EC.
	EN 60601-1	Type B applied part Ref.: CEI 60417-5840	-

		EN 60601-1	Earth of protection (ground) Ref.: CEI 60417-5019	-
		EN 60601-1	Refer to the instruction manual/brochure Ref.: ISO 7010-M002	-
	RoHS	2011/65/UE and 2015/863/UE	RoHS	RoHS Directive
		MCPCEIP	China ROHS	-
		ISO 15223-1	Manufacturing date N° ISO 7000-2497	-
		2012/19/EU directive	Symbol for EEE marking	Indicates the EEE are subject of a separate collection.
		EN 60601-1	General security sign N° ISO 7010-W001	-
		IEC60417-5957	For indoor use only	Identifies the electrical equipment designed primarily for indoor use.
	MD	ISO 15223-1	Medical Device	Indicates the item is a medical device.

2 Federal US law label caution


CAUTION: FEDERAL US LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN OR AN OPTOMETRIST LICENCED BY THE LAW OF THE STATE IN WICH HE PRACTISES TO USE OR ORDER THE USE OF THIS DEVICE.
DANGER: EXPLOSION HAZARD. DO NOT USE IN PRESENCE OF FLAMMABLE ANESTETICS OR IN OXYGEN-RICH ATMOSPHERE.
CAUTION: ELECTRIC SHOCK HAZARD. DO NOT OPEN. REFER SERVICING TO QUALIFIED SERVICE PERSONNEL.

3 "User Manual available in electronic format" label:
COMMISSION REGULATION (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices.


WARNING: THE SYSTEM SHOULD ONLY BE USED BY QUALIFIED HEALTHCARE PROFESSIONALS TRAINED BY QUANTEL MEDICAL OR BY QUALIFIED QUANTEL MEDICAL DISTRIBUTORS.
THE SYSTEM USER MANUAL IS AVAILABLE IN ELECTRONIC FORMAT.
E-mail: contact@quantel-medical.fr
Web site: www.quantel-medical.com

4 Brazil importation label


WARNING: THE SYSTEM SHOULD ONLY BE USED BY QUALIFIED HEALTHCARE PROFESSIONALS TRAINED BY QUANTEL MEDICAL OR BY QUALIFIED QUANTEL MEDICAL DISTRIBUTORS.
THE SYSTEM USER MANUAL IS AVAILABLE IN ELECTRONIC FORMAT.
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CAUTION: ELECTRIC SHOCK HAZARD. DO NOT OPEN. REFER SERVICING TO QUALIFIED SERVICE PERSONNEL.
Detentor do registro : **Mandala Brasil Importaçao de e Distribuiçao de Produto Médico Hospitalar LTDA**
ABSOLU
*Registro ANVISA: **80686369020***
Fabricante: **Quantel Medical - França**
INMETRO
Compulsório
Segurança

1.2 Right panel

Ref.	Label & Description			
1	Probes & footswitch connectors label			
	Options			
		Footswitch	15MHz probe (B1)	A probe	LIN 50MHz probe (BHF-50LIN)
	Options			
		Footswitch	15MHz probe (B1)	Standardized A probe	LIN 50MHz probe (BHF-50LIN)

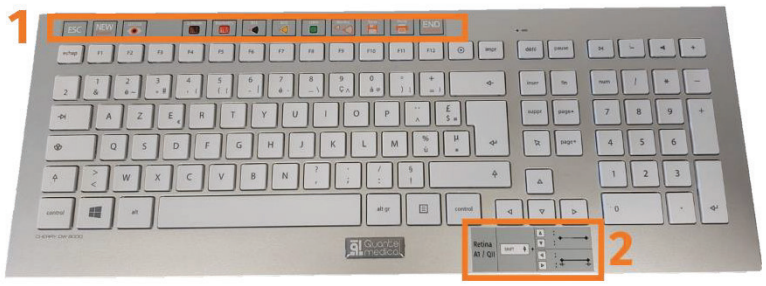
1.3 Left panel

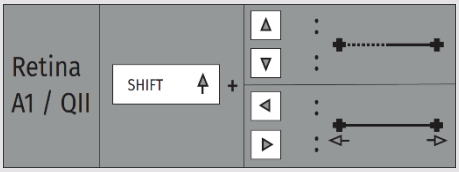
Ref.	Label & Description		
1	20MHz-5A Probe (B20-5A)		
	Options		
		20MHz-5A probe (B20-5A)	

1.4 Footswitch

Ref.	Label & Description
1	Quantel medical BY LUMIBIRD MEDICAL **IP44** (According to IEC 60529) Footswitch / Pédale : XE AAA PED
	IP44 (According to IEC 60529): - Protection against the penetration of foreign solid bodies of diameter Ø ≥ 1 mm. - Protection against splashing water.
	Electrical/electronic equipment in accordance with the Directive 2012 /19 / EU (WEEE) Do not dispose with domestic household wastes. 

1.5 Keyboard (option)

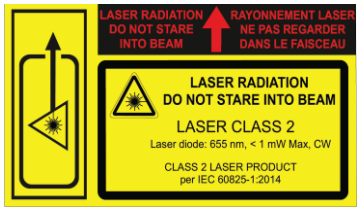
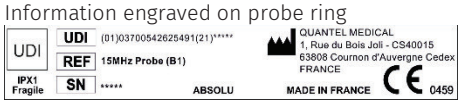
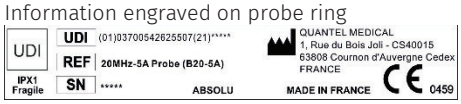
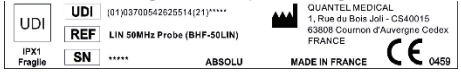


Ref.	Label & Description
1	Keyboard shortcut label*
	
2	Keyboard shortcut label for S mode*
	

*For more details about keyboard shortcuts, refer to ABSolu User Manual - Chapter V – General Setup & Maintenance - Section 1.10 – Keyboard shortcuts

1.6 Probes labels and marks

WARNING
The connector is not protected from liquid penetration.

Probe type	Labels	Pictures
STANDARDIZED A PROBE GTIN: 03700542625118	Information on probe: QUANTEL MEDICAL – FRAGILE IPX7 Ref: Std-A - 8 MHz	
REGULAR BIOMETRY PROBE GTIN: 03700542625095	Cable information: Unique Device Identification for the Biometry Probe (GTIN = 03700542625095) QUANTEL MEDICAL - FRAGILE IPX7 Ref: TP-01-b- 11MHz	
PROBEAM BIOMETRY PROBE GTIN: 03700542625101	Cable information: Unique Device Identification for the ProBeam Biometry Probe (GTIN = 03700542625101) QUANTEL MEDICAL – FRAGILE - IPX7 PROBEAM - Ref: TP-02-las - 11MHz	
	Laser radiation danger label (Avoid direct eye exposure)	
15 MHZ PROBE (B1) GTIN: 03700542625491	Information engraved on probe ring 	
20MHz - 5A PROBE (B20-5A) GTIN: 03700542625507	Information engraved on probe ring 	
LIN 50 MHZ PROBE (BHF-50LIN) GTIN: 03700542625514	Information engraved on probe ring 	

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	B (protection against electrical shocks)
Protection degree	IP20 (protection from solid substances > 12.5 mm)

2.2 Electrical requirements

Power supply	80V-264Vac
Frequency	47/63 Hz
Mains consumption	50 - 65 VA

WARNING
To avoid any risk of electric shock, this equipment must only be connected to supply mains with protective earth.

2.3 ABSolu computer system specifications

Processor	Intel i5-6300U 2.40 GHz (Dual Core,15W)
Memory	2x 8GB DDR42133MHz SDRAM
Graphics	Intel® HD Graphics 520
Storage HDD	2xSATA2.5" 1TB + 1 x 128GB SSD
Operating System	Windows 10 Enterprise LTSC 1809
Display	Display type: 21.5" LED backlight (16:9)
	Display type: 21.5" LED backlight (16:9)
Peripherals	Ethernet: 2 x Gigabit Ethernet (1.5KV isolated) interface (RJ-45) 4 x USB3.0 1 x USB2.0 1 x HDMI 1 x power connector (internal 12-24VDC)

2.4 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 60 601-2-37	Medical electrical equipment-Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.
IEC 62 366	Medical devices – Application of usability engineering to medical devices
IEC 62 304	Medical device software – Software life cycle processes (IEC 62A/474/CDV)
ISO 14 971	Medical devices – Application of risk management to medical devices
93/42/EEC & amendment	Medical devices – Medical devices directive

WARNING
Precautions to take with other devices using power supplies: the ABSolu conforms to IEC standard 60 601-1 (electric compatibility). All the other devices used in conjunction with the ABSolu must be conformed to this standard.

CAUTION
Precautions to take to avoid electromagnetic interferences with other devices: the ABSolu conforms to IEC standard 60 601-1-2 (electromagnetic compatibility). Make sure that all other devices used in the same room are in accordance with this standard.

2.5 Dimensions

Width Min = 54,5 cm (21,46 in) (Without probe holders)

Width Max = 84,0 cm (33,07 in) (With probe holders)

Depth: 28,5 cm (11,22 in)

Height: 44,5 cm (17,52 in)

Weight: 10,6 kg (23,37 lbs.) (without probes)

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 Probes specifications

2.8.1 Biometry probe (option)

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 mm2
Axial resolution	0.15 mm (at – 6 dB)

2.8.2 Standardized A probe

Probe Reference	STD-A
Frequency	8 MHz
Focal Length	Non focused
Emission running mode	Pulsed
Emission Repetition Rate	67 Hz
Axial resolution	0.2 mm (at – 6 dB)

2.8.3 15MHz Probe (B1) (option)

Probe Reference	15MHz Probe (B1)
Sector angle	50°
Frequency	15 MHz
Emission-running mode	Pulsed
Emission Repetition Rate	2720 Hz
Focal length	23 mm to 25 mm
Active diameter	7.5 mm
Active surface	44 mm²
Axial resolution	115 µm (at -6 dB)
Lateral resolution	400 µm (at -6 dB)

2.8.4 LIN 50MHz Probe (BHF-50LIN) (option)

Probe Reference	LIN 50MHz Probe (BHF-50LIN)
Scanning amplitude	16 mm
Frequency	50 MHz
Emission Repetition Rate	3413 Hz
Focal length	9 mm to 11 mm (transducer)
Axial resolution	35 µm
Lateral resolution	60 µm

2.8.5 20MHz-5A Probe (B20-5A) (option)

Probe Reference	20MHz-5A Probe (B20-5A)
Sector angle	50°
Frequency	20 MHz
Emission-running mode	Pulsed
Emission Repetition Rate	21600 Hz
Focal length	22 mm
Active diameter	9 mm
Axial resolution	80 µm
Lateral resolution	200 µm

2.9 ABSolu measurements accuracy

2.9.1 ABSolu electronic resolution for the echograms

	B15 (B1) (Orbit/Long Vitreous)	B15 (B1) (Eye/Vitreous)	B20-5A (Eye)	B20-5A (Vitreous)	Lin50 (BHF-50LIN)
Points in X axis	1500	2133	2000	2000	2048
Points in Y axis	256/160	256/160	450	270	384
Electronic resolution	0.05 mm at 1550 m/s	0.025 mm at 1550 m/s	0.02 mm at 1550 m/s	0.02 mm at 1550 m/s	0.01 mm at 1550 m/s

2.9.2 Accuracy in A mode

The accuracy is achieved by the electronic resolution: ± 0.04 mm. The overall precision in A mode depends on these parameters:

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

2.9.3 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.

2.10 Physiological limits of measurement

Physiological limits of measurements (auto)		Minimum (mm)	Maximum (mm)
Phakic mode	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 mode	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 mode	Total length at 1532 m/s	14	45

C = Cornea; AC = Anterior chamber; L=Lens; V= Vitreous

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 80mm.

2.11 ABSolu software

2.11.1 General

Number of user data files with personal IOL files	No limitation (Only depends on the database maximum size)
Patient data files	Database on the computer

2.11.2 A-Std mode acquisition

Displayed depth preset	Orbit: 80 µs / Eye: 40 µs Zoom: 20 µs
Axial-length acquisition technique	Immersion / Immersion basic
Acquisition mode	Manual only
Eye type selection	Phakic / Dense-Long / Aphakic / PMMA / Acrylic / Silicone
Vitreous selection	Silicone 1000 / Silicone 5000
Number of echograms per result table	Lesion Q-I: 10 / Retina A1: 1 Retina Q-II: 3 / Muscle profile: 6 / optic nerve: 2 Axial length: 10
Statistical algorithm	Axial length: Average, STAT-2 and Standard deviation Muscle profile: SNI / MI
Dynamic display	Fixed dynamic at 50 dB

2.11.3 Axial length acquisition

Displayed depth preset	60 mm / 80 mm Continuous adjustable zoom
Axial-length acquisition technique	Contact & Immersion
Acquisition mode	Auto + Save / Auto / Manual
Eye type selection	Phakic / Dense-Long / Aphakic / PMMA / Acrylic / Silicone
Vitreous selection	Silicone 1000 / Silicone 5000
Number of echograms per eye	10
Statistical algorithm	Average, STAT-2 and Standard Deviation
Adjustable dynamic display	From 20 to 90 dB with D1 mode From 15 to 25 dB with D2 mode

NOTE
In Bio B mode, the eye type selection and vitreous selection are only available. Acquisition technique and acquisition mode are not available.

2.11.4 B scan diagnostic imaging

Displayed depth preset:	B15: 40 mm / 60 mm B20-5A: 40 mm only Lin50: 20 mm only Continuous adjustable zoom
B-Scan image with CV (with A-scan crossing vector)	Unlimited
Tool measurement	Unlimited
Variable gain on a frozen image	From 20 dB to 110 dB
Displayed adjustable dynamic	From 20 to 90 dB
Cineloop:	Up to 400 images can be stored. It is possible to display the Cineloop images in sequence or one by one.

2.11.5 IOL calculation

Per eye, four IOL calculations on the screen.

Number of formulae:

6 IOLs formulae	• Binkhorst II • SRK-II • SRK-T • Holladay • Hoffer-Q • Haigis
For Post-Refractive surgery eyes	• Double-K / SRK-T from Dr Aramberri • History Derived • Refraction Derived • Rosa Regression • Shammas Regression • Contact Lens.

2.11.6 Documentation

The images are saved inside the patient database. It is possible to print the reports on the printer connected to the PC. For a better quality, it is recommended to print on a laser printer with photo-quality paper. It is also possible to directly print the images on an USB video printer.

2.11.7 Data entry limits

The ABSolu will accept values within the ranges listed below as valid data entries. 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: a0	-10	+10
Constant for Haigis formula: a1, a2	-1	+1
Haigis constants: combined limits for a (1.16 to 7mm) ACD range	$-2 < a_0 + 3.37\ a_1 + 23.39\ a_2 < 12$ $-2 < a_0 + 2.53\ a_1 + 20.00\ a_2 < 12$ $-2 < a_0 + 3.50\ a_1 + 27.00\ a_2 < 12$	
Anterior Chamber in STS mode (automatic detection at1532m/s)	1.4 mm	5.5 mm
Lens in STS mode (automatic detection @1641m/s)	0.96 mm	6.0 mm
STS distance in STS mode (automatic detection @1550m/s)	5.9 mm	15.5 mm

2.12 Tissue exposure to ultrasound energy

The ABSolu unit is designed for use in ophthalmology only.

WARNING
This device is not intended for fetal use.

2.12.1 ALARA (as low as reasonably achievable)

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 on centimeters, which is the point of measurement.

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

2.12.2 Sonic values

Transducer parameters show considerable variation from transducer to transducer. The measured and calculated values given in the sections below (2.12.2.1 / 2.12.2.2 / 2.12.2.3 / 2.12.2.4 / 2.12.2.5 / 2.12.2.6) 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 < 190W/cm2
$P_{R.3}$	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, fc 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).

2.12.2.1 A-Scan probe

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

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

Acoustic output			MI	$I_{SPTA.3}$ (mW/ cm^2)	$I_{SPPA.3}$ (W/ cm2)
Maximum value			0.160	0.140	
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	(µm)			
	PRF	(Hz)			
	EBD	Az (cm)			
		E1 (cm)			

NOTE
All acoustic values can be provided upon request. Please contact QUANTEL MEDICAL Service Department or your local distributor.

2.12.2.2 Standardized A probe

Probe reference	STD-A
Type	A-Scan
Material	PZT ceramic
Frequency	8 MHz
Application	Ophthalmic Biometry
Thermal index (T.I.)	<1

Ultrasonic intensities in tissue at measured transducer focus.

Acoustic output			MI	$I_{SPTA.3}$ (mW/ cm²)	$I_{SPPA.3}$ (W/ cm2)
Maximum value			0.19	1.08	
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	(µm)			
	PRF	(Hz)			
	EBD	Az (cm)			
		E1 (cm)			

NOTE
All acoustic values can be provided upon request. Please contact QUANTEL MEDICAL Service Department or your local distributor.

2.12.2.3 15MHz probe (B1) (option)

Probe reference	15MHz Probe (B1)
Type	B-Scan
Material	Composite material
Frequency	15 MHz
Application	Ophthalmic
Thermal Index (T.I.)	<1

Ultrasonic intensities in tissue at measured transducer focus (about 24mm from probe tip).

Acoustic output			MI	$I_{SPTA.3}$ (mW/ cm²)	$I_{SPPA.3}$ (W/ cm2)
Maximum value			0.118	1.117	
Associated Acoustic Parameters	$P_{r.3}$				
	W_0				
	f_c				
	Z_{sp}				
	Beam Dimension				
	PD				
	PRF				
	EBD				

NOTE
All acoustic values can be provided upon request. Please contact QUANTEL MEDICAL Service Department or your local distributor.

2.12.2.4 LIN 50MHz probe (BHF-50LIN) (option)

Probe reference	LIN 50MHz Probe (BHF-50LIN)
Type	B-Scan
Material	Composite material
Frequency	50 MHz
Application	Ophthalmic
Thermal Index (T.I.)	<1

Ultrasonic intensities in tissue at measured transducer focus.

Acoustic output			MI	$I_{SPTA.3}$ (mW/ cm²)	$I_{SPPA.3}$ (W/ cm2)
Maximum value			0.042	0.006	
Associated Acoustic Parameters	$P_{r.3}$				
	W_0				
	f_c				
	Z_{sp}				
	Beam Dimension				
	PD				
	PRF				
	EBD				

NOTE
All acoustic values can be provided upon request. Please contact QUANTEL MEDICAL Service Department or your local distributor.

2.12.2.5 20MHz-5A probe (B20-5A) (option) (USA only)

Probe reference	20MHz-5A Probe (B20-5A)
Material	Composite material
Frequency	20 MHz
Application	Ophthalmic
Thermal Index (T.I.)	<1

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

Acoustic output			MI	$I_{SPTA.3}$ (mW/ cm²)	$I_{SPPA.3}$ (W/ cm2)
Maximum value			0.22	0.44	
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	(µm)			
	PRF	(Hz)			
	EBD	Az (cm)			
		E1 (cm)			

NOTE
All acoustic values can be provided upon request. Please contact QUANTEL MEDICAL Service Department or your local distributor.

2.12.2.6 20MHz-5A probe (B20-5A) (option) (rest of the world)

Probe reference	20MHz-5A Probe (B20-5A)
Material	Composite material
Frequency	20 MHz
Application	Ophthalmic
Thermal Index (T.I.)	<1

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

Acoustic output			MI	$I_{SPTA.3}$ (mW/ cm^2)	$I_{SPPA.3}$ (W/ cm2)
Maximum value			0.35	0.57	
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	(µm)			
	PRF	(Hz)			
	EBD	Az (cm)			
		E1 (cm)			

NOTE

All acoustic values can be provided upon request. Please contact QUANTEL MEDICAL Service Department or your local distributor.

3. EMC DATA AND GUIDELINES

WARNING
Carefully read these warnings concerning EMC data and guidelines:

- Medical electrical equipment needs special precautions regarding EMC. The following EMC guidelines must be observed during installation and commissioning of the ABSolu.
- Portable and mobile RF communications equipment can affect medical electrical equipment.

Guidance and manufacturer's declaration – electromagnetic emissions		
The ABSolu is intended for use in the electromagnetic environment specified below. The operator of the ABSolu has to make sure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment - Guidance
RF emission acc. to EN 55011	Group 1	The ABSolu uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to impair nearby electronic equipment.
RF emissions acc. to EN 55011	Class A	The ABSolu is suitable in all establishments other than those in living areas and those directly connected to the public low voltage power supply network that also supplies buildings used for living.
Harmonic emissions acc. to IEC 61000-3-2	Class A	
Voltage fluctuations / Flicker emissions acc. to IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The ABSolu is intended for use in the electromagnetic environment specified below. The operator of the ABSolu has to ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the ABSolu, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Conducted RF disturbances according to IEC 61000-4-6	3 Veff 150 kHz to 80 MHz	10 V	d=0.35√P
Radiated RF disturbances according to IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	10 V/m	d=0.35√P for 80MHz to 800MHz d=0.35√P for 800MHz to 2,5GHz
			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: 
NOTE 1: At 80 MHz and 800 MHz the separation distance for the higher frequency range applies. NOTE 2: This guidance 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 ABSolu is used exceeds the applicable RF compliance level above, additional measures may be necessary, such as reorientation or relocating the ABSolu. In case unusual performance is witnessed, additional measures may be required such as change of orientation or location of the ABSolu. [b] Field strength should be less than 3 V/m in the range between 150 kHz and 80 MHz			

Recommended separation distances between portable and mobile RF communications equipment and the ABSolu			
The ABSolu is intended for use in an electromagnetic environment in which the radiated RF disturbances are controlled. The ABSolu user can help prevent electromagnetic interference by maintaining a minimal distance between portable and mobile RF communications equipment (transmitters) and the ABSolu 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√P	80 MHz to 800 MHz d=0.35√P	800 MHz to 2,5GHz d=0.7√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
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			

Guidance and manufacturer declaration – electromagnetic immunity			
The ABSolu is intended for use in the electromagnetic environment specified below. The operator of the ABSolu has to ensure that it is used in such an environment.			
Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment - Guidance
Electrostatic discharge (ESD) acc. to IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic materials, the relative humidity should be at least 30%.
Electrical fast transients/ burst acc. to IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	The quality of the supply voltage should correspond with one characteristic for a typical commercial or hospital environment.
Surge acc. to IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	The quality of the supply voltage should correspond with one characteristic for a typical commercial or hospital environment.
Voltage dips, short-term interruptions, and voltage variations on power supply input lines acc. to 61000-4-11	<5% during 0,5 period 40% during 5 periods 70% during 25 periods <5% during 5 s	<5% during 0,5 period 40% during 5 periods 70% during 25 periods <5% during 5 s	The quality of the supply voltage should correspond to one characteristic for a typical commercial or hospital environment. If the user of the ABSolu requires a continuous function of the appliance also during interruptions of the power supply, it is recommended to supply the ABSolu out of an uninterruptible power supply or a battery
Power frequency (50/60Hz) magnetic fields acc. to IEC 61000-4-8	3 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic for commercial or hospital environments

4. UNIT DESCRIPTION

4.1 Front panel description

Ref.	Description
1	Probes holder: 20MHz-5A probe (B20-5A) & Biometry probe Biometry test block (10mm at 1550m/s)
	NOTE: When using a Standardized probe on ABSolu S, the tissue model is placed as indicated below.
	
2	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. • press the knob to select another marker.
3	21.5'' Color LCD LED screen
4	Probes holder: 15MHz probe (B1) & LIN 50MHz probe (BHF-50LIN)

4.2 Right panel description

WARNING
Do not force on the connectors.

Ref.	Connector	Description
1	Footswitch	The footswitch connector is an Audio type connector.
2	15MHz probe (B1)	To avoid installation errors, each probe type has a specific connector shape that can only match its corresponding connector onto the Emitter Receiver boards. The probe type can be identified looking at its ring color and label. Refer to Section 1.2 Right panel.
3	Biometry probe	The biometry probe has a LEMO four-pin connector. It is a push-pull type connector with a locking system.
4	LIN 50MHz probe (BHF-50LIN)	See Description for reference 2, 15MHz probe (B1)

4.3 Left panel description

WARNING
Do not force on the connector.

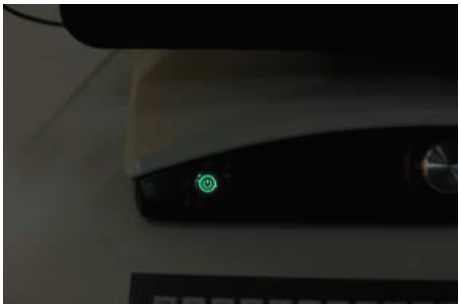
Ref.	Connector	Description
1	20MHz-5A probe (B20-5A) connector	The probe type can be identified looking at its ring color and label. Refer to Section 1.3 Left panel.
2	USB port	1 x USB2.0.

4.4 Back panel description

> Switch the main switch to **1** to power on the unit, or

> Switch the main switch to **0** to turn it off.

Before switching the main switch to **0**, make sure all applications are closed and the PC is turned off. This can be done by using the Windows 10 closing process or by pressing the **Start / Stop** button on the front panel of the device.



When the PC shutdown process is completed, the LED button turns orange.

With the front LED button in this orange color status, the main switch can then be switched to **0** to power off the system.

This will prevent any PC malfunction as well as any unfortunate loss of data from the database.

4.5 Under the screen

1	USB 3.0 connectors	There are 4 USB connectors: which can be used to connect a printer, a data storage key, or an external keyboard
2	HDMI connector	This connector can be used to connect the ABSolu to a High-Definition Multimedia Interface
3	Network connector (RJ-45)	This connector can be used to connect the ABSolu to a network

5. INSTALLATION: TECHNICAL INFORMATION

5.1 Probe holders assembling

CAUTION

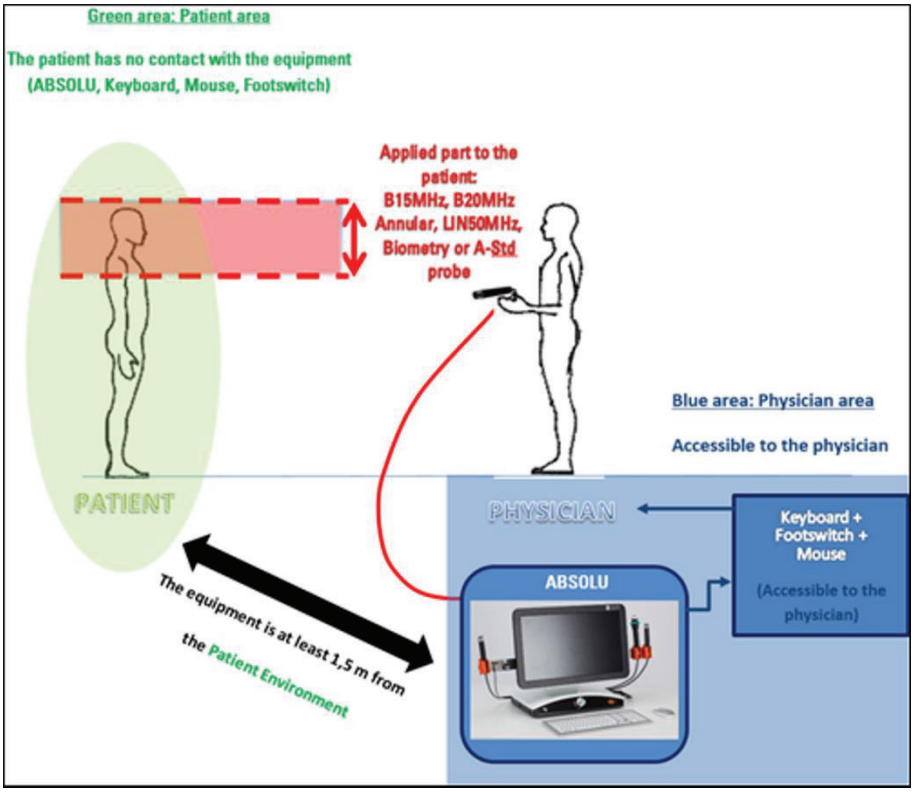
Before any intervention on the device, switch off the ABSolu device as described in Section 4.4 Back panel description and unplug the mains cord (behind the unit). Disconnect all probe connectors and footswitch.

Two probe holders can be assembled to the unit depending on the available probes.

To affix the holders to the ABSolu main frame:

1. Take the probe holders (left and right) and the hexagon socket screws delivered with the ABSolu unit.
2. Slide the probe holders in the corresponding guides on the ABSolu unit back panel as indicated below and screw on the hexagon socket screw with an Allen key.

5.2 Patient exam area



Applied part to the patient:

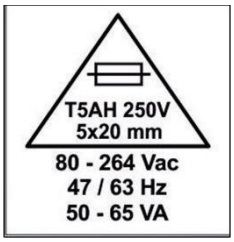
The probes area corresponding to the applied part is indicated with the blue color mark underneath.

BIOMETRY PROBE (Tp-01-b-11MHz)	
PROBEAM BIOMETRY PROBE (Tp-02-las-11MHz)	
STANDARDIZED A-SCAN PROBE (Std-A - 8 MHz)	
15MHz PROBE (B1) OR 20MHz-5A PROBE (B20-5A) :	
LIN 50MHz PROBE (BHF-50LIN)	

5.3 Power supply

WARNING
To avoid any risk of electric shock, this equipment must only be connected to supply mains with protective earth.

The power supply has to respond to the following specifications:



5.4 Probes and footswitch connectors

All probes and footswitch connectors are located on the right panel of the ABSolu unit. To avoid wrong connections, each connector has a different shape.

WARNING
Do not force on the connectors.

> Connect probes on the right and left panels as indicated in section 4.2 Right panel description and 4.3 Left panel description.

5.4.1 Footswitch connection

The footswitch connector is and Audio-type connector.

5.4.2 Biometry probes connection

The Biometry probes are equipped with a push-pull type connector with a locking system.

> Before inserting the connector, rotate it slightly to find the good position.

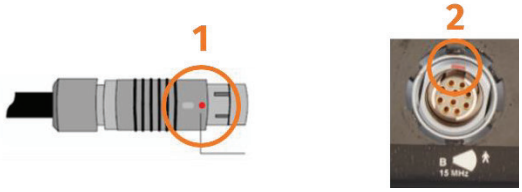
> To disconnect the probe, pull the connector body (instead of the cable).

5.4.3 B probes connection

To avoid installation errors, each probe type has a specific connector shape that can only match its corresponding connector onto the Emitter Receiver boards.

The probe type can be identified via its ring color and label. Refer also to section 1.6 Probes labels and marks.

Connections locations on the board



1. Connect the B probes to their corresponding spot on the Emitter Receiver boards. Use the red dots on the connectors.
2. Make sure the probe connector red dot matches the red marking above the connector.
3. To enable connection, position the connector so that the red dot is directed upward.

5.5 USB, Network, HDMI connections

The USB port, Network port (RJ45) and HDMI port are located under the screen of the ABSolu unit.

CAUTION
The Network RJ45 cable length must be less than 30m.

CAUTION
Be cautious when connecting devices other than the ones provided with the ABSolu by QUANTEL MEDICAL.

> Move the screen in the backward position to have access to the different ports.

The USB ports are used to connect the following peripherals:

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

Refer also to Section 4.5 Under the screen.

To comply with the IEC 60 601-1 Standard for “Medical Systems”, the configuration must respect the following regulations:

- Accessories installed in the “Patient Environment” are considered medical devices and must comply with the IEC 60 601-1 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.
- Non-medical electrical equipment may be connected to the ABSolu 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.

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.

III – Using the ABSOLU

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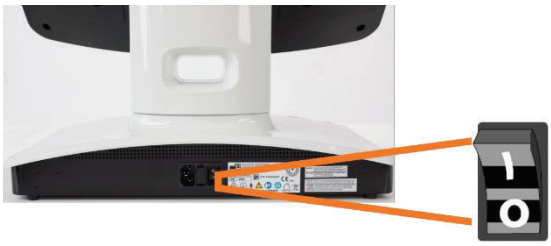
2018 CE 0459
Directive 93/42/EEC

TABLE OF CONTENTS

1. STARTING UP THE SYSTEM

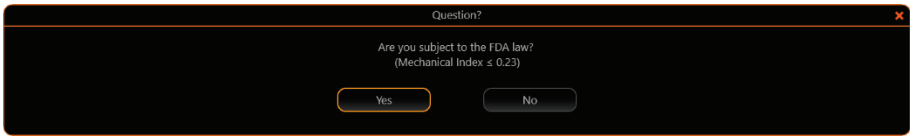
1.1 Main switch

The main switch on the back panel of the ABSolu allows the user to supply power to the system. When it is turned on (I position), the orange LED startup button on the front panel lights up.



1.2 Switch on the ABSolu

1. Press on the orange startup button to boot up the system. The LED startup button turns green. The first time you turn on the device, this message will appear:

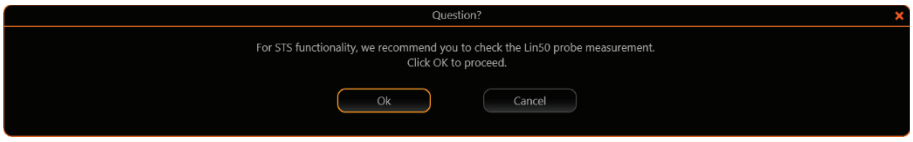


2. Respond to the question, depending on the geographical region:
   - For USA, click **Yes**. The US values will be set. Refer also to ABSolu User Manual – Chapter II – Technical information Section 2.11.2.5 20MHz-5A probe (B20-5A) (option) (USA only)

   OR
   - For all countries except USA, click **No**. The according values will be set. Refer also to ABSolu User Manual – Chapter II – Technical information Section 2.11.2.6 20MHz-5A probe (B20-5A) (option) (for the rest of the world).

   OR
   - Close the dialog box (**X**). This message will reappear every time the device is turned on.

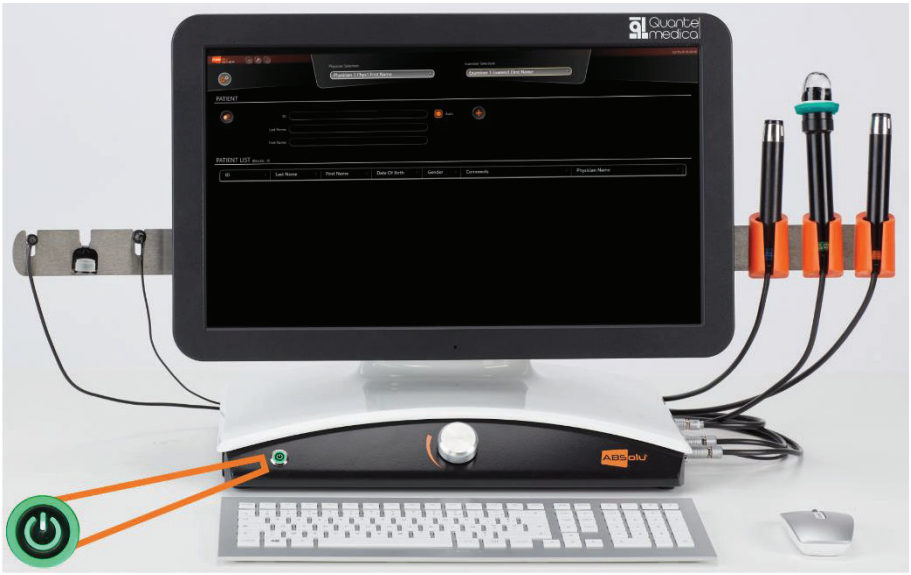
   If the STS option is activated in the keycode, the next message will appear:



3. Respond to the question:
   - Click **OK**. The **STS Probe Checking** dialog box appears. Refer to section ABSolu User Manual – Chapter V - General Setup & Maintenance.
   - Click **Cancel**. The STS functionality can be activated later.
   - Close the dialog box (**X**).

NOTE
To use the probe for sizing, the probe calibration should systematically be checked. Refer to ABSolu User Manual – Chapter V - General Setup & Maintenance.

When startup and/or STS probe check completed, the **Welcome** screen is displayed.



2. WELCOME SCREEN

The Welcome screen is the starting point for physician and data entry.

2.1 Selecting a Physician and Examiner name

To start the exam, a Physician name and an Examiner name should be selected.

1. Select a Physician name from the Physician drop-down list.
2. Select an Examiner name from the Examiner drop-down list.

To create a new physician or examiner, refer to ABSolu User Manual – Chapter V - General Setup & Maintenance - Section 1.2. - User Management.

2.2 Selecting /Creating a Patient

Select a patient from the database or create a new patient file.

2.2.1 Selecting a Patient from the database

> To search for a Patient in the database:
  - Type in the first known digit for the ID, Last Name or First Name and press “Enter”.
  - The PATIENT LIST will then display all Patients corresponding to this criterion.

> Type ‘*’or ‘%’ in any of those fields to display the complete Patient list with all names.

Before performing a new search, reset all fields using the Eraser.

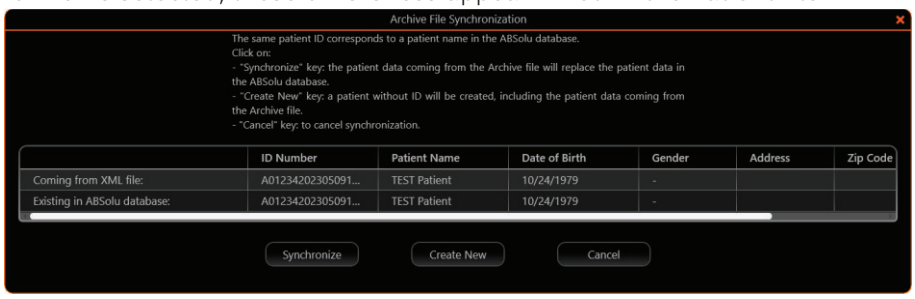
To search in the DICOM database, the DICOM option must be activated. Then, the following icon allows the user to search for a Patient in the DICOM database. Refer to ABSolu User Manual – Chapter IV – DICOM option.

NOTE: If the option is activated in the keycode, Patient files in .absir or .xml format can be imported to the ABSolu database. The default folder path is set in the Main Settings in the General Setup..

In case the ID is the same, but at least one piece of Patient data is different (e.g., first name, last name, date of birth, gender) between the file to import and the ABSolu database, a “Select a Patient” window appears.

- If the Patient to be imported is not the same as in the ABSolu database, a new patient file can be created.
- If the Patient to be imported is the same as in the ABSolu database, the patient information can be synchronized. The information from the import file will be transferred and updated in the ABSolu database.

In the “File synchronization” window, any differences will be displayed in red. When “Synchronize” is selected, these differences appear in red in the Patient file



2.2.2 Creating a new patient

1. To create a new Patient, enter the Patient Last Name and First name in the corresponding fields.

2. Click (+) to enter all Patient information. The following screen is then displayed.

2.2.2.1 Patient information

The following Patient information fields can be filled in:

- Patient Gender and Date Of Birth (the Patient age is then automatically displayed).
- Address, Zip code, City, Phone number and other Comments.

Patient ID

- If the Auto checkbox is selected, the ID is automatically generated by the system and will not be modifiable.
- If the user wants to enter a specific ID, this box should be left unchecked.
- To create a Patient file, it is mandatory to enter an ID (automatic or manual).

2.2.2.2 Keratometry

The screen is separated into 2 columns: right eye (OD) and left eye (OS). For each eye, the following Patient data can be filled in:

Parameter	Description
Ame	Enter the Patient eye Ametropia value. The possible range for the Ametropia field input is: -20 to +20 Diopters.
Refraction Data	KERATOMETRY MEASUREMENTS Enter the Keratometry measurements in the corresponding fields: Enter K1 and eventually K2 if the measurement is different. The Keratometry average value for the selected eye is performed and displayed. The possible range for the Keratometry data field input is: 5 to 13 mm (or 25 to 68 Diopters). K1 and K2 must be entered in the same unit mm or Diopters CAUTION: For Haigis Formula users, it is necessary to enter the Keratometry in mm, especially if the index value, used by the Keratometer is not known. If the values are entered in Diopters, the following warning message will be displayed: Warning: the K values have to be filled in mm to use Haigis Formula REFRACTION DATA When the Refraction Data checkbox is selected, all of the following refraction data can be entered: Axis values for K1 and K2 (positive values ranging from 0 to 180° - by step of 1°) Sphere value (from -40.00D to 20.00D – by step of 0.01) Cylinder value (from -40.00D to 20.00D – by step of 0.01) Cylinder axis value (positive values ranging from 0 to 180° - by step of 1°) NOTE: The refraction data are for information only: they are not used for calculation. Those values are displayed in the IOL report.
Refraction surgery case: enter available data	REFRACTIVE SURGERY CASE All available Post Refractive calculations data can be filled in: • Pre-Op Keratometry. • Pre-Op Refraction • Post-Op Refraction • Contact Lens Curve • Refraction with the Contact Lens. NOTES: The Post-Op Refraction might easily be determined using the last spectacles correction.

	The actual Refraction may be modified by a cataract: in this case, the direct evaluation can be altered. Only known information should be entered Different IOL determination methods and formulas are then available, depending on the existing patient information. For more information, please refer to the ABSolu User Manual – Chapter VI – Appendix: IOL formulae

2.2.3 Saving Patient data before a new exam session

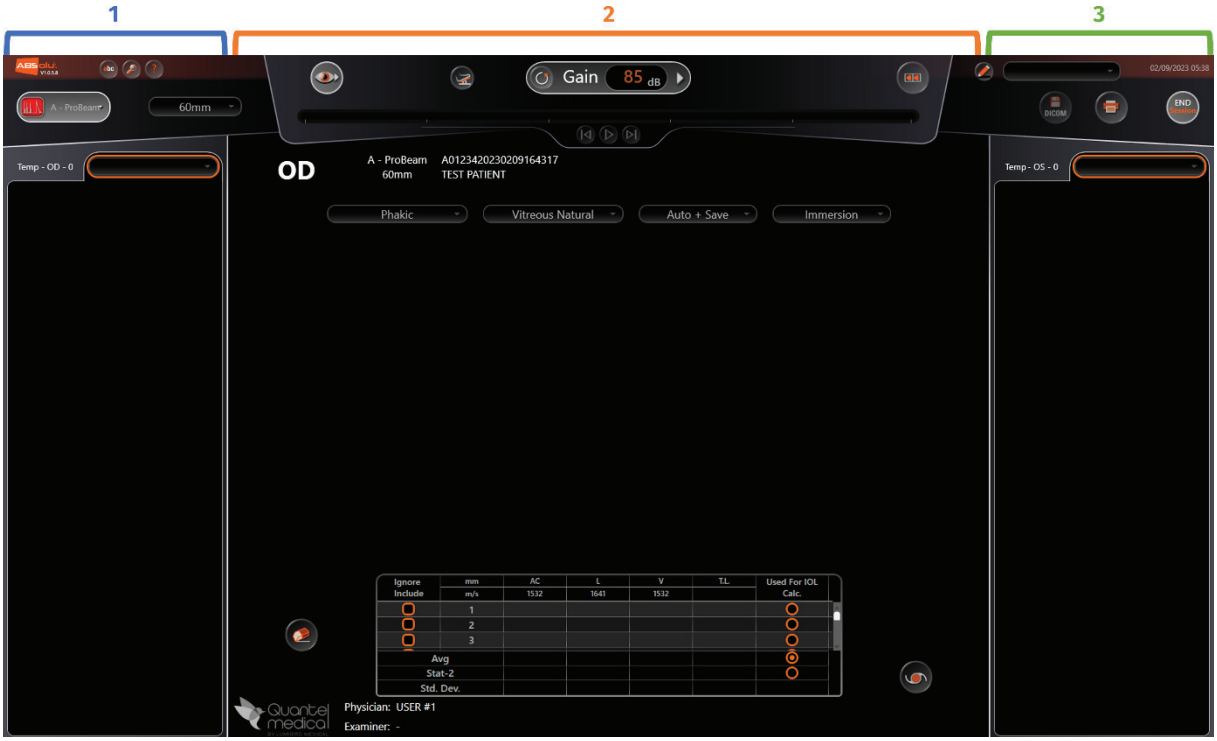
> Save all updated Patient data using the **Save** icon:

> To perform a new exam session for the selected Patient, select:

2.2.4 Other Patient screen functionalities

Icon	Functionality
	Escape a Patient file to return to the Welcome screen. When modifications are made without saving them, a dialog box appears.
	Erase a Patient file. When a Patient file is erased: all corresponding exams are definitively deleted.
	This function allows the user to access all documents for the selected Patient: • Draft documents: all saved documents, not yet printer, nor exported • Official documents: all exported or printed documents 
	Access the **General Setup** screen: Refer to ABSolu User Manual – Chapter V - General Setup & Maintenance

3. EXAM SCREENS: GENERAL FUNCTIONALITIES



Pre-exam area (1)

Allows to select the probe before making the acquisition.

Per exam area (2)

Allows to adjust the image settings: Gain, Dyn, TGC etc. during the acquisition.

Post exam area (3)

Allows to add comments, tools, save, and print after the acquisition.

NOTE
To access the Exam screen, first select a Patient name or at least an ID value.

3.1 Probe selection

To perform an exam, select the corresponding probe:

- A-Bio or A-ProBeam or Bio-B (biometry guided with B15 or B20 probe) to perform an exam in Biometry mode.
- B15 to perform an exam in B-SCAN mode (image of the eye and orbit) or Bio-B mode.
- B20 to perform a high frequency mode exam with the B 20MHz Annular probe (high resolution image of the eye and orbit) or Bio-B mode.
- LIN50 to perform a high frequency mode exam or an STS (sulcus-to-sulcus) exam with the Linear 50MHz probe (high resolution image of the anterior chamber).
- A-Std to perform a standardized mode exam.

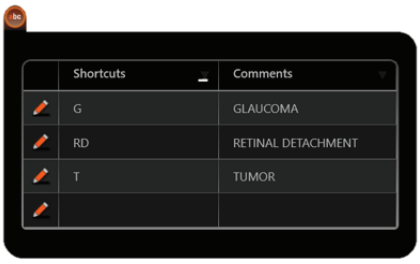
NOTE
These functionalities depend on the activated options, with the keycode and the number of installed probes.

3.2 Comments shortcut list

The Comments Shortcuts list enables to quickly add recurring comments to exams.

> Select the icon:

The following window is displayed:



> Enter shortcuts and associated comments. Each shortcut and comment must be unique.

> Right-click in a shortcut or comment to delete it.

3.3 Search tool

The Search tool enables to easily search information in the ABSolu database based on selected exam criteria. Follow these steps to perform a search.

1. Click the Search icon.

The following window is displayed.

The table below explains how to use the Search tool window.

Step 1	Step 2	Step 3	Step 4
Select search criteria.	Validate selected search criteria one by one using the orange arrow.	Validated criteria are displayed. For each of them, fill in the fields.	Run the search.

The search result list is then displayed in the left side of the screen.

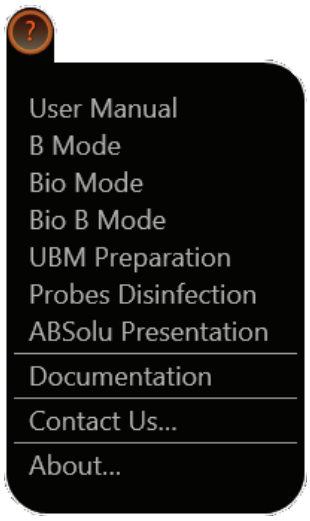
2. Choose one of the following actions:
   - Select a search entry to display the scan image on the right side of the screen. Then right-click in an image to select these options:
     - Go to Exam.
     - Export to JPEG with or without anonymized User and/or Patient information.
     - Hotline Export.

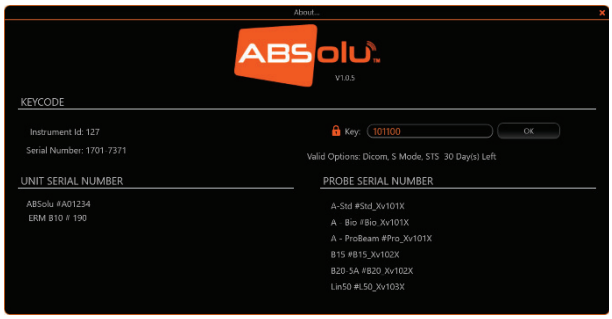
   OR
   - Double-click a search entry to directly access the Exam screen.
3. To reset a search query, use the Eraser:

3.4 Other functionalities

Click the Question mark:

The following menu is displayed:



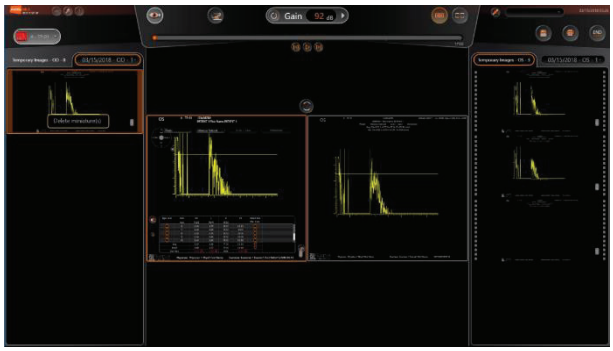
Function	Allows user to:
User manual Link Bio B Link	The user manual and other documentation links are accessible to the user by selecting the corresponding link.
Documentation	Save new documentation links clicking the (+) option. Then import a documentation file, enter a file name, and select a language. Added documentation files must be copied in D:\Quantel\Documentation\User Files
Contact Us...	
About	This window displays: • The ABSolu unit Serial Number • Emitter Receiver board(s) Serial Number(s) • Probes Serial Number At the user's request, QUANTEL MEDICAL can generate a keycode using the unit Serial Number and Instrument ID. DICOM, S mode, STS, Import XML, and Shared Database options can be activated by entering the correct keycode in the keycode field.
	

3.5 Exam functionalities

This section explains generic exam functionalities available in the ABSolu unit and details the use of the Cineloop function.

3.5.1 Generic exam functionalities

Icon	Functionality
	Select the left or right eye by clicking on the eye icon. In case the wrong eye type was selected during examination, user can change the eye on a saved exam. In this case, a warning message is displayed to make sure the eye selection is changed on purpose for error rectification. Reports created with the wrong eye selection will automatically be deleted. In case of IOLs calculations: they will have to be redone on the biometry exam with corrected eye. Important: following this action, the user has to verify the concerned images and Cineloop have been correctly modified.
	
	To start / stop the acquisition.
	The knob allows the user to: • adjust the default gain (during acquisition). • adjust all the numeric fields as described in the next functions (Gain, Dyn, TGC). • select the next “marker” in biometry / Bio B mode (when pressing the knob). • adjust the position of the CV line as described in the next function: CV • adjust the position of the markers in biometry.
	 Select the Gain, Dynamic (Contrast) and TGC fields to adjust the acquisition signal display. TGC stands for Time Gain Control. It is used to reduce the Gain at the beginning of the echoes and progressively recover the whole Gain at approximatively 20mm for B15 (23mm) and B20-5A (18mm) probes, 8mm for LIN50 and 25mm for Bio. When selecting one of those numeric fields, use the numeric keyboard, the mouse scroll or use the ABSolu front knob to change values.
	User can reset the Gain, Dyn and TGC parameters to their default values. This depends on the parameters in the probe settings. (e.g., Gain: 110dB, Dyn: 70dB and TGC: 10dB).
	The Pin icon allows the user to keep the menu displayed.

	The icon allows the user to display 2 exams scans (OS / OD):  NOTE: if there is a measure difference superior or equal to 0.3 mm between the OD exam and the OS exam; it is necessary to redo the exam measurements.
	The icon allows the user getting a full screen image when the double screen function is selected. NOTE: By double-clicking on this icon, the full screen function is locked down and will be automatically used when a new miniature is created. Click once again on the icon to deactivate the automatic display.
Cineloop	 Key features: • Record a video sequence corresponding to the last 20 seconds of examination before freezing (200 images by default) • Review the whole sequence on loop or as individual images. • The number of seconds depends on the probe speed. • Cineloop size is set in the General Setup.
	Save the exam.
	Save the exam on the DICOM server.
	Select this icon to: • Open the Report Screen (Section 8.2 Print reports on the Windows printer) • Print on the USB video printer (Option – Section 8.1 Print an image on a USB video printer).

3.5.2 Using the Cineloop function

> To navigate the Cineloop, press the arrow keys (↑ ↓ ← →) or the N (for Next image) and the B (for Before image) keys.

> To pause or stop, press the spacebar or C key (C such as Cineloop)

How to retrieve a sequence of images from the Cineloop

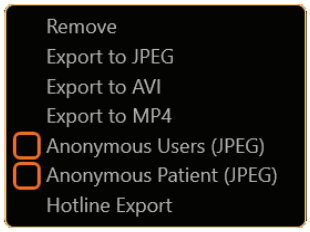
1. In the progress bar, hold down the left mouse button on the orange pointer and move it to the left or to the right. Then release the mouse button to keep the sequence (in red).

2. To shorten or lengthen the sequence by 1 image at a time, press SHIFT+N or SHIFT+B.
3. To navigate the Cineloop progress bar while maintaining the sequence, press the N or B key.

When reusing the key combination SHIFT+N or SHIFT+B, the distance between the pointer and the sequence is either excluded from or included in the sequence.

4. Save the sequence:
   - Click the Save icon in the upper right corner.

   OR
   - Right-click in the image and export to .jpeg/.avi/.mp4 format. The default folder path is set in the Export Settings in the General Setup.

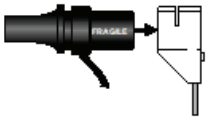


4. BIOMETRY EXAM (A-SCAN EXAM SCREEN)

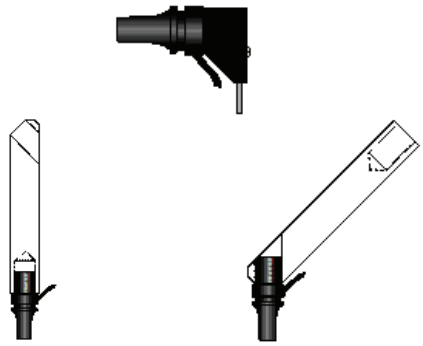
4.1 A-SCAN probes

Standard biometry probe (TP-01-b)

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



A handpiece may be used to handle the probe more easily, either at 45 degrees or vertically.



ProBeam probe (TP-02-las)

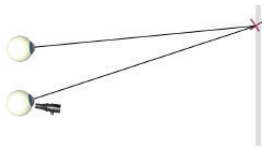
The ProBeam is an optional probe with a laser aiming beam.

WARNING
A laser radiation is emitted at the back of the ProBeam probe. Avoid direct eye exposure! Please refer to the sticker warnings on the ProBeam.

Use of the ProBeam probe:

In the acquisition screen, 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 eye to be measured and the ProBeam are in good alignment.



Without ProBeam (misalignment)

With ProBeam
(good alignment)

Standardized probe (A-Std)

The 8 MHz standardized probe is unidirectional and unfocused: it emits a parallel beam.

NOTE
Only the immersion technique is available with the A-Std probe.

4.2 Biometry techniques and precaution of use

The probe must be cleaned between 2 patients to avoid contaminations. Please refer to the ABSolu User Manual – Chapter I – Regulatory & Safety information - Section 2.3 How to prevent a transfer of infection.

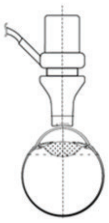
The cornea should be anaesthetized. See the table below for biometry techniques.

WARNING
Be sure the probe calibration is correct. Please refer to the ABSolu User Manual: V – General Setup & Maintenance Section 1.6. – Probe Settings.

WARNING
The contact must be very light (with no hard pressure on the cornea).

Contact technique

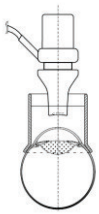
The probe is placed directly, smoothly, on the cornea (at the center). The tear film should be sufficient to make contact and allow ultrasound transmission (if not, artificial tears solutions may be used).



Immersion technique

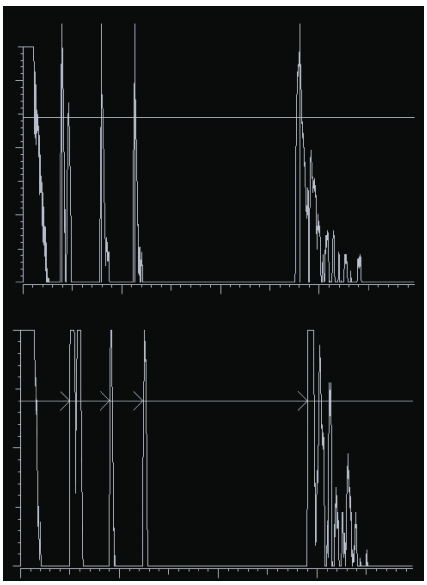
The immersion technique involves the use of scleral shells. Different diameters are available depending on the diameter of the patient's cornea (from children to myopic eyes).

- Choose the appropriate size.
- Place the shell directly on the sclera over the limbus.
- Fill it with physiologic serum or BSS.
- Position the probe in the liquid, close to the cornea, in the visual axis.



4.3 Biometry display modes

2 display modes are available in Biometry.



Display mode: D1 (adjustable dynamic)
The markers are positioned at the top of the echoes picks.
Displayed Dynamic: 35 dB

Display mode: D2 (fixed dynamic at 20dB)
The markers are positioned on the rising edge of the echoes at the threshold level.
Displayed Dynamic: 20 dB (more contrasted image)
NOTE: Only the immersion technique is available in D2 mode.

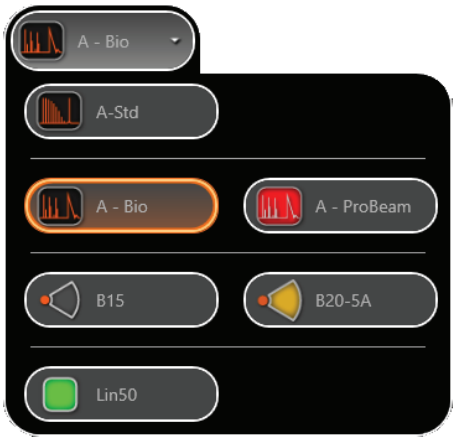
4.4 Biometry mode (A-SCAN) Exam screen

To perform an A-SCAN mode exam, select the corresponding probe in the Exam screen:

- A-Bio (Tp-01-b).

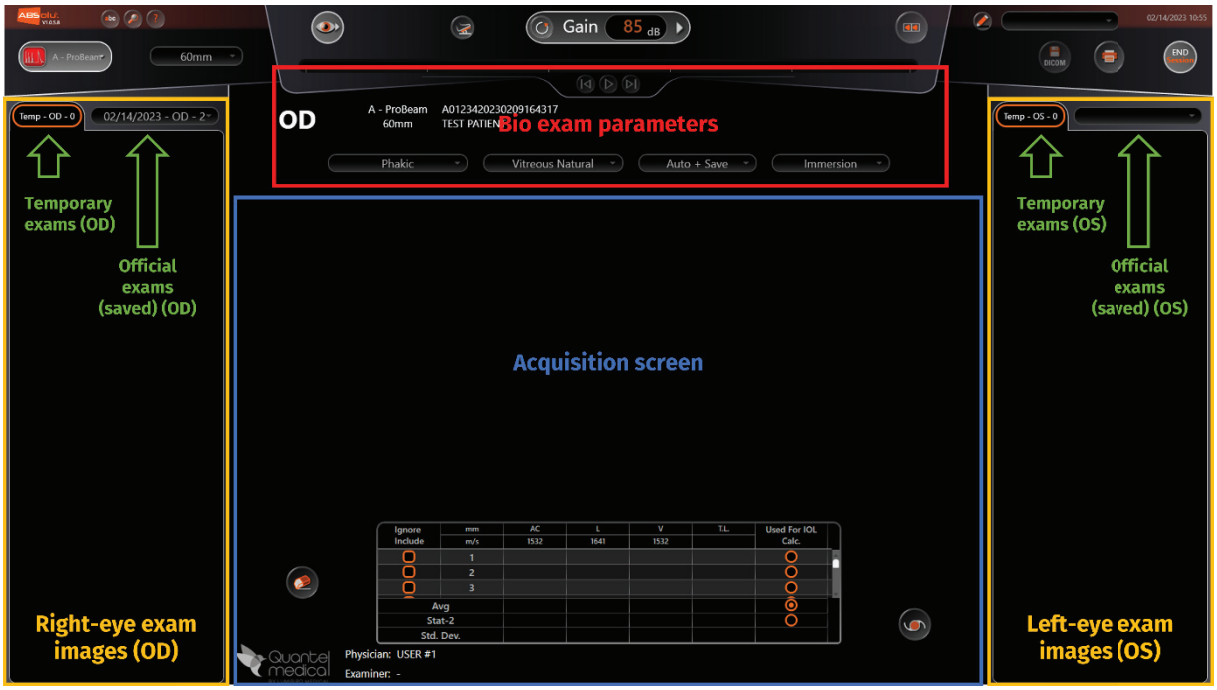
OR

- A-ProBeam (Tp-02-las).

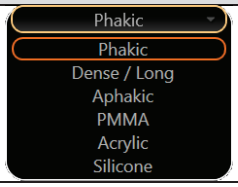
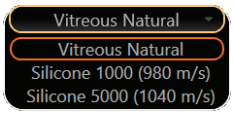
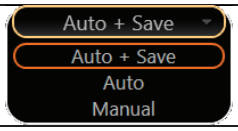
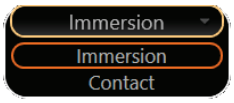


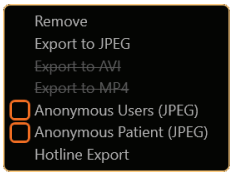
WARNING
If both the Biometry probe (A-Bio) and ProBeam probe (A-ProBeam) are installed on the ABSolu unit, select the probe which is connected to the ABSolu unit. This is to ensure that the correct probe parameters are used for the acquisition. If the incorrect parameters are selected, measurements will be wrong.

4.4.1 Biometry mode: Exam screen functions



Exam parameters specific to Bio exam

Icon	Allows user to:
	The eye type can be selected from the drop-down list at the top of the screen.
	The vitreous type can be selected from the drop-down list at the top of the screen. To add other Vitreous types, refer to Section 4.4.3 Biometry (A-Scan) Acquisition – Running the exam.
	The acquisition mode can be selected from the drop-down menu at the top of the screen. Refer to Section 4.4.3 Biometry (A-Scan) Acquisition – Running the exam.
	The measurement method can be selected from the drop-down menu at the top of the screen. Refer to Section 4.4.3 Biometry (A-Scan) Acquisition – Running the exam.

	Right click on a frozen image to: • Delete the image • Save the image in JPEG format • Save the acquisition in AVI format. This option becomes active when selecting images in the Cineloop progress bar. • Save the acquisition in MP4 format. This option becomes active when selecting images in the Cineloop progress bar. • Check the "Anonymous" boxes to export exams (JPEG or AVI) without User and /or Patient name. In the image, the names will be replaced by "Anonymous". • Hotline Export.

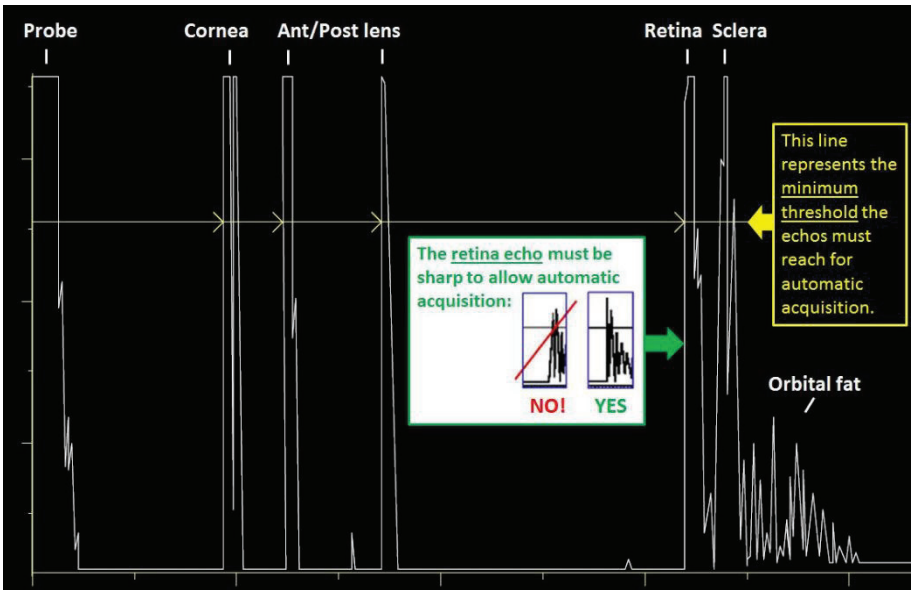
Footswitch functions in A mode, by using the single footswitch

Acquisition state	Unfrozen image (during acquisition)		Frozen image	
Action on footswitch	Short pressure (<1s)	Long pressure (>1s)	Short pressure (<1s)	Long pressure (>1s)
Manual	Freeze the image		Unfreeze the image	Save
Auto + Save	No action	Automatic acquisition inhibition	Unfreeze the image	Save
Auto				Include or ignore the results

NOTE
For ABSwitch, refer to the document delivered with ABSwitch to know the different functionalities or to Chapter 5 B-Scan Exam screen.

4.4.2 Automatic mode acquisition

The ABSolu program is set to automatically freeze a measurement in automatic AUTO mode (AUTO and AUTO+SAVE modes) when the conditions explained below are met.



Threshold level & retina slope test	Scleral Echo detection
The green dotted line is representing the minimum threshold the echoes should reach for automatic acquisition. Moreover, the acquisition software has also been designed to freeze the A-scan when the probe direction is in the visual axis i.e., the rising edge of the retina should be as much perpendicular to the base line as possible. To reach this goal, the retinal spike sharpness criterion is tested.	In Automatic mode, in addition to the Retina Slope Test, the presence of the scleral echo is expected. Its amplitude must be above the threshold. It is the case if the probe is aligned with the macula. If the scleral spike is not detected, the probe is aligned along the optic nerve, which is not a correct position.

4.4.3 Biometry (A-SCAN) acquisition – Running the exam

1. Select the eye on which the exam is to be performed (OD-right or OS-left). To do so, select the icon to display OD or OS in the exam screen.

2. Adjust the parameters for the biometry exam (in the menu above the acquisition screen):
   - Eye type (Phakic / Dense / Aphakic / PMMA / Acrylic / Silicone).
   - Vitreous type (Vitreous Natural / Silicone 1000 (980m/s) / Silicone 5000 (1040 m/s)).
   - Measurement method (Contact / Immersion).
   - Acquisition mode (Manual / Auto / Auto + Save).

NOTE
Refer to Section 4.4.1 Biometry mode: Exam Screen functions for more detailed information about biometry parameters.

3. To trigger the acquisition, press the footswitch or select the icon.

EXAMPLE:

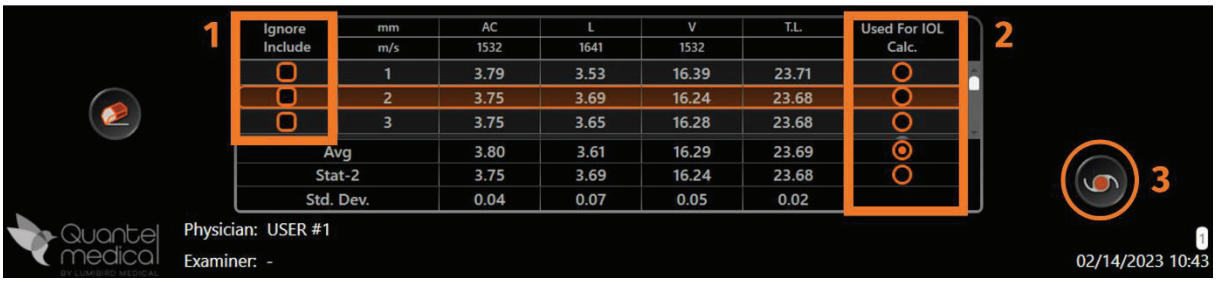
Acquisition in AUTOMATIC + SAVE mode on RIGHT EYE (OD) with other parameters selected: Phakic Eye / Vitreous natural / Immersion

In AUTO + SAVE mode, the measurements are automatically recorded 10 times in a row when all auto mode conditions are met (explained Section 4.2 Automatic mode acquisition).

NOTE
The examiner may inhibit the automatic detection at any time by pressing on the footswitch (to adjust probe position). If the ProBeam is used, the laser aiming beam is ON. Ask the patient to fix the projected red point.

Once all 10 measurements have been performed, a “special” beep notifies the examiner that the AUTO + SAVE mode acquisition is completed. The following screen is displayed.

4. Choose the results used for IOL calculation.



<u>1 Ignore or Include a result line</u>

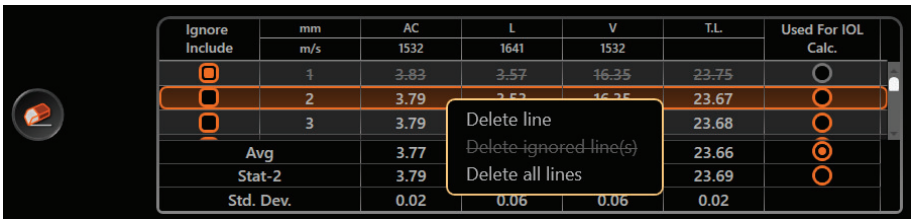
When the Std. Dev. is out of the recommended limits, it is displayed in red color in the result table with a warning sign:

When this is the case, the user can either select the “Ign. Incl.” checkbox to ignore a result line or adjust the markers so that the Std. Dev. falls in between the recommended limits.

The system automatically selects “Avg” for IOL calculation (when the checkbox is activated on “Avg” line).

NOTE

It is possible to ignore one line by double-clicking the chosen line. It is also possible to delete a line by right-clicking on it.



2 Used for IOL Calculation

The user can choose the result line that will be used for IOL calculations:

- Specific result line.
- The Avg result line.
- The Stat2 result line. The "Stat-2" can combine the 2 echograms considering the following segments:

[the longest value of (Ant.Chamber+Lens]+[the shortest vitreous length]

  - The longer anterior chamber corresponds to the exam done with the lowest pressure applied on the eye.
  - The smallest Vitreous corresponds to the exam done with the sharpest retinal slope (where the probe's position is at its best).

> To reset all table values and restart acquisition, click the Eraser:

3 Select the IOL icon to display the IOL results

> To access the IOL result screen, click the IOL icon:

4.5 IOL result screen

The following screen with 4 IOLs results tables is displayed:

1 IOL selection; 2 IOL formula; 3 Ametropia; 4 Increment

In each IOL table, the parameters in the procedure below can be adjusted.

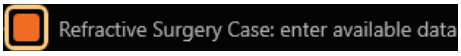
1. 1 IOL selection: The IOLs values selected by default are displayed in each of the 4 tables when opening the IOLs result screen. In each table, it is possible to choose a different IOL from the displayed drop list:

2. Formula selection: The formulae selected by default are displayed in each of the 4 tables when opening the IOLs result screen. In each table, it is possible to choose a different formula from the displayed drop list:

NOTE
For more information about IOL formulae, please refer to the ABSolu User Manual: VI - Appendix: IOL formulae.

3. Post operation ametropia: In each table, select the Ametropia field and enter the chosen numeric value. The possible values have to be selected between -20 to +20 diopters. The software will then automatically calculate the refraction table centering the closest value to the chosen refraction.
4. Increment: IOLs can be incremented by steps of 0.25 or 0.5.
5. To apply the parameters set in the first IOLs result table to the other tables, click Arrow besides each parameter.

6. Post refractive method: The PR IOL methods list is displayed in the drop list only when the **Refractive Surgery** checkbox has previously been selected in the Patient screen.



Refer also to Section 2.2.2 Creating a new patient. The PR method can be selected from the drop list.

NOTE
For more information about PR IOL methods, refer to ABSolu User Manual: VI - Appendix: IOL formulae.

7. Select the IOL Table icon to display the IOL table.

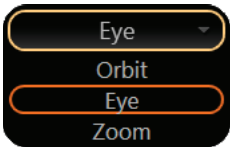
4.6 Standardized (A-SCAN) Exam screen and acquisition

To perform a Standardized A-SCAN mode exam, select the corresponding probe in the exam screen: A-Std.

WARNING

The ABSolu should be equipped with the Standardized EMITTER Receiver board. The following screen is displayed (Standardized A mode diagnosis features circled in red):

For each method, the depth of field displayed in the A-Std acquisition screen can be chosen between Orbit (80µs), Eye (40µs), and Zoom (20 µs).



4.6.1 LESION Q-I diagnosis method

This diagnosis method allows the user to perform quantitative and qualitative analysis of intraocular and orbital lesions.

With the LESION Q-I diagnosis method, it is possible to:

- Measure the thickness of a lesion.
- Calculate the percentage of reflectivity between 2 gates.
- Automatically calculate the Angle Kappa (automatic display of tissue absorption).

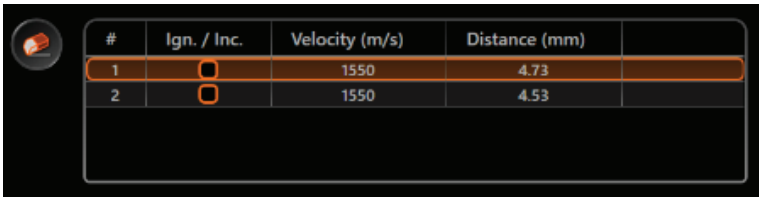
LESION Q-I screen parameters:

Icon	Allows user to:
	Activate / deactivate the markers.
	Display the Kappa angle with integral curve (Only available with depth of field: Orbit)
	Display the Kappa angle (Only available with depth of field: Orbit)
	Shift the curve position along the X axis. Only available with depth of filed: Eye (40µs) or Zoom (20 µs)

4.6.1.1 Lesion thickness measurement

1. Select “LESION Q-I”
2. Select the **M** icon to display the two markers on the curve (with upward yellow arrows on the X axis).

3. To measure the mass lesion, the two markers have to be positioned at the lesion’s borders. Use the mouse (or the ABSolu front knob) to select and position the markers:



The distance between the markers is displayed in the results table at the bottom of the screen:

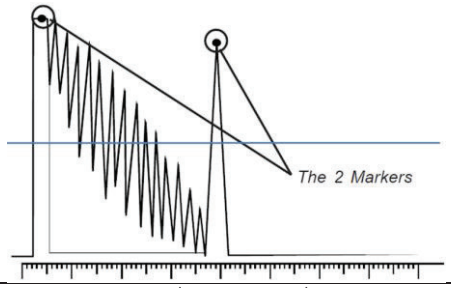
NOTE
The ultrasound propagation speed is displayed by default at 1550 m/s. However, it can be adjusted to correspond to the type of tissue (speed range: 500 to 5000 m/s).

4.6.1.2 Percentage of reflectivity between two gates with QUANTITATIVE-I factor

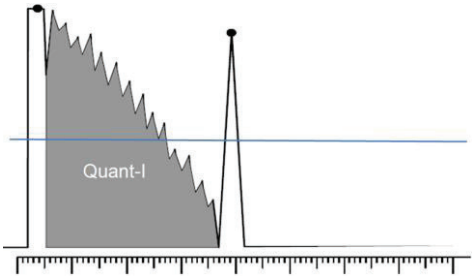
The Quant-I (T) factor is the automatic calculation of internal reflectivity (in %). It allows the user to evaluate the internal reflectivity by measuring the surface covered by the echoes between two markers.

NOTE
Densely packed cells give low reflectivity, whereas large spaces give high reflectivity. When the two markers are placed as in the example below:

Threshold level at dynamic 50%

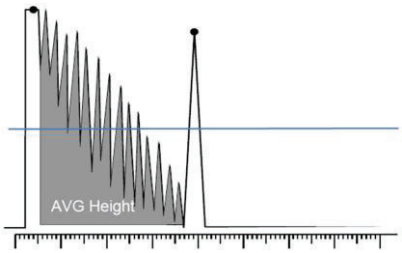


The QUANT-I is the surface limited by the top of the echo spikes



QUANT-I=100% if all echoes are saturated between the markers.

The average height (AVG Heigh) is the surface limited by the echoes (tops and valleys)

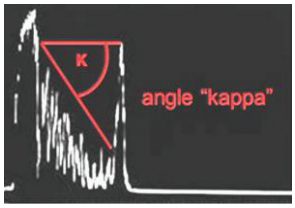


The Average Height (AVG Height) is displayed (in %) for Quant-I (T) and Quant-I (T+9).

4.6.1.3 Kappa angle and attenuation

With the “LESION Q-I” diagnosis method selected, and the two markers positioned as explained above, the “Kappa” angle is automatically calculated.

NOTE
The “Kappa” angle is the angle between the baseline and the line than runs through the lesion spikes peaks.



High Kappa angle (more than 45°): lesion with many vacuoles or internal spaces such as Cavernous Hemangioma.

Low Kappa angle (less than 45°): lesion with homogeneous histological structure such as Lymphoproliferative structures.

<u>Kappa angle and attenuation with ORBIT mode selected</u>

The Kappa angle is the quantification of the attenuation angle in the ORBIT screen. The calculation is a linear regression between the two markers (taking into account all picks and valleys). It is given in dB/mm.

Two conditions are necessary to measure the Kappa angle:

- The ORBIT mode should be selected.
- The AVG Height value should be contained between 49% and 51%.

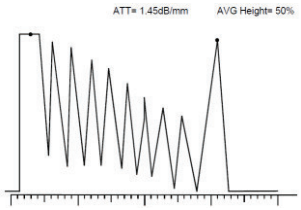
Select the following icon to automatically calculate the Kappa angle.

Select the following icon to display the Kappa angle with integral curve.

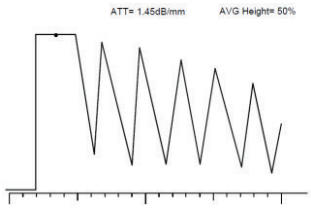
Attenuation with EYE or Zoom (20 µs) modes selected

In those modes, the horizontal axis is dilated: as a consequence, the angle is not preserved, and the Kappa angle icons are no longer available:

EYE mode selected:



Zoom (20µs) mode selected:



4.6.2 RETINA A1 diagnosis method

The RETINA A1 method allows the user to differentiate a retinal detachment from intraocular membranes.

The software analyses the reflectivity level and number of high frequency nodules displayed on the tracked spike.

When using the RETINA A1 diagnosis method:

- A tracking segment is automatically displayed at 75% of the saturation level (which is the minimum threshold).
- The number of nodules is detected between 10% and 95% of the saturation level.

NOTE
All ORBIT, EYE or Zoom (20µs) display modes can be used with the RETINA A1 diagnosis method.

Examination technique

1. Select “Retina A1” (The gain is set at tissue sensitivity (T) gain. T value cannot be modified.
2. Press the footswitch and during the exam, select and move the horizontal segment (automatically set at 75% of the saturation level) over the retinal area. The width of the tracking segment can also be adjusted.

Tracking process

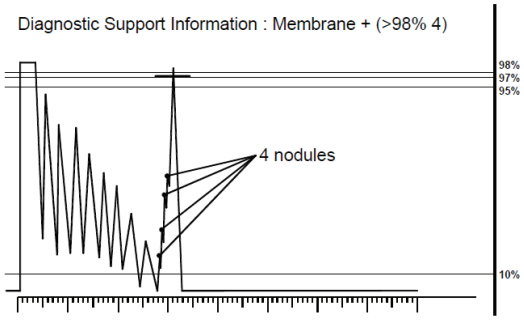
The tracking is in process while the footswitch is pressed. The software analyses the reflectivity level of the tracked spike and records the spike with the highest detected amplitude. When the footswitch is released, the result screen with the selected image and analysis results is displayed.

Results table and analysis

Height of the echo (% of the reflectivity)	Number of nodules	Diagnosis information
>98%	0	Retina +++
	1	Retina ++
	2	Retina +

	3	Equivocal Result
	4	Membrane +
	5	Membrane ++
	> 5	Membrane +++
≥97% and ≤98%	**0 ; 1 ; 2**	**Equivocal Result**
	3	Membrane +
	4	Membrane ++
	> 4	Membrane +++
≥75% and <97%	0 ; 1 ; 2	Membrane +
	3	Membrane ++
	> 3	Membrane +++
<75%	The last image is frozen	Max Spike Height < 75%

Example:



The selected echo height is above 95%, between 97% and 98%.
The number of nodules between levels 10% and 95% is 4.
The A1 sign for this echo is thus “Membrane ++”

4.6.3 RETINA Q-II diagnosis method

The RETINA Q-II is another method for differentiating retinal detachment versus intraocular membranes.

This method consists of tracking the pseudo membrane’s reflectivity and compare it with the reflectivity of the sclera used as a natural landmark.

The software will record the highest reflectivity level for each of the tracked tissues (membrane, sclera, and pre-sclera).

It is crucial to maximize the reflectivity levels by ensuring the perpendicularity of the ultrasound beam with the tissues.

Three echograms will be stored containing three maximized echoes for:

1. Membrane
2. Pre-sclera
3. Sclera

The following calculations will give the algebraic difference between the three amplitudes in dB:

- Diff M-S = Membrane amplitude – Sclera amplitude
- Diff Ps-S = Pre-sclera amplitude – Sclera amplitude
- Diff M-Ps = Membrane amplitude – Pre-sclera amplitude

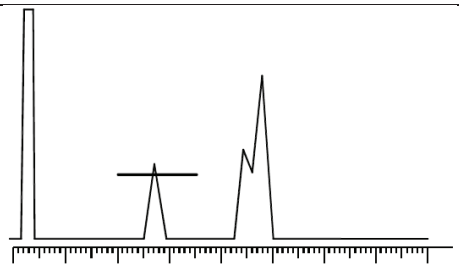
Those results will be a guidance for diagnosis.

In the “RETINA Q-II” diagnosis method, the gain is set to the Tissue Sensitivity gain value and can be modified during acquisition but not when the image is frozen.

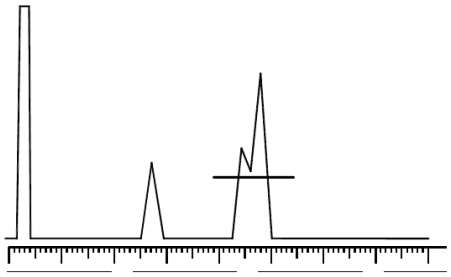
NOTE
All ORBIT, EYE or zoom (20 µs) display modes can be used with the RETINA Q-II diagnosis method.

4.6.3.1 *Tracking program*

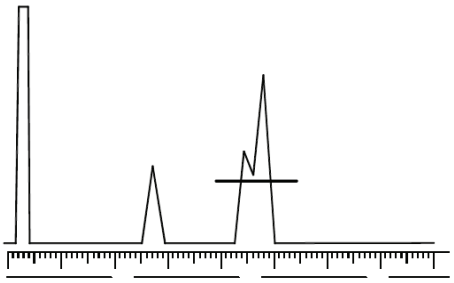
Step 1. Tracking the membrane. Press and release the footswitch to start the acquisition. Position the markers (segment) over the membrane echo and press the footswitch again to freeze the image.



Step 2. Tracking the sclera. The sclera echo corresponds to the highest acquisition echo. Usually, the sclera echo has such a high amplitude that it may be necessary to adjust the Gain to avoid saturation. Press and release the footswitch to start the acquisition again. This time, position the markers (segment) over the sclera echo and press the footswitch to freeze the image.



Step 3. Tracking the pre-sclera. The pre-sclera will be the first echo in the sclera area segment. Press and release the footswitch to start the acquisition again. This time, position the markers (segment) over the pre-sclera echo and press the footswitch to freeze the image.



Once the footswitch is released, the result table displays the following algebraic differences between the pre-sclera and the sclera amplitude (Ps-S) and between the membrane and pre-sclera amplitude (M-Ps):

Ign. / Inc.	QUANT-II	Difference	dB
☐	Membrane	M-S	1.33
☐	Sclera	Ps-S	-2.33
☐	Pre-Sclera	M-Ps	3.67

4.6.3.2 *Results tables and analysis*

Results after the Membrane (M) and the Sclera (S) tracking:

M-S result (Membrane amplitude – Sclera amplitude)	Diagnostic Support Information	Additional Message
1° -13≤ M-S≤ -5dB	R.D. ++	
2° -15<M-S<-13dB	R.D. +	
3° -16<M-S≤ -15dB	R.D. (+)	1) Try to get better M 2) Try to get the Pre-Sclera
4° -17<M-S≤ -16dB	Equivocal	1) Try to get better M 2) Try to get the Pre-Sclera
5° -18<M-S≤ -17dB	Membrane (+)	1) Try to get better M 2) Try to get the Pre-Sclera
6° -19<M-S≤ -18dB	Membrane +	
7° -20<M-S≤ -19dB	Membrane ++	
8° -35<M-S≤ -20dB	Membrane +++	

Results after the Membrane (M), the Sclera (S) and Pre-Sclera tracking:

M-S result (Membrane amplitude – Sclera amplitude)	Ps-S result (Pre-Sclera amplitude – Sclera amplitude)	Diagnostic Support Information	Additional Message
1° -13≤ M-S≤ -5dB	-35≤ Ps-S≤ -15dB	R.D. +++	
	-15<Ps-S≤ -14dB	R.D. ++	
	-14<Ps-S≤ -13dB	R.D. +	
	-13<Ps-S≤ -5dB	Contradiction	Try to get better S
2° -15<M-S<-13dB	-35≤ Ps-S≤ -15dB	R.D. ++	
	-15<Ps-S≤ -14dB	R.D. +	
	-14<Ps-S≤ -13dB	R.D. (+)	Try to get better echoes: 1) Sclera; 2) Membrane
	-13<Ps-S≤ -5dB	Contradiction	Try to get better S
3° -16<M-S≤ -15dB	-35≤ Ps-S≤ -15dB	R.D. +	
	-15<Ps-S≤ -14dB	R.D. (+)	Try to get better echoes: 1) Sclera; 2) Membrane
	-14<Ps-S≤ -13dB	Equivocal	Try to get better echoes: 1) Sclera; 2) Membrane
	-13<Ps-S≤ -5dB	Contradiction	Try to get better echoes: 1) Sclera; 2) Membrane
4° -17<M-S≤ -16dB	-35≤ Ps-S≤ -15dB	R.D. (+)	Try to get better echoes: 1) Pre-Sclera; 2) Membrane
	-15<Ps-S≤ -14dB	Equivocal	Try to get better echoes: 1) Pre-Sclera; 2) Membrane
	-14<Ps-S≤ -13dB	Membrane (+)	Try to get better echoes: 1) Pre-Sclera; 2) Membrane
	-13<Ps-S≤ -5dB	Membrane +	
5° -18<M-S≤ -17dB	-35≤ Ps-S≤ -15dB	Contradiction	Try to get better echoes: 1) Pre-Sclera; 2) Membrane
	-15<Ps-S≤ -14dB	Membrane (+)	Try to get better echoes: 1) Pre-Sclera; 2) Membrane
	-14<Ps-S≤ -13dB	Membrane +	
	-13<Ps-S≤ -5dB	Membrane ++	
6° -19<M-S≤ -18dB	-35≤ Ps-S≤ -15dB	Contradiction	Try to get better echoes: 1) Pre-Sclera; 2) Membrane
	-15<Ps-S≤ -14dB	Membrane (+)	Try to get better echoes: 1) Pre-Sclera; 2) Membrane
	-14<Ps-S≤ -13dB	Membrane +	
	-13<Ps-S≤ -5dB	Membrane ++	
7° -20≤ M-S≤ -19dB	-35≤ Ps-S≤ -15dB	Contradiction	Try to get better Ps
	-15<Ps-S≤ -14dB	Membrane +	
	-14<Ps-S≤ -13dB	Membrane ++	
	-13<Ps-S≤ -5dB	Membrane +++	
8° -30<M-S≤ -20dB	-35≤ Ps-S≤ -15dB	Contradiction	Try to get better Ps
	-15<Ps-S≤ -14dB	Membrane ++	
	-14<Ps-S≤ -13dB	Membrane +++	
	-13<Ps-S≤ -5dB	Membrane +++	

Results after the Membrane (M) and the Pre-Sclera (Ps) tracking when the sclera is impossible to detect:

M-Ps result (Membrane amplitude – Pre-Sclera amplitude)	Diagnostic Support Information	Additional Message
1° M-Ps≤ -6dB	Membrane ++	
2° -6<M-Ps<-3dB	Membrane +	
3° -3≤ M-Ps≤ -2dB	Membrane (+)	Try to get better Ps
4° -2<M-Ps≤ +1dB	Equivocal	
5° +1<M-Ps≤ +3dB	D.R. (+)	Try to get better M
6° +3<M-Ps<+6dB	D.R. +	
7° M-Ps≥+6dB	D.R. ++	

4.6.4 MUSC. PROFILE diagnosis method

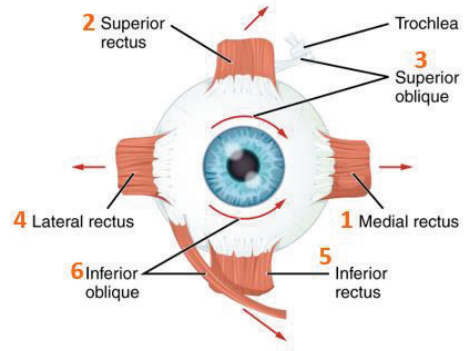
The “MUSC. PROFILE” diagnosis method is used for the characterization of orbitopathies involving extra ocular muscles.

The technique consists in the screening of the 4 straight and 2 oblique muscles in order to calculate two indexes:

- the Superonasal Index (SNI), and
- the Muscle Index (MI).

To calculate those indexes, an acquisition sequence is set to measure the thicknesses of:

1. Medial rectus
2. Superior rectus
3. Superior oblique
4. Lateral right
5. Inferior right
6. Inferior oblique



Anterior view of the right eye

NOTE
The user can adjust the Velocity (m/s) for each acquisition. It can range from 500m/s to 4000m/s.

4.6.4.1 Acquisition sequence

<u># 1 Medial Rectus (MR)</u>

1. Perform an acquisition.
2. Then, use the mouse (or the ABSolu front knob) to select and position the markers and measure the MR thickness. The # 1 MR measurement is displayed in the results table.

<u># 2 Superior Rectus (SR)</u>

1. After the previous acquisition, press on the footswitch to unfreeze the A-scan and make a new acquisition for the Superior Rectus.
2. Then, use the mouse (or the ABSolu front knob) to select and position the markers and measure the SR thickness. The # 2 SR measurement is displayed in the results table.

<u># 3 Superior Oblique (SO)</u>

> Follow the same procedure for this muscle as above (#2). The Superonasal Index is the thickness average of the Medial Rectus, the Superior Rectus and the Superior Oblique. This “SNI” result is calculated and displayed in the results table.

#7 SNI=1/3 (MR+SR+SO)

<u># 4 Lateral Right (LR)</u>

> Follow the same procedure for this muscle as above (#2).

<u># 5 Inferior Right (IR)</u>

> Follow the same procedure for this muscle as above (#2).

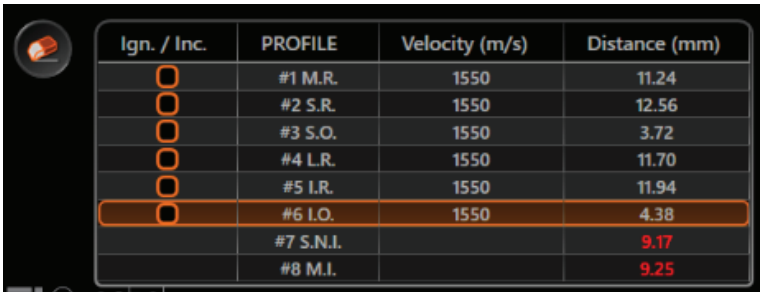
6 Inferior Oblique (IO)

> Follow the same procedure for this muscle as above (#2). The result is calculated and displayed in the result table. The MI Muscle Index is the thickness average of the Medial Rectus, the Superior Rectus, Superior Oblique, Lateral Right, Inferior Right and Inferior Oblique:

#8 MI=1/6 (MR + SR + SO + LR + IR + IO)

4.6.4.2 Results table

All measurements are displayed in the results table:



The S.N.I. gives an indication of Compressive Optic Neuropathy (CON) risk. The value is “Normal” when less than 6.5mm. The risk is indicated by color as the value gets further away from 6.5.

Low risk (Light orange triangle)	6.5≤ S.N.I. <6.75
Medium risk (Orange triangle)	6.75≤ S.N.I. <7.0
High risk (Red triangle)	S.N.I. ≥7.0

The M.I. index classifies the extend and severity of muscle thickening. The value is “Normal” when less than 4.5mm. The risk is indicated by color as the value gets further away from 4.5.

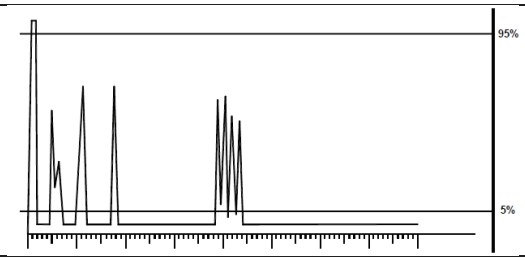
Low risk (Light orange triangle)	4.5≤ M.I. <5.5
Medium risk (Orange triangle)	5.5≤ M.I. <6.5
High risk (Red triangle)	M.I. ≥6.5mm

Optional functionality: Optic nerve measurements are used to assess different kinds of optic nerve pathologies. Thanks to 2 markers, the optic nerve diameter will be measured twice: once at rest and once after exercise. For the “exercise”, the patient will be asked to move the eye in Abduction and Adduction (nasal and temporal) continuously for about 1 minute.

4.6.5 Axial Length measurement (with A-Std probe)

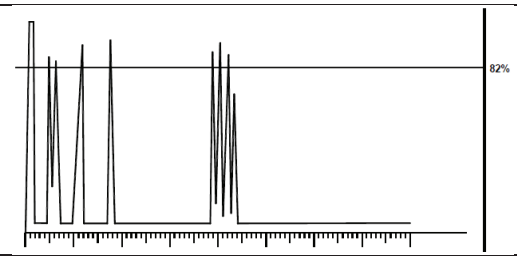
When the Standardized A probe is installed and Axial Length option is activated, the following acquisition techniques may be used:

Immersion technique



The gain must be adjusted so that the top of the echoes appears within the two horizontal lines (5% & 95% of the saturation level).
A low gain of T-20dB allows the user to easily visualize all structures.

Immersion Basic



The minimum threshold the echo is set at 82% of the saturation level.
Recommended gain: T to T-6dB.
NOTE: Except in dense mode: 50%.

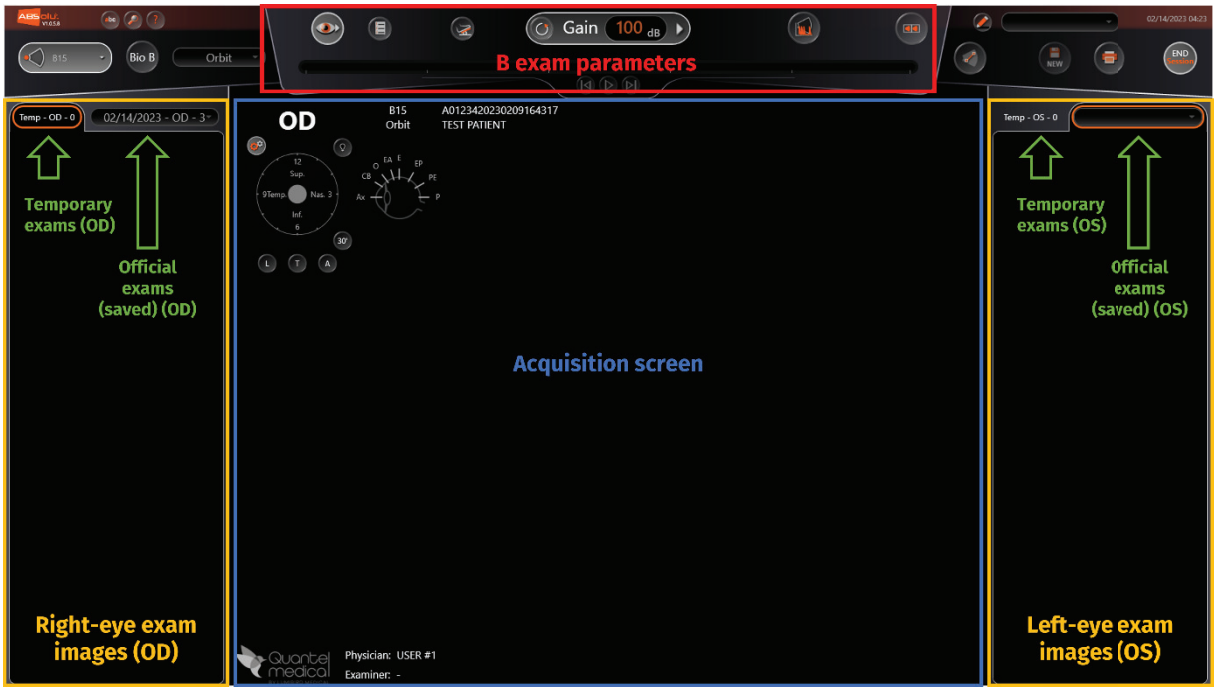
NOTE
This technique may be difficult to use for beginners.

5. B-SCAN EXAM SCREEN

> To perform a B-SCAN mode exam, select the corresponding probe in the Exam screen:

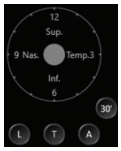
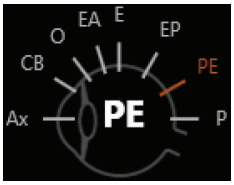
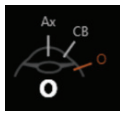
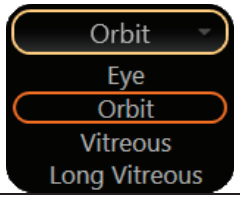
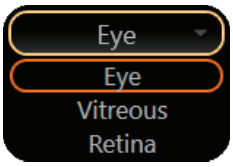
- B15 icon to perform a B-SCAN mode (image of the eye and orbit) or Bio-B mode exam
- B20 icon to perform a high frequency mode exam with the B 20MHz Annular probe (high resolution image of the eye) or in Bio-B mode.
- LIN50 icon to perform a high frequency mode exam with the Linear 50MHz probe (high resolution image of the anterior chamber) or STS mode exam.

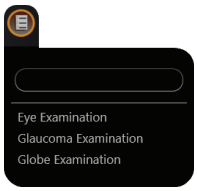
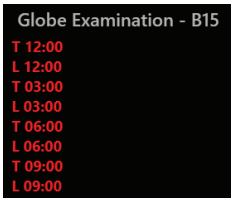
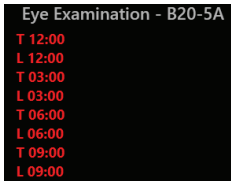
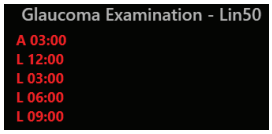
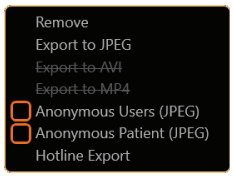
The following screen is displayed:



Exam parameters specific to B exam

Icon	Allows user to:
	When the B-SCAN mode is selected, the following icon is available when selecting the eye icon: 
	This function allows the user to specify the probe position during the examination. When this function is activated (highlighted), the position tools are displayed.
	To select the probe orientation, click on:  for Longitudinal  for Transverse  for Axial

Icon	Allows user to:
	 When selected, the exam area turns orange, and the probe is positioned on the clock  for Longitudinal  for Transverse  for Axial
	To adjust to half hour, select:  For the B15MHz or B20MHz-5A probes, the anatomical location can be selected by clicking on the letters AX, CB, O, EA, E, EP, PE or P:  **AX** Axial **CB** Ciliary Body **O** Ora serrate **EA** Equator towards anterior **E** Equator **EP** Equator towards posterior **PE** Posterior towards equator **P** Posterior For the LIN50MHz probe, the anatomical location can be selected by clicking on the letters AX, CB or O  for Axial  for Ciliary Body  for Ora serrata NOTE: Select the probe position before the probe is activated for the exam or before saving the exam.
	When Bio B mode is selected for B15MHz or B20MHz-5A probes, the probe orientation must be Axial. 
	When the STS-option is selected for the LIN 50MHz probe, the probe orientation must be Axial.  The STS probe check can then be selected from the position tools. 
	This drop list can be used to select the B-Scans field depth. The list depends on the selected probe: B15  B20-5A  Lin 50 

	The exam protocol list is displayed when selecting this icon. Once selected, the protocol sequence is displayed in the Exam screen    To setup a new protocol, please refer to ABSolu User Manual – Chapter V - General Setup & Maintenance - Section 1.8 – Protocol Settings.
	Enter repetitive keywords to select. The keyword list is available in the Scan screen as a pull down menu
	To display the Cross Vector line (CV) on a B mode image, press on the corresponding icon. Selecting the numeric field and changing the value allows the user to move the CV line up or down
	Right click on a frozen image to: • Delete the image • Save the image in JPEG format • Save the acquisition in AVI format. This option becomes active when selecting images in the Cineloop progress bar. • Save the acquisition in MP4 format. This option becomes active when selecting images in the Cineloop progress bar. • Check the “Anonymous” boxes to export exams (JPEG, AVI or MP4) without User and /or Patient name. In the image, the names will be replaced by “Anonymous”. • Hotline Export. NOTE: The resolution of the JPEG, AVI and MP4 format can be modified in the General Setup menu. Refer to ABSolu User Manual – Chapter V - General Setup & Maintenance - Section 1.9. – Export settings

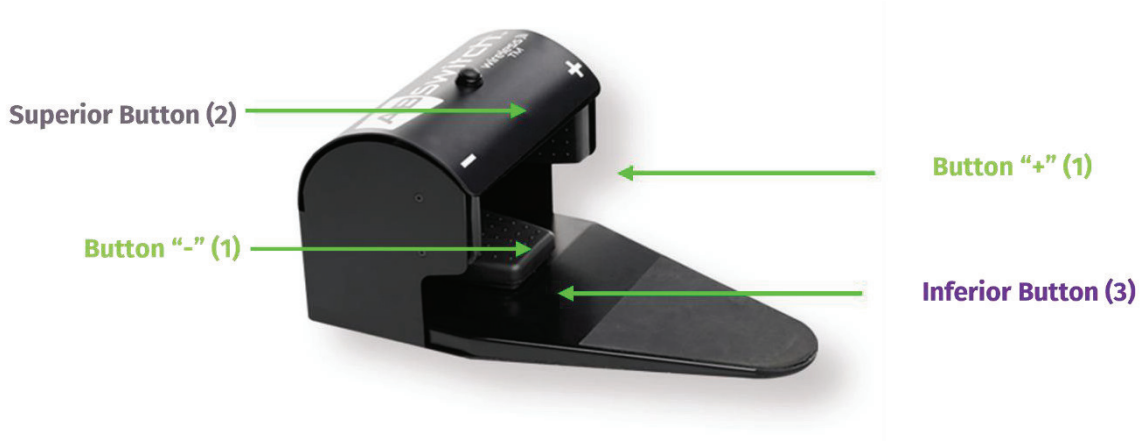
Single Footswitch functions in B mode

Acquisition state	Unfrozen image (during acquisition)		Frozen image	
Action on footswitch	Short pressure (<1s)	Long pressure (>1s)	Short pressure (<1s)	Long pressure (>1s)
Allows to:	Freeze the image or acquisition		Unfreeze the image	Save

Single footswitch

ABSwitch

Acquisition state	Unfrozen image (during acquisition)	Frozen image
ACTIONS	ALLOWS TO	ALLOWS TO
Press Buttons + / - (1)	Adjust the gain	Select previous or next images
Press Superior Button (2)	Insert tags	Calibrate the automatic detection of the probe (IMU)
Press Inferior Button (3)	Stop acquisition, (long pressure)	Unfreeze the image/save images (long pressure)

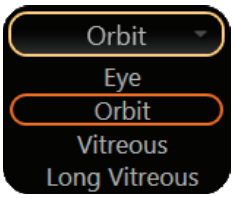


ABSwitch

5.1 B-Scan image acquisition with 15MHz probe (B1)

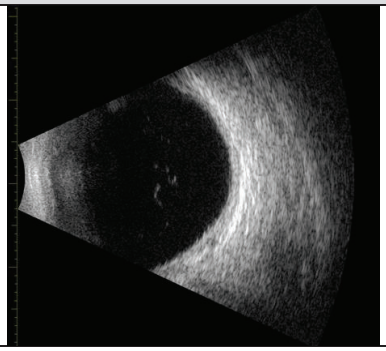
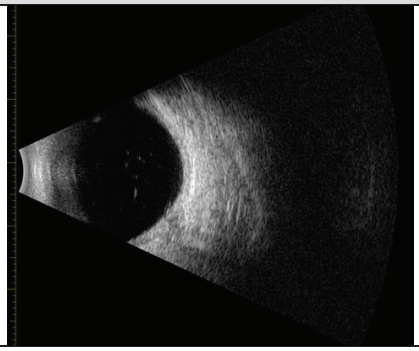
The 15MHz probe (B1) is focused about 24mm. It is used to create images of the eye and orbit.

1. Select from the B-Scans field depth:



The 15 MHz probe (B1) may directly be used on the eyelid.

2. First of all, place some gel on the lid. Then place the probe on the eye.
3. To reach certain zones on the globe, ask the patient to look in different directions.

40mm depth can be used to display the eye globe	The visualized depth can be increased to 60mm depth.
	

WARNING
Placing excessive pressure on the B-scan probe will cause discomfort to the patient.

NOTE
Fast modes (Vitreous/long vitreous) not recommended for Bio B type of examination.

5.2 B-Scan image acquisition with 20MHz-5A probe (B20-5A)

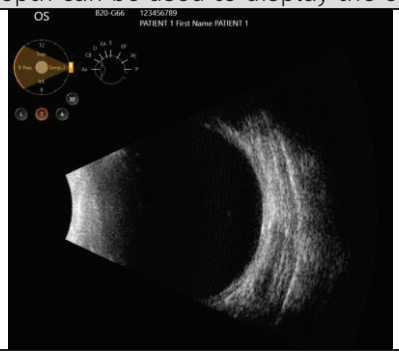
The 20MHz-5A probe (B20-5A) integrates an annular transducer. With this new technology, the resolution of the image is well improved over a large depth of field.

The 20MHz-5A probe (B20-5A) is focused at 22mm. It is used to create high resolution images of the eye.

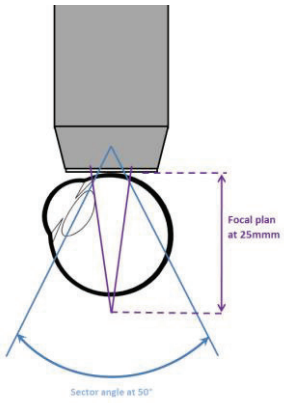
The B-Scans field depth can be adjusted as for the 15MHz probe (B1): Eye / Vitreous / Retina.

The 20MHz-5A probe (B20-5A) may directly be used on the eyelid.

1. First of all, place some gel on the lid. Then place the probe on the eye.
2. To reach certain zones on the globe, ask the patient to look in different directions.

40mm depth can be used to display the eye globe


This probe can be used for retinal examination. To optimize the image quality, the probe can be placed in contact with the conjunctiva. The lens must be avoided. Topical anesthetics must be used, and an ophthalmic gel can be applied to improve contact and ultrasound transmission. Both sector angles will result in an efficient image acquisition.

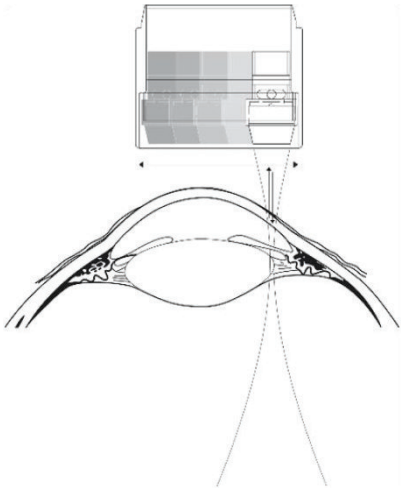


WARNING
Placing excessive pressure on the B-scan probe will cause discomfort to the patient.

NOTE
Fast mode (vitreous) not recommended for Bio B type of examination.

5.3 B-Scan image acquisition with LIN 50MHz probe (BHF-50LIN)

The LIN 50MHz probe (BHF-50LIN) integrates a high frequency transducer that allow the user to visualize the anterior chamber. The transducer linear motion technology implicates better image resolution by improving the perpendicularity of the ultrasound beam over the anterior chamber structures.



The LIN 50MHz probe (BHF-50LIN) enables to visualize:

- The angle for glaucoma diagnosis.
- The sulcus, lens and posterior capsule for cataract and refractive surgery.
- Mass lesions.

Two modes can be used:

- Ciliary body.
- Lens.

The optional STS module enables to perform automatic measurements of the sulcus to sulcus, Irido Cornea Angle Left/Right (semi-automatic measurement), lens curvature and anterior chamber depth.

WARNINGS
Carefully read these warnings for probes care.

- The removable window and the ClearScan® are for single use only. For each new patient:
  - The removable window / ClearScan® should be removed and discarded.
  - The sterile water should be drained out from the probe and the probe's body cleaned with a disinfecting cleaning wipe.
  - For the next patient, the probe should be prepared as described in section 5.3.1 Probe preparation.
- The LIN 50 MHz probe should be prepared / cleaned and disinfected / used according to the procedure provided with the LIN 50 MHz probe: Procedure for Linear 50MHz probes: Preparation – Cleaning and disinfection – Usability (Documentation code NI00045).

CAUTIONS
Carefully read these cautions for probes care.

Refer also to ABSolu User Manual – Chapter I – Regulatory & Safety information – Section 2.2 Probes care and Section 2.3 How to prevent a transfer of infection.

5.3.1 Probe preparation

To prepare the LIN 50MHz probe (BHF-50LIN), use a removable window or ClearScan®.

5.3.1.1 Preparing the probe using a removable window

When using a removable window, prepare:

- Operator clothing: single use overall and disposable gloves.
- Distilled water.
- Removable window (single-use only).

Probe preparation steps:

CAUTION
Only start the probe motion when it is filled with sterile water.

Step 1. Fill the probe while pressing on the draining button. This is to remove air from inside the probe.	
Step 2. When the sterile water leaks from the spout hole, release the draining button. Fill the probe until a meniscus is formed at the top of the probe.	
Step 3. Install the removable window on the probe aperture by firstly positioning one side of the window. The probe is now ready to be used. NOTE: A small air bubble is acceptable as it should disappear when the probe is in position of use.	
	

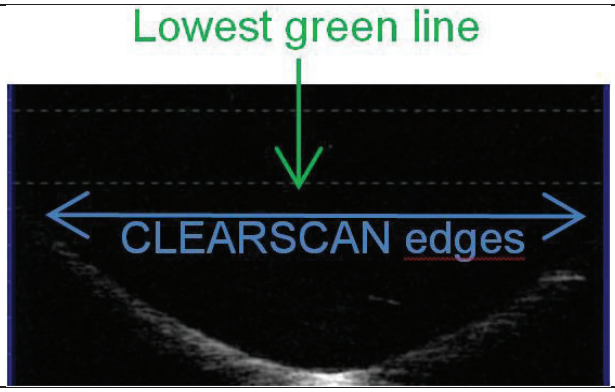
5.3.1.2 Preparing the probe using ClearScan®

CAUTION
If the probe is used with ClearScan®, do not place the removable window on the probe.

When using ClearScan®, prepare:

- Operator clothing: single use overall and disposable gloves.
- Distilled water.
- ClearScan® (single-use only).

Probe preparation steps:

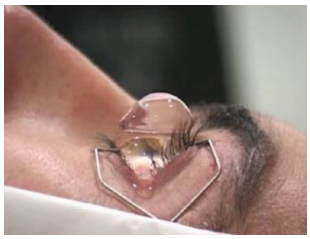
Step 1. Fill the bag with sterile water. Make sure the silicone ring is positioned on the top.	
Step 2. Slowly insert the probe into the ClearScan® while pressing on the draining button. Stop when sterile water leaks from the spout hole.	
Step 3. Start the probe and adjust the ClearScan® positioning until the plastic film image can be seen as shown on the scan below. The ClearScan® edges must be visible reading the lowest green line.	
	
Step 4. Stop the probe.	

5.3.2 Patient preparation for examination

The preparation of the patient for examination depends on whether the probe is used with gel or ClearScan®.

5.3.2.1 Using the probe with gel for examination

The patient must be in reclined position.



1. Instill anesthetics drops to the eye.
2. Put some ophthalmic gel on the patient eye. The amount of gel should be important to help adjusting the probe's position and get well-focused images.
3. Use clean tissues to absorb any extra gel around the eye.

5.3.2.2 Using the probe with ClearScan® for examination

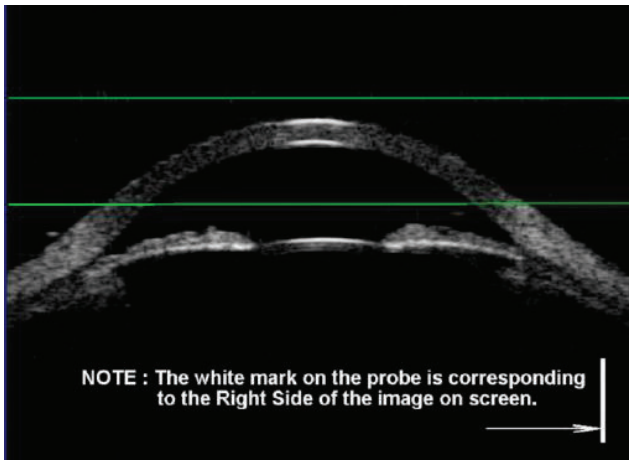
The patient can be in seated position.

1. Ask patient to slightly tilt head.
2. Instill anesthetics drops to the eye and prior to the ultrasound exam. Artificial tears may be used to improve the ultrasound transmission.
3. Use the thumb of one hand to push the upper eye lid upward and use the other hand to hold the probe while pulling downward.

For more information, refer to the ClearScan® manufacturer instructions (ESI).

5.3.3 Image of the cornea

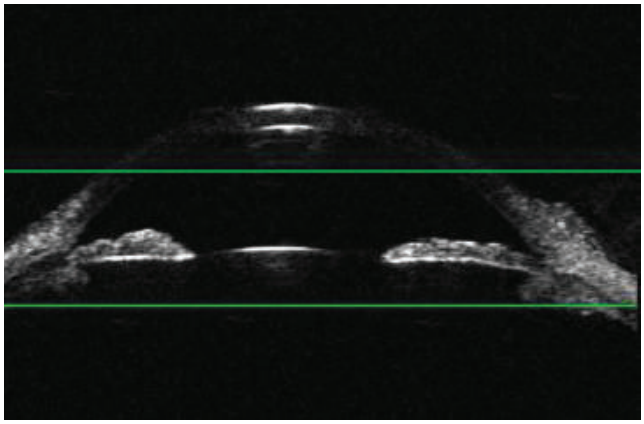
To visualize the cornea, move the probe away from the eye, in order to have the cornea located between the two green lines.



The focal area is located between the two green lines on the computer screen. The probe can be used either with the white window cover and ophthalmic gel or with the ClearScan® cover.

5.3.4 Image of the iris and ciliary body

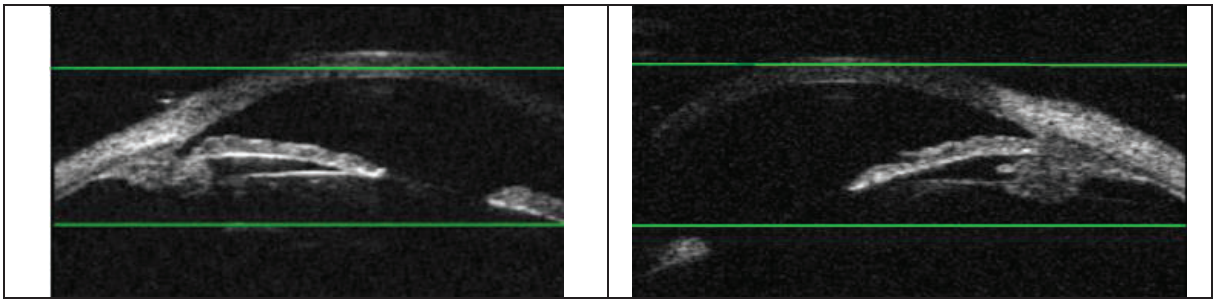
For visualizing the iris and the structures located behind the iris, the probe should be positioned closer to the cornea. The area of interest must be located between the two green lines.



The focal area is located between the two green lines on the computer screen.

5.3.5 Image of the angles

Position the probe over the angle area and ask the patient to look on the left or on the right.



5.4 B-Scan exam tools

A set of exam tools is available, depending on the selected probe.

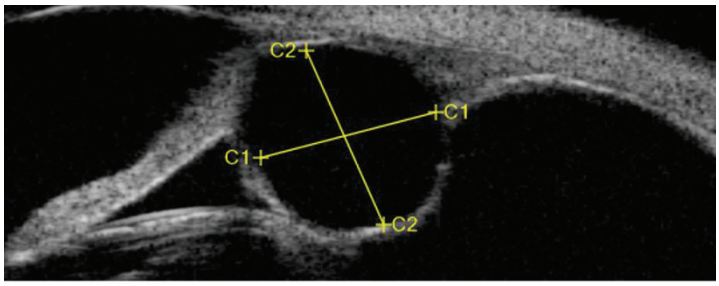
5.4.1 Exam tools for 15MHz probe (B1) and 20MHz-5A probe (B20-5A)

> Select the following icon (right side of the screen) to display the tools:

NOTE
The availability of the Advanced Caliper tool (Adv Cal) depends on the software installed on the ABSolu and the probe version.

5.4.1.1 Caliper tool

The caliper enables to measure a straight line between two points.



C1 (1550 m/s) = 2.43 mm
C2 (1550 m/s) = 2.56 mm

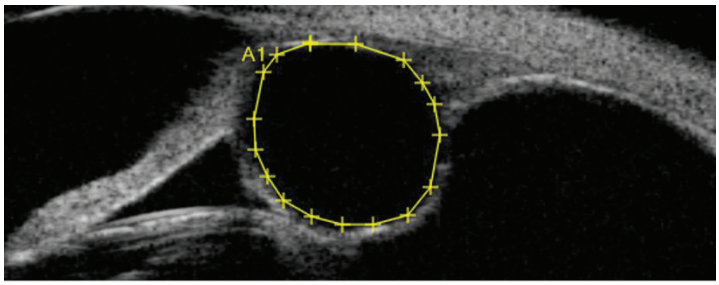
1. Select the Caliper tool.
2. Place the pointer over the desired location on the image and left-click on the mouse to freeze its position.
3. Repeat this procedure to place the second marker. The caliper reference “C#” is displayed for each point in the image.
   The “C#” reference with result is displayed in the tools result table

<u>To move the caliper:</u>

1. Left-click on the caliper to be moved (the selected caliper will be highlighted in red).
2. Release the mouse button.
3. Move the mouse to reposition the caliper.
4. Left-click again to validate the new position.

5.4.1.2 *Area tool*

The Area tool enables to draw a field and calculate the surface area.



A1 (1550 m/s) = 4.97 mm²

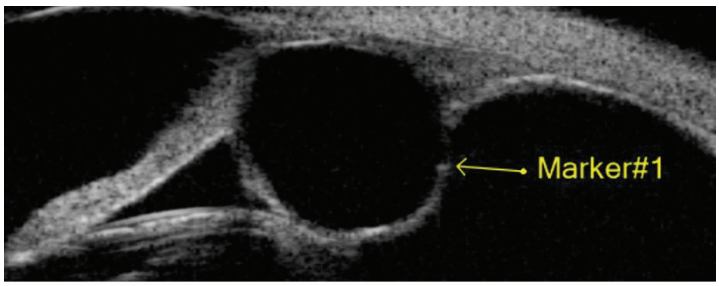
1. Select the Area tool.
2. Position the pointer over the desired location and left-click to set the first point.
3. Repeat as necessary to surround the area to be selected.
4. Right-click to validate the final point. The area reference “A#” is displayed next to the first selected point in the image.
   The reference “A#” with result is displayed in the tools result table.

<u>To move a point on the area selection:</u>

1. Left-click on the point to be moved (the selected point will be highlighted in red).
2. Release the mouse button.
3. Move the mouse to set the new area point position.
4. Left-click again to validate the new position.
5. Right-click to validate the field point.

5.4.1.3 *Marker tool*

The Marker enables to indicate a particular point in an image and provide comments.



M1

1. Select the Marker tool.
2. Position the pointer by left clicking to set the front part of the arrow.
3. Adjust the arrow direction and left-click to validate final position. The marker reference “M#” is displayed next to the marker on the image.
   The reference “M#” is displayed in the list of the tools result table

<u>To move a marker:</u>

1. Left click on the marker to be moved (the selected marker will be highlighted in red).
2. Release the mouse button.
3. Move the mouse to set the new marker position.
4. Left click again to validate the new position.

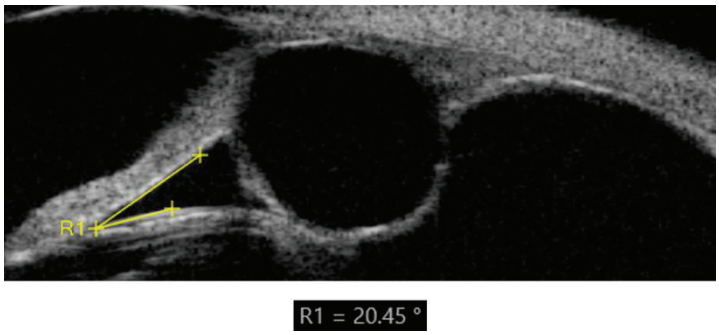
5. To only move the name of the marker (e.g., M1), repeat steps 1 to 4 selecting the marker name.

To modify the name of the marker:

1. Double-click on the marker name (e.g., M1). The selected text will be highlighted in red and becomes editable.
2. Change the name of the marker.
3. Press Enter.
4. If needed, set the new marker name position.
5. Left click to validate the new position.

5.4.1.4 Angle tool

The Angle tool enables to measure an angle in an image.



1. Position the pointer on the vertex desired location and left-click to freeze its position.
2. Left-click again to set the angle first and second segments. The angle reference “R#” is displayed next to the angle location.
   The “R#” reference with result is displayed in the list of the tools result table

To move an angle position:

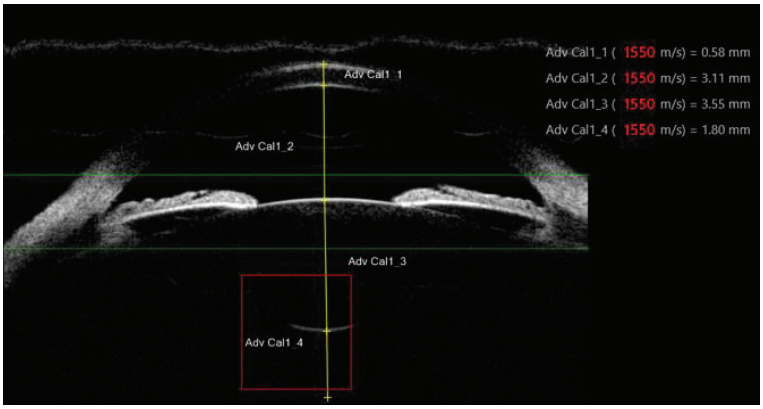
1. Left-click on the angle point to be moved (the selected point will be highlighted in red).
2. Release the mouse button.
3. Move the mouse to set the new angle point position.
4. Left-click again to validate the new position.

5.4.1.5 Advanced Caliper tool

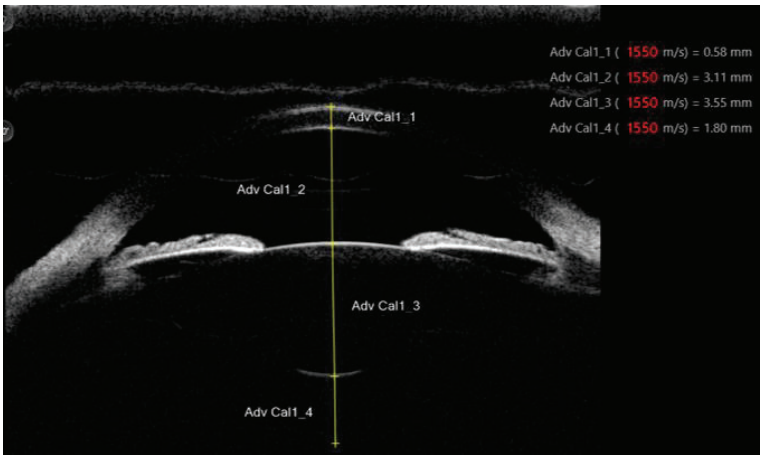
The Advanced Caliper tool enables to measure consecutive straight-line distances between two points. By default, the number of measurements to place in one sequence is set to 4 (see image below as an example).

NOTE
The ultrasound speed is 1550m/s by default. This parameter can be modified in the General Setup – Ultrasound Speed menu when launching the ABSolu application in Setup mode. The number of segments is also managed in this menu.

NOTE
The availability of the Advanced Caliper (Adv Cal) tool depends on the software installed on the ABSolu, the probe version and the probe used during the acquisition (not available on an image made with an older generation probe).



1. Select the Advanced Caliper tool.
2. Position the pointer over the desired location in the image and left-click to set the first point.
3. Move the caliper over the area to be measured and left-click to set the second point. The “Adv Cal1_1” reference with result is displayed in the tools result table.
4. Repeat steps 2 and 3 for the next measurements.
   - Right-click to validate the final point (even when the maximum number of measurements is not achieved).
   - Hold the SHIFT key to place consecutive calipers in a straight line (see image below).



The caliper reference “Adv Cal#_#” is displayed for each point in the image.
The “Adv Cal#_#” reference with result is displayed in the tools result table.

<u>To move a caliper:</u>

1. Left-click on a caliper point to be moved (the selected point will be highlighted in red).
2. Release the mouse button.
3. Move the mouse to reposition the caliper.
4. Left-click again to validate the new position.

5.4.1.6 Delete an exam tool and other tool actions

> To delete a tool, select it in the tools result table and press the “Delete” key on the keyboard.

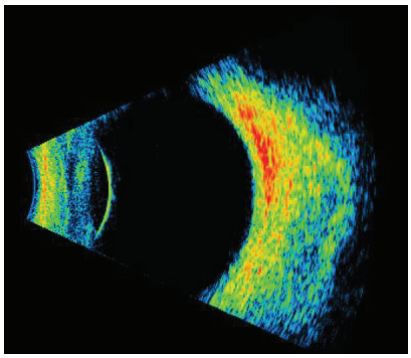
> To delete all tools at once, use the Eraser from the Tools menu:

> When selecting a tool, it is possible to use it and add the measurement to the post processing table. Then the tool function is automatically disabled.

> By double-clicking on a tool, the feature stays enabled. It is then possible to add additional measurements to the post processing table without having to reactivate the function. To disable the function, select the tool icon for the last time.

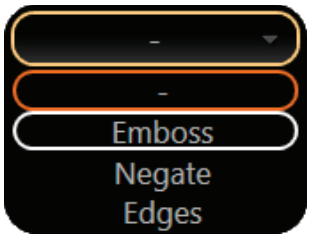
5.4.1.7 Color processing tool

> Select the Color Processing tool to display colors as in the example below.



5.4.1.8 Filters

> To apply a filter on a displayed B Scan image, select it from the drop list:



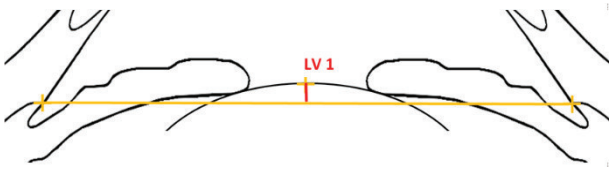
5.4.2 Advanced exam tools for LIN 50MHz probe (BHF-50LIN)

Advanced tools are available for the LIN 50MHz probe (BHF-50LIN) only. They allow semi-automatic measurements in the anterior with only 3 clicks:

- LV: Lens Vault.
- AOD: Angle Opening Distance.
- TIA: Trabecular Iris Angle.
- IT: Iris Thickness.
- ARA: Angle Recess Area.
- TISA: Trabecular Iris Space Area.

5.4.2.1 LV (Lens Vault) tool

The LV tool allows the user to easily measure the perpendicular distance between the anterior pole of the crystalline lens and a horizontal line joining 2 scleral spurs:



1. Select a scleral spur (right or left).
2. Select the opposite scleral spur.
3. Select the anterior face of the lens.
   A perpendicular line is automatically displayed, and LV measurement is displayed in the result table.

NOTES

Lens induced glaucoma (=phacomorphic glaucoma) refers to a marked swelling of the lens. It may convert an anterior chamber of medium depth into a shallow one and subsequently precipitates acute angle closure.

Lens size measurement is critical (A-scan) and lens vault is a quantitative factor helping to determine the risks of angle closure.

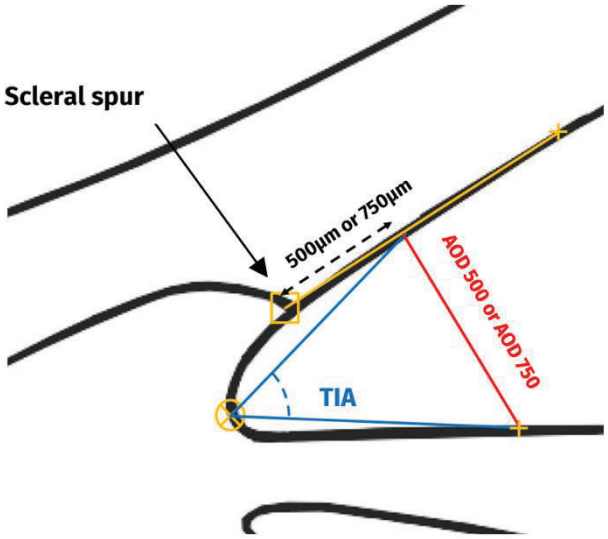
5.4.2.2 AOD and TIA tools

AOD (Angle Opening Distance)

This tool allows to measure the distance between the cornea and the iris at 500µm / 750µm from the scleral spur. This perpendicular line will automatically be displayed at 500µm / 750µm from the first marker: its length will be added in mm in the tools result table.

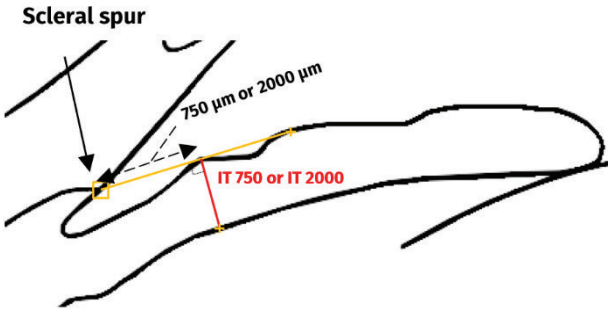
TIA (Trabecular Irido Angle)

The TIA tool can be selected after AOD selection. It allows the user to place a marker on the iris recess and measure the angle between the point on the trabecular meshwork at a distance of 500µm / 750µm and the point on the iris perpendicularly.



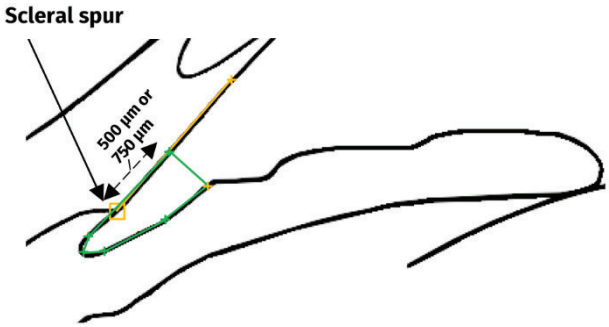
5.4.2.3 IT (Iris Thickness) tool

This tool allows measuring the iris thickness at 750µm / 2000µm from the scleral spur. A perpendicular line will automatically be displayed at 750µm / 2000µm from the first marker. This line will be displayed in mm in the tools result table.



5.4.2.4 ARA (Angle Recess Area) tool

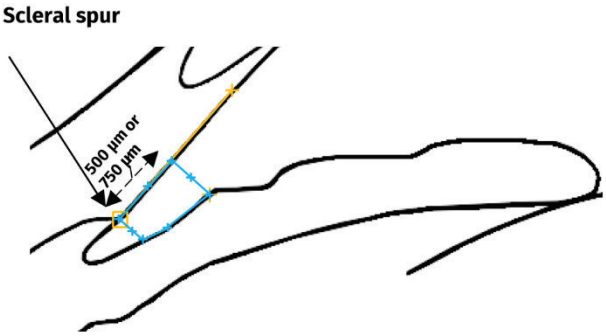
The ARA tool allows the user to easily measure the area of triangle between angle recess, iris, and cornea at 500µm / 750µm from scleral spur.



1. Select the scleral spur.
2. Pull the cursor along the posterior face of cornea and left click to place the second marker. The area of triangle between angle recess, iris, and cornea (at 500µm / 750µm from the scleral spur) is automatically detected.
3. Adjust markers to fill in the angle recess.

5.4.2.5 TISA (Trabecular Iris Space Area) tool

The TISA tool allows the user to easily measure the area of trapezoid between the iris and cornea from sclera to 500µm / 750µm.



1. Select the scleral spur.
2. Pull the cursor along the posterior face of cornea and left click to place the second marker. The area between the cornea and the iris (at 500µm / 750µm from the scleral spur) is automatically detected.
3. Adjust markers to form the best trapezoid shape.

6. BIOMETRY GUIDED BY B-MODE EXAM (B-SCAN EXAM SCREEN)

Bio-B exam can be performed using the 15MHz probe (B1) or the 20MHz-5A probe (B20-5A).

1. Access the Exam screen:

2. Select the B-scan probe.
   Bio B mode exam can be performed either with:
   - the 15Mhz probe (B1): select the B15 icon.

   OR
   - the 20MHz-5A probe (B20-5A) (annular transducer technology): select the B20 icon.
3. Provide the appropriate exam condition.
   To carry out this exam, the patient must be lied down. The easiest location for the examiner is to be behind the patient's head and have the ABSolu unit in front of the patient.
4. Select the eye on which the exam is to be performed (OD-right or OS-left). To do so, select the icon to display OD or OS in the exam screen:

5. Select the Bio B mode to display the biometry measurement table at the bottom of the acquisition screen.

6. Select the probe position on the eye (probe marker in the nasal or temporal position):
   - Press on the footswitch or the corresponding icon to activate the probe.

   - Adjust the probe position on the Patient eye as indicated in the “Calibration of the Probe Detection” window (if activated) and press on the footswitch to save the calibration, or select the Save icon:

NOTE
Probe orientation must be Axial.

7. Adjust the parameters for the Bio-B exam (in the menu above the acquisition screen):
   - Eye type (Phakic / Dense / Aphakic / PMMA / Acrylic / Silicone)
   - Vitreous type (Vitreous Natural / Silicone 1000 (980 m/s) / Silicone 5000 (1040 m/s))

NOTE
Refer to Section 4.4.1 Biometry mode: Exam screen functions for more detailed information about biometry parameters.

8. To trigger the acquisition, press the footswitch or select:

Biometry in B mode procedure

1. Use either ophthalmic gel directly on the cornea or the scleral shell technique.
2. Place the probe on the corneal vertex with the probe marker in the nasal or temporal position.
3. Find the macula and cornea.
4. When the appropriate scan is obtained, press the footswitch to freeze.
5. When the scan is complete, press the footswitch and select the best loop scan with the Cineloop function.

CAUTION
Be careful not to exercise any pressure on the cornea when measuring axial length.

6. Check that the CV line is well positioned: it should go through the center of the cornea and lens and then it should reach the macula.
7. The position of the CV line can be adjusted if necessary:
   - Left-click to select the line. It turns from yellow to red.
   - Move the CV line up or down.
   - Left click again to set the final position (or select the CV field and use the knob to modify the position of this CV line).
8. If necessary, modify the markers position.
9. Select the BIO icon to add the measurements from the selected loop to the table.

10. Repeat the measurements several times to get an average.
11. Select the IOL icon to display the IOL calculation results screen.

12. Save the results.

7. STS MEASUREMENT (B-SCAN EXAM SCREEN)

The optional STS module enables to perform automatic measurements of the sulcus to sulcus, Irido Cornea Angle Left/Right (semi-automatic measurement), lens curvature and anterior chamber depth.

This chapter outlines the preparation steps of an STS exam and how to start acquiring STS measurements.

7.1 STS Exam screen

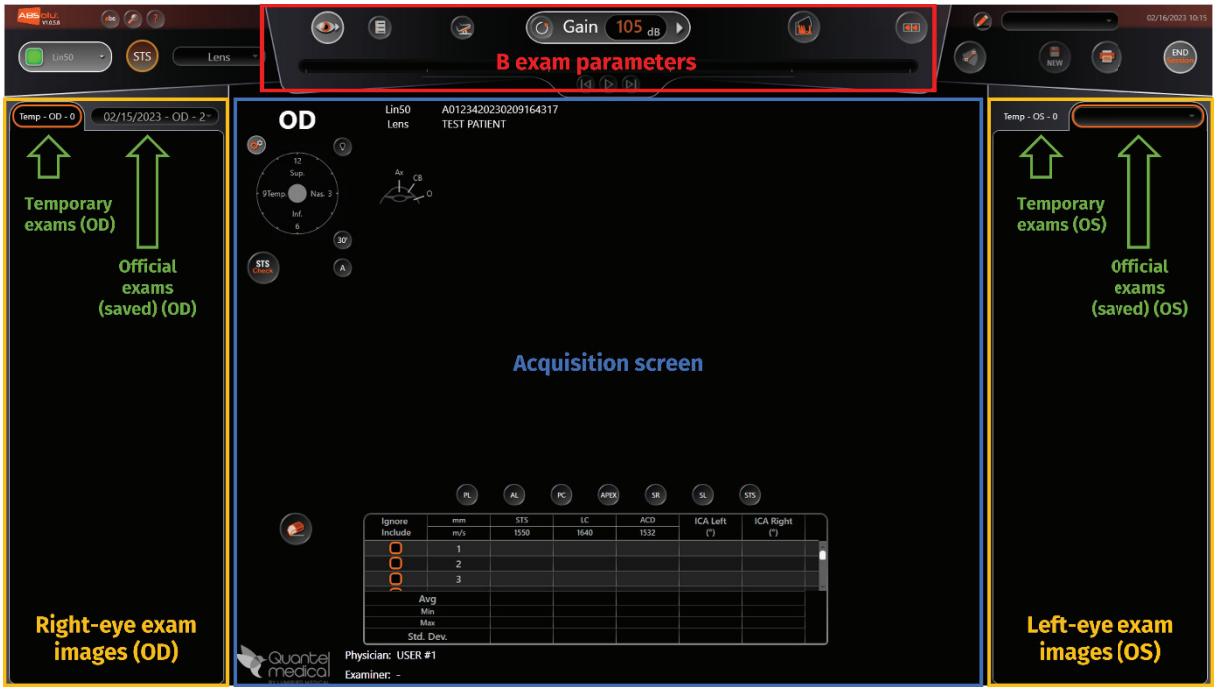
The optional STS module is available when the LIN 50MHz probe (BHF-50LIN) is selected.

To access the STS Exam screen:

1. Start a new session:

2. In the Exam screen, select the LIN 50MHz probe (BHF-50LIN).
3. Select the STS option to display the STS measurement table at the bottom of the acquisition screen.

The following screen is displayed:



4. Probe calibration should systematically be checked. If not performed yet, the warning message "Probe Checking NOT Approved" appears in the Exam screen. If needed, perform a probe check:

Refer also to ABSolu User Manual – Chapter V - General Setup & Maintenance.

7.1.1 STS parameters and tools

Most exam parameters are similar to B-Scan parameters which are explained in Chapter 5 B-Scan Exam screen. For STS measurements, the probe position is set to Axial by default.

All B-Scan exam tools are available in the STS Exam screen. Refer to Section 5.4 B-Scan exam tools.

CAUTION
The probe must be used only with removable windows and scleral shell for STS measurement. ClearScan® is not allowed for STS measurement, because the ClearScan® risks altering measurement precision.

7.1.2 Audible feedback for STS measurements

- High frequency sound: an image is saved / an automatic STS measurement is captured and visible in the results table.
- Low frequency sound: when the footswitch is pressed during acquisition, to inhibit the automatic measurement and the criteria are reached.
- Two successive sounds: all ten automatic STS measurements have been acquired. The probe automatically stops.

7.2 Acquisition with automatic STS detection

The procedure in this section explains how to obtain automatic STS measurement detection.

NOTE
To use the probe for sizing, the probe calibration should systematically be checked. Refer to ABSolu User Manual – Chapter V - General Setup & Maintenance section

7.2.1 Automatic STS detection using the immersion shell

The patient must be in reclined position on the examination table.

1. Use a probe equipped with removable window. Refer to Section 5.3.1.1 Preparing the probe using a removable window.
2. Instill anesthetics drops to the eye.
3. Put some ophthalmic gel on the edge of the immersion shell.
4. Position the immersion shell on the patient eye. The scleral shell must be centered on the pupil.

5. Fill the immersion shell with physiological serum.
6. Insert the probe in the immersion shell.

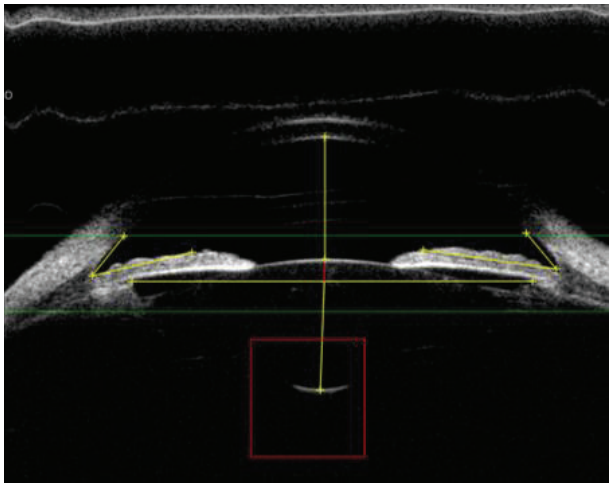
CAUTION
Applying excessive pressure on the eye will cause discomfort to the patient.

7. To maintain a stable eye position, make sure the patient is looking at a fixation point on the ceiling. When using a laser pointer, the point must be fixed and in the eye axis.
8. Center the probe in the eye cup to get a centered image in the Exam screen.
9. To obtain automatic measurements, position the probe in the axis of the eye and with the correct height in the eye cup.

7.2.1.1 Red square

The posterior lens within the red square is the first criteria to start the automatic STS measurement detection.

> Adjust the height of the probe in the eye cup to display the posterior lens in the red square.



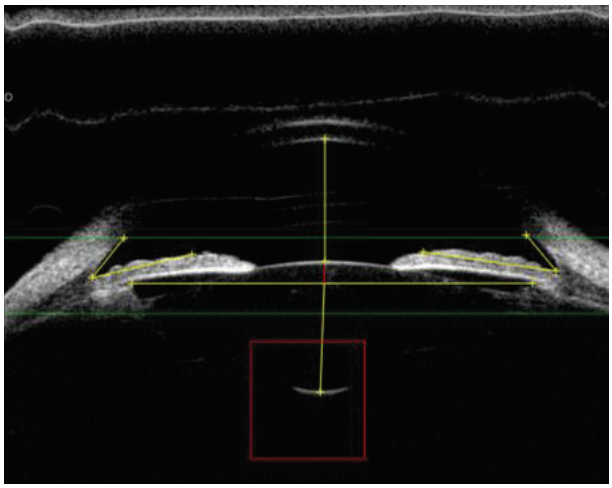
7.2.1.2 Green lines

The highest image quality lies between the green lines (e.g., focal area), where:

- Intensity of the echoes is maximum.
- Echoes are best separated and thus obtain optimal measurement accuracy (e.g., best definition).

For automatic STS detection, it is necessary to display the Iris between the two green lines, in the best horizontal position.

> Adjust the inclination of probe so that the Iris plate is as much horizontal as possible and between both green lines.



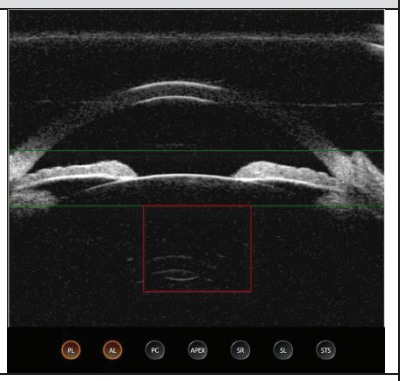
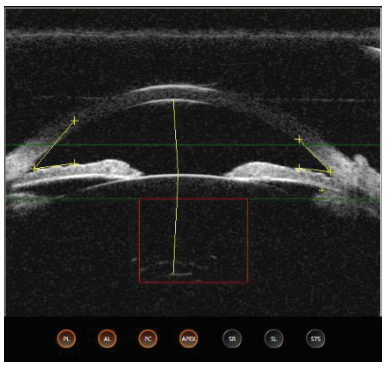
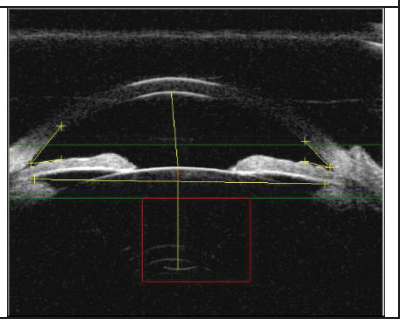
7.2.1.3 LED indicators for anatomical landmarks

The seven LED indicators correspond to anatomical landmarks checked by the system during the image and measurements acquisition.

At the beginning of the examination, all LEDS are turned off: none of the criteria required to trigger an automatic STS measurement has yet been filled.

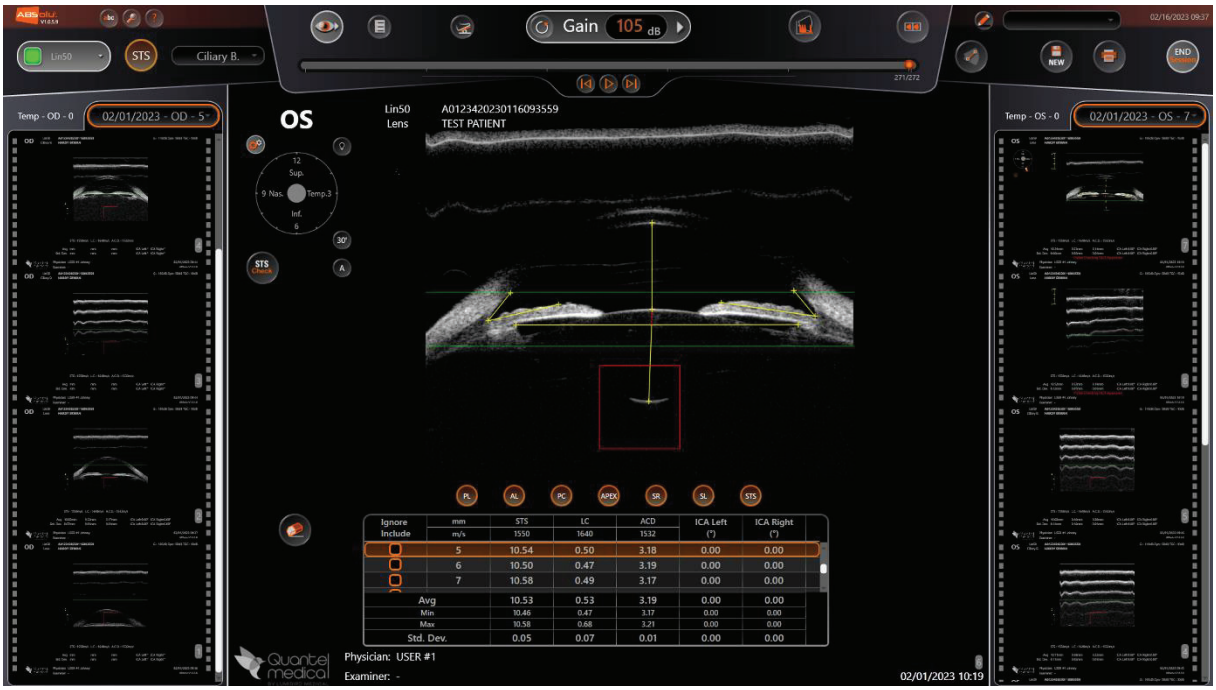
To trigger an automatic measurement, all LEDS must successively have turned on from left to right. When all criteria are turned on simultaneously, the automatic measurement is acquired and listed in the STS results table. For each measurement, a beep sound is emitted.

The table below lists the conditions to validate each criterion.

LED	Criterion	Why is the LED turned off?	Condition to turn LED on	Correct image visualization
PL	Posterior Lens	The Posterior Lens is not displayed in the red square.	• Adjust the height of the probe in the scleral shell to display the posterior lens within the red square.	
AL	Anterior Lens	The Anterior Lens is not in the axis of the probe.	• Adjust the position of the probe to get the Iris between the two green lines. • Check the probe is centered on the pupil and perpendicular to the cornea. • When the probe is correctly adjusted, the Iris plate is displayed horizontally between the two green lines.	
PC	Posterior Cornea	The Posterior Cornea signal is not detected.	• Incline the position of the probe to get the posterior cornea signal.	
APEX	Apex	The "APEX" criterion is switched on when the previous 3 criteria are validated: • Posterior Lens. • Anterior Lens. • Posterior Cornea.	• Adjust the position of the probe to get the correct image, as described in the previous steps. • The yellow vertical line is displayed when "APEX" is validated.	
SR	Sulcus Right	The Sulcus Right is not detected.	Make sure the probe is correctly centered in the eye cup to visualize both Sulcus on the image between the two green lines. **NOTE**: The Sulcus (right or left) signal cannot be validated if the "APEX" criterion has not been validated.	
SL	Sulcus Left	The Sulcus Left is not detected.		
STS	Sulcus To Sulcus	The Sulcus Left or the Sulcus Right is not detected.		

7.2.2 STS results table

The STS results table can list between 1 and 10 measurements.



These measurements are displayed in the results table:

- STS (*Sulcus to Sulcus*) Sulcus-To-Sulcus in mm.
- LC (*Lens* Curvature) Lens Curvature in mm to measure the distance between the Anterior Lens and the STS measurement. A red line in the image identifies the LC length.
- ACD (*Anterior Chamber Depth*) Anterior Chamber Depth in mm. A yellow line between the posterior cornea and the anterior lens identifies the ACD length.
- ICA (*Irido-Cornea Angles*) Irido-Cornea Angles measurement (in °).

The lines corresponding to the minimum and maximum STS measurements are automatically ignored. They are not included in the average (Avg) and Standard Deviation (Std. Dev.) lines.

Actions in the results table:

> Use the Ignore/Include checkbox to determine whether a line is included in or excluded from the calculation.

> To delete a line, right-click on it.

> Use the Eraser to clear all measurements.

8. REPORTS

Reports are edited documents that can be printed or digitally transmitted (PDF, EMR or DICOM, not JPEG).

A copy of those edited documents is stored in the database. With a Patient selected, the user can display all official edited documents as well as draft documents by clicking the documents icon:

Official documents cannot be modified nor deleted.

NOTE
Reports may automatically be deleted in case the user modifies the eye for a saved exam (with the OD/OS function in the examination screen).

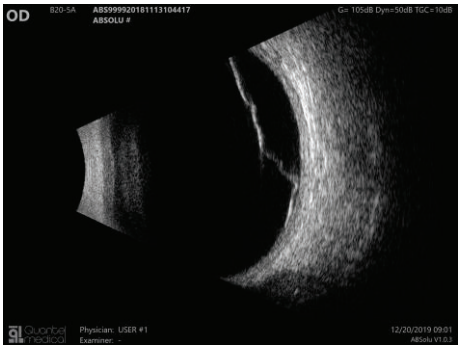
Temporary images are not accessible for reports; only the saved images can be printed.

8.1 Print an image on a USB video printer

To use the video printer, the option must be activated. Refer to ABSolu User Manual – Chapter V - General Setup & Maintenance Section 1.1. Main Settings.

> In the Exam screen, click the Printer icon and choose to print the image on the video printer.

Video printer image example:



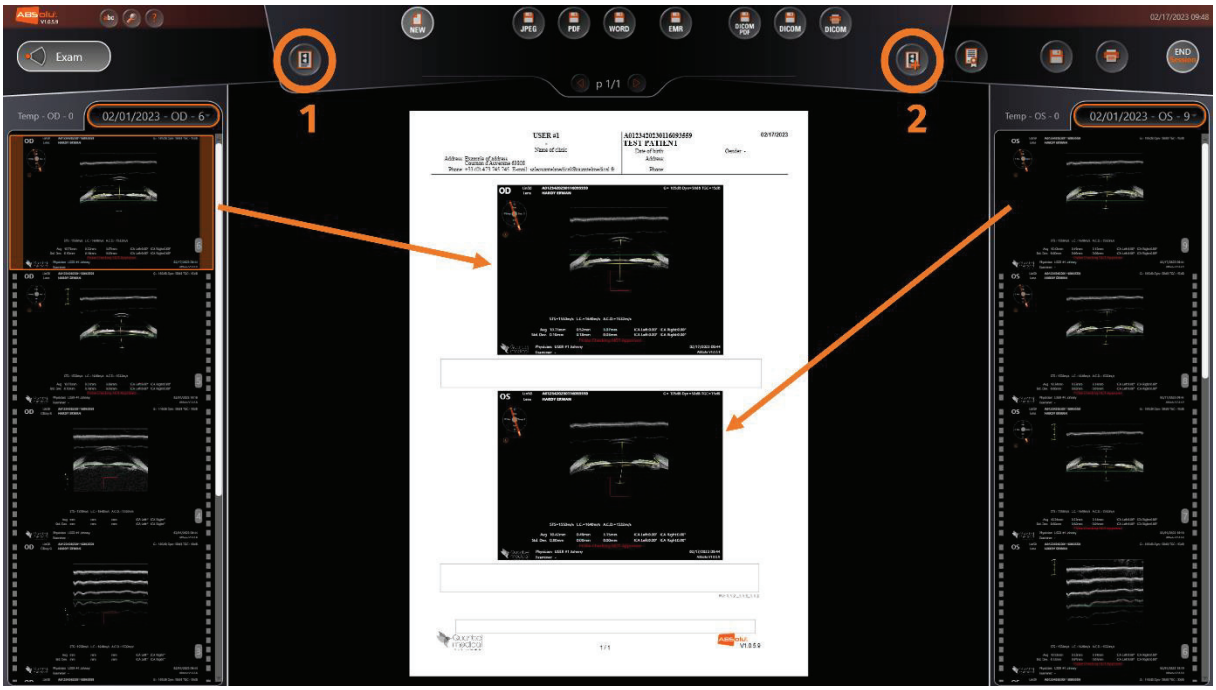
The image has to be saved in order to print it on the video printer. Only one image can be printed on the video.

8.2 Print the reports on Windows printers

When an A-SCAN or B-SCAN exam session is ended and exams are saved, the user can create exam reports.

1. In the Exam screen, click the Printer icon and choose to print the image on the Windows printer.

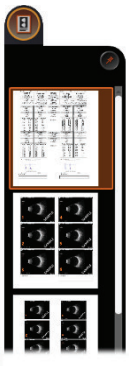
The Report screen is displayed.



1  Enables to select a template.

2  Enables to add a new page with another template.

2. Select the Templates icon to modify the current template (e.g., single or multi picture template or IOL report template) from the drop list:



Double-click or drag images or IOLs results in the selected template. Up to 8 images can be displayed on one page.

3. If necessary add notes in these areas:
   - Report title.
   - Comments.
   - Footer.

NOTE
Report title and footer comments are available depending on the header/footer templates selected in the General Setup.

4. Right-click on the title or comment text to personalize it. Any modifications are automatically applied in the entire text zone, not on a specific text part.

From the contextual menu, select:
   - Font size. This can be modified only for comments . The Report title has a fixed font size (10pt.).
   - Bold, italic, or underlined text.
   - Left, center, or right text alignment.
   - Cut, copy, paste text.
5. If needed, add new report pages with different templates. A report can consist of up to 12 pages.
6. To erase create a new report, click the New icon:

The current report must be deleted in order to create a new one.

8.3 Report export options

The table below lists the options to export a report.

NOTE
For DICOM functionalities and report export options, refer to ABSolu User Manual – Chapter IV – DICOM option.

Export all images inserted in the report pages in .jpeg format to D:\ABSolu\JPEG

Export reports to .pdf format to D:\ABSolu\PDF

Export reports to Word format to D:\ABSolu\WORD
NOTE: Reports containing IOL data cannot be exported to Word format.
NOTE: The layout may be altered depending on the installed Word version.

Export Electronic Medical Record (EMR) files to D:\ABSolu\EMR

These are default paths. To change the export folder, refer to ABSolu User Manual – Chapter V - General Setup & Maintenance - Section 1.9. - Export settings.

9. ENDING THE EXAM SESSION

Once all exams for the selected Patient have been performed and saved and the reports have been generated, end the session in order to return to the Welcome Screen.

NOTE
When closing the exam session, a message indicates that all temporary images and temporary reports will be deleted.

IV – Data transfer

EMR

(Electronic Medical Record)

DICOM Option

(Digital Imaging and COmmunications in Medicine)

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Website: www.lumibird-medical.com

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1. EMR (ELECTRONIC MEDICAL RECORD)

The EMR function allows the user to export:

- To .xml format:
  - User and Patient data.
  - Measurements (axial length, exam parameters and calculations)
- To .jpeg format:
  - Pictures (A mode, B mode : 15MHz – 20MHz-5A – LIN 50)

To export an exam:

1. Set the EMR parameters as explained in the ABSolu User Manual – Chapter V – General Setup & Maintenance Section 1.9.- Export settings:
   - Activate the EMR Icon in Report Screen.
   - Indicate the location where the EMR files should be exported by default.
2. To export an exam to EMR format, select Printer icon in the Exam screen.

3. In the Report screen, choose the EMR option for export:

See also ABSolu User Manual – Chapter III – Using the ABSolu Section 8.2.- Print the reports on Windows printers.

NOTE
Import of patient data in .xml format is optional and must be activated in the keycode. This option is managed in an .xsd file. To know which tags to import, contact QUANTEL MEDICAL or the local distributor for delivery options of the .xsd file.

2. DICOM

DICOM (Digital Imaging and Communications in Medicine) is a global information technology standard that is used in virtually all hospitals worldwide.

The ABSolu DICOM option allows the user to:

- Save the exams (with Patient data) on a Picture Archiving and Communication System (PACS) using the DICOM protocol.
- Activate Modality Performed Procedure Step (MPPS) to gather information about the activities, conditions, and results of an imaging procedure performed on the ABSolu
- Import Patient data as a work list (Modality Work List) in DICOM format.
- Print on a DICOM printer.

This function must be validated as explained in section 2.1.

2.1 DICOM function activation

The DICOM function must be activated by a code. This code (software keycode) is unique to each ABSolu unit. To generate this unique keycode, QUANTEL MEDICAL and/or your local distributor will need the following information:

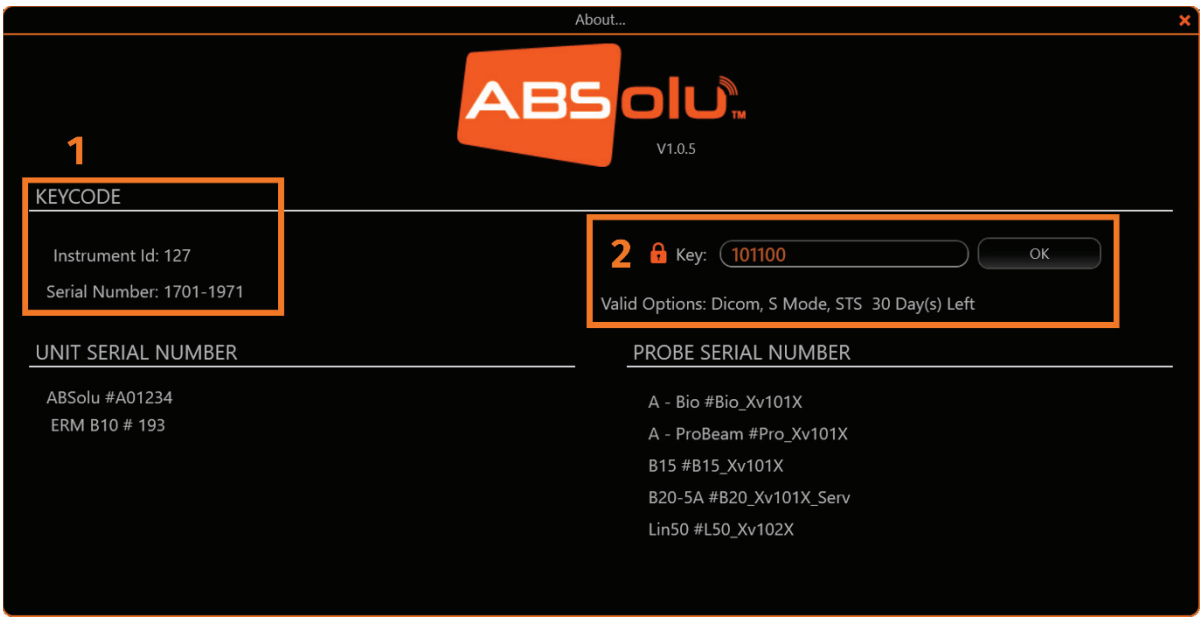
- Unit Serial Number.
- Instrument Identification number (Instrument ID).

<u>To check if DICOM is activated:</u>

1. Click the Question mark.

2. Select About...

The following screen is displayed:



1 Information for QUANTEL MEDICAL to generate the keycode; 2 Enter the keycode

NOTE
A free keycode (e.g., 101100) can be used for a 30-day trial.

2.2 ABSolu operability with DICOM

The ABSolu Software works together with network components (ABSolu Application Entity) to provide connectivity to a DICOM network.

Picture Archiving and Communication System (PACS) servers are used to retrieve digital medical images (e.g., from ultrasound unit) in order to store files in DICOM format.

Example:

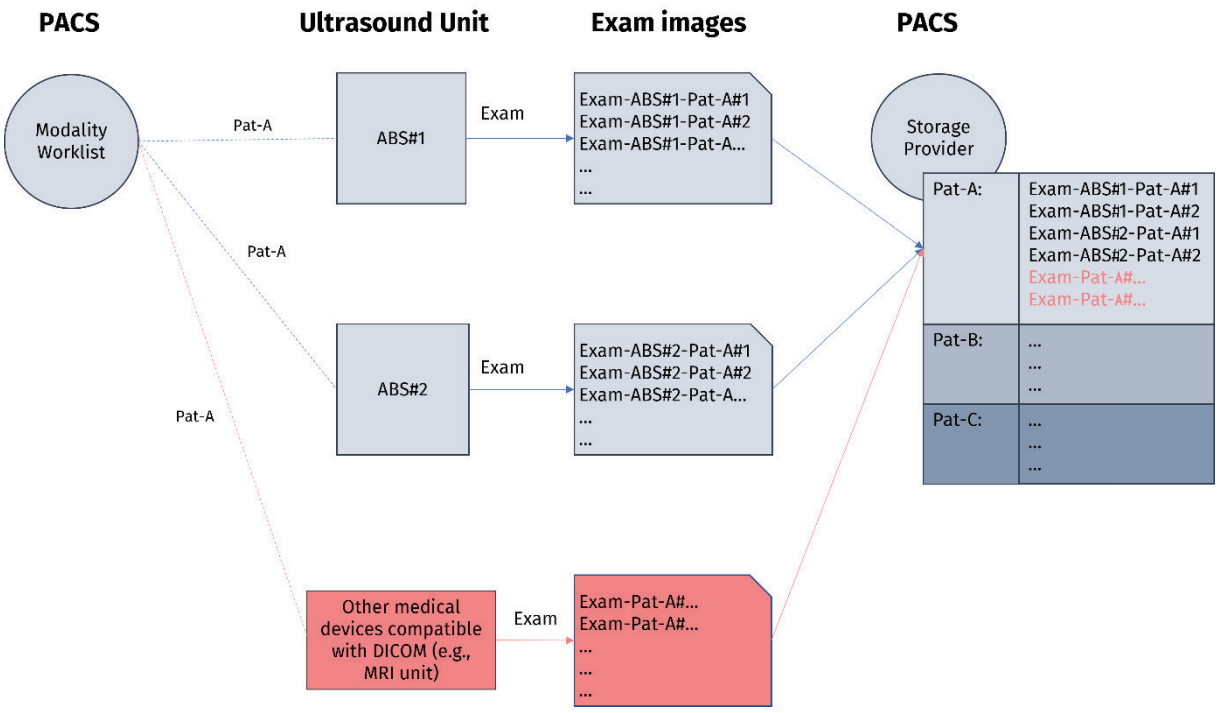
A file for patient A (Pat-A) is created in the DICOM Worklist. The data from the patient file can then be imported in the ABSolu devices. In this example, 2 devices are used:

- ABS#1
- ABS#2

The user can now examine patient A on ABS#1 or ABS#2 and save the results on the DICOM network. If patient A has been examined on both devices, the results will be stored in the same patient file in the DICOM network; there is no difference between exams realized on ABS#1 or ABS#2.

Exams stored in the DICOM network cannot be downloaded on the ABSolu.

The figure below illustrates how the ABSolu device operates with DICOM.



3. DICOM CONNECTION PARAMETERS

3.1 Set up DICOM parameters

1. From the Patient Selection screen, access the General Setup screen:

2. From the drop list, select “10 – Dicom Settings”.

NOTE
The “10 - DICOM Settings” entry is only displayed if the DICOM option has been activated in the “About” screen.

3. Enter DICOM connection parameters (see example in the image below). If needed, contact the network administrator.

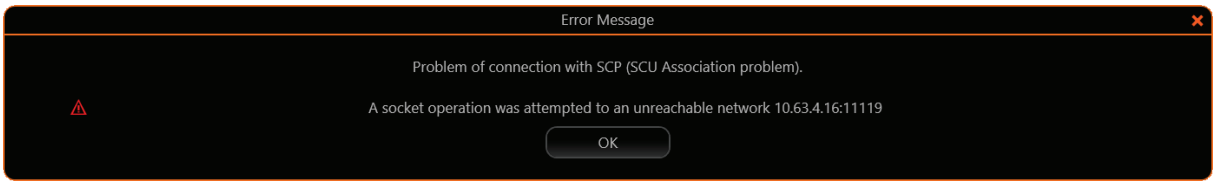
All parameters must be set in order to use all DICOM functionalities:

- Use Worklist :
  - Select a Defined Term (ISO_IR 92, ISO 2022 IR 6 etc.) for a Specific Character Set (Latin alphabet No. 1, Latin alphabet No. 2 etc.).
  - Enables to access the list of Patients on the DICOM server.
- Use MPPS (Modality Performed Procedure Step) When configured, enables to gather information about the activities, conditions, and results of an imaging procedure performed on the ABSolu.
- Use Storage:
  - Select a Defined Term (ISO_IR 92, ISO 2022 IR 6 etc.) for a Specific Character Set (Latin alphabet No. 1, Latin alphabet No. 2 etc.).
  - Enables to save images and/or reports on the DICOM server.
- Use Print Enables to print images and/or reports using a DICOM printer.

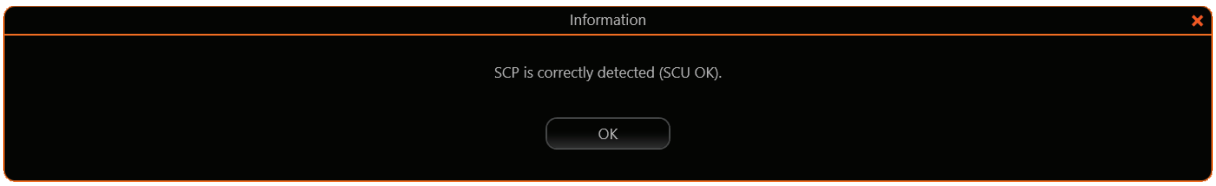
When the parameters are set, the Test option can be used to verify the connection:

> When the “Problem of connection with SCP (SCU association problem)” message is displayed, then the communication is not correct. PC connection and DICOM parameters should be rechecked.

NOTE
To display the message in detail, click the red triangle in the dialog box.



> When the “SCP is correctly connected (SCU OK)” message is displayed, then the communication is correct. Data can be received from and sent to the PACs server.



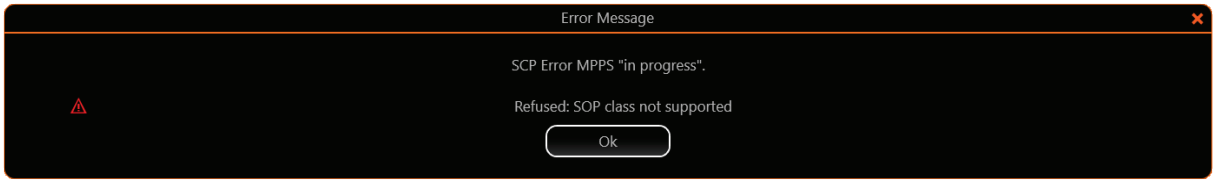
3.2 MPPS parameters

When MPPS parameters are set in the DICOM Settings, it enables to provide information about the examen, the number of images and the exam status. MPPS is a network message sent at the beginning and at the end of a session to the PACs.

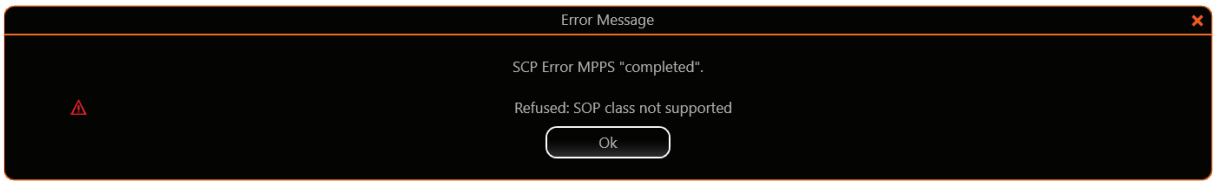
The error messages below may appear in the ABSolu unit concerning MPPS connection.

NOTE
To display the message in detail, click the red triangle in the dialog box.

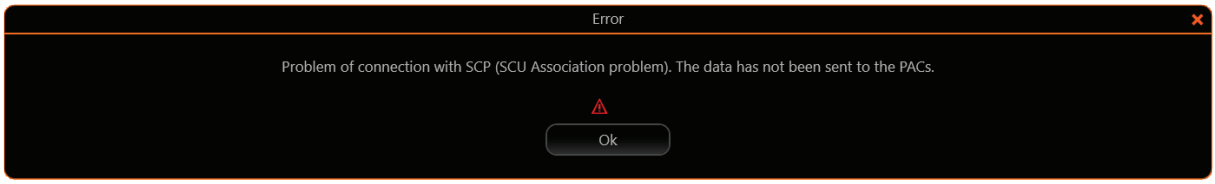
> When the error message below is displayed upon a new session, then the communication is not correct. The message could not be sent at the beginning of the acquisition because the SOP class is not supported. PC connection and MPPS parameters should be rechecked.



> When the exam is done and user saves the results, the error message below appears in line with the previous message. It indicates a connection problem because the SOP class is not supported. MPPS data has not been sent to the PACs at the end of the acquisition.

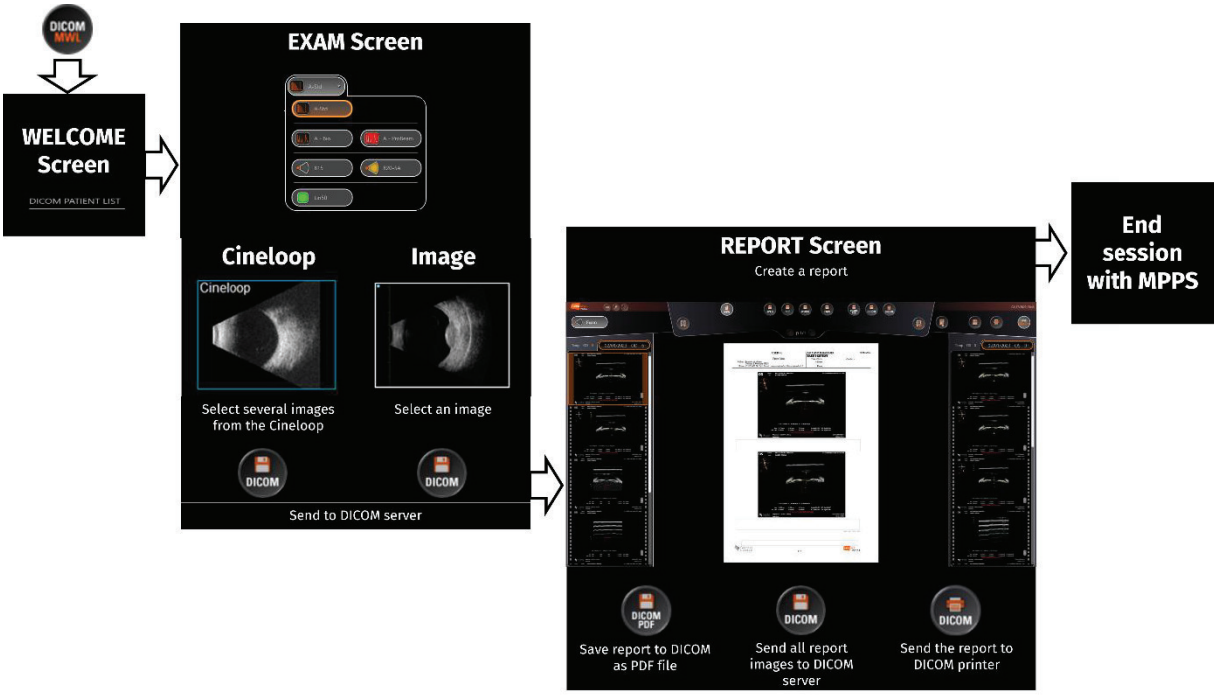


When MPPS messages could not be sent at the beginning and the end of the acquisition, the error message below appears. It indicates a connection problem because the SOP class is not supported.



4. DICOM FUNCTIONALITIES

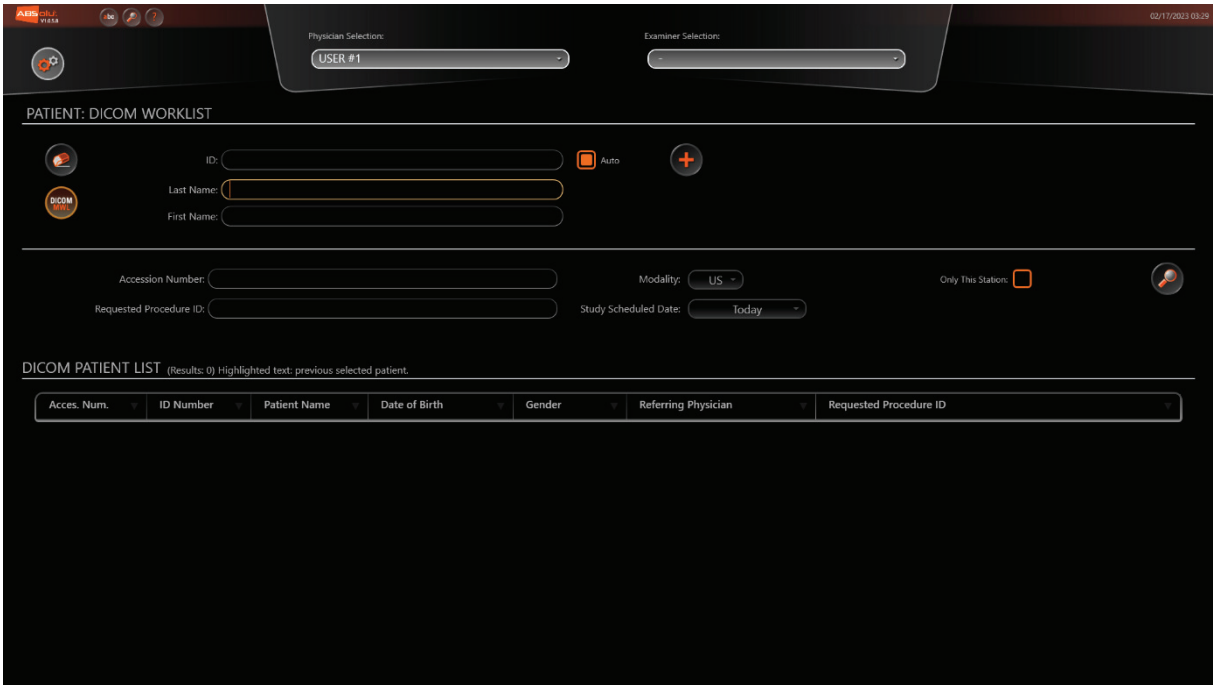
The diagram below is an overall view of DICOM functionalities.



4.1 Worklist function

If the DICOM function is validated and the option “Use Worklist” is checked in the “DICOM Connection parameters” screen (See Chapter 3 - DICOM connection parameters), then the Worklist button will be displayed in the Welcome screen:

When selected, the following screen is displayed:



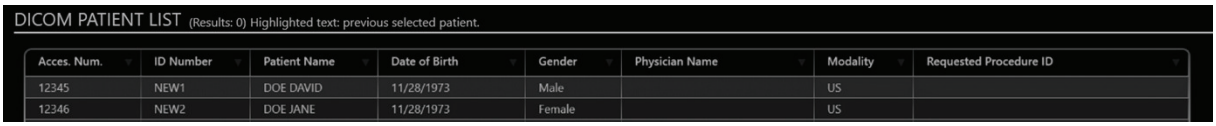
> To search for a Patient in the DICOM database, type in the first known digit for the ID, Last Name or First Name and press “Enter”.

> Type ‘*’or ‘%’ in any of those fields to display the complete Patient list with all names.

Click the Search button to display the patients in the DICOM database. These columns may be indicated in the results table.

Accession Number	ID Num.	Patient Name	Date of Birth	Gender	Physician Name	Modality	Requested Procedure ID

Example:



NOTE
The list and order of the displayed parameters in the Worklist can be updated. Please contact QUANTEL MEDICAL or your local distributor for more information.

Actions in the DICOM Patient list:

> If the **Only this station** option is checked, only the Patients selected for in the “ABSolu AE Title Station” will be displayed in the resulting list.

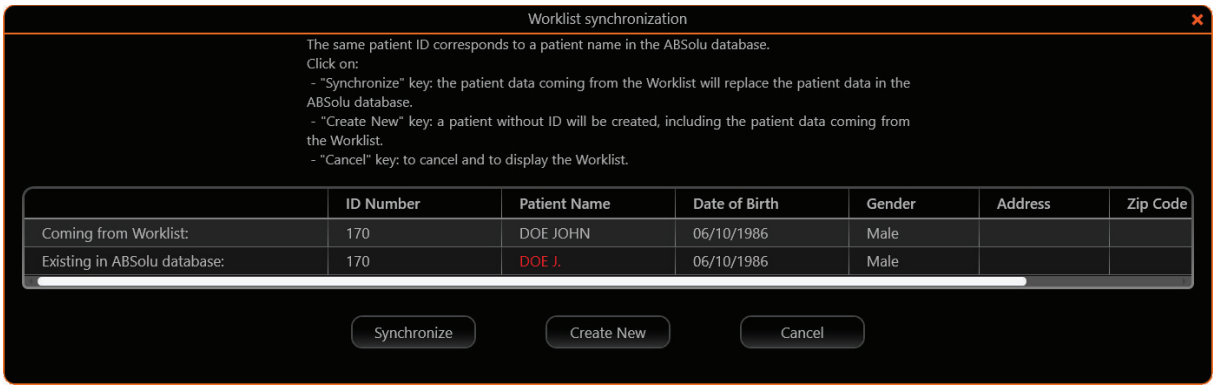
> Double click on a selected Patient in the Worklist to import this Patient information to the ABSolu software. Previously selected patients are highlighted in the DICOM Patient List.

> All Patient data can be selected and saved to be integrated to the ABSolu database. Patient data can be added or modified if necessary.

> In case the ID is the same, but at least one piece of Patient data is different (e.g., first name, last name, date of birth, gender) between the Worklist database and the ABSolu database, a “Select a Patient” window appears.

- If the Patient in the DICOM database is not the same as in the ABSolu database, a new patient file can be created.
- If the Patient in the DICOM database is the same as in the ABSolu database, the patient information can be synchronized. The Worklist information will be transferred and updated in the ABSolu database.

In the “Worklist synchronization” window, any differences will be displayed in red. When “Synchronize” is selected, these differences appear in red in the Patient file.



4.2 Print/storage function

4.2.1 Using the “Save to DICOM” function

When the DICOM option is activated, the save function becomes available in the Exam screen:

Exam can then be saved to the DICOM server as an image.

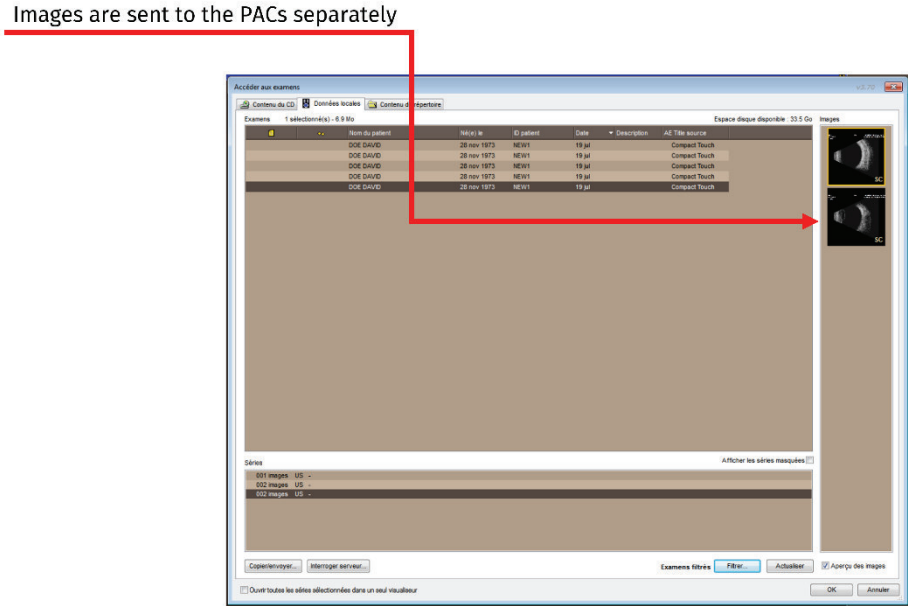
4.2.2 Using the report function

NOTE
This section uses the simulation of a DICOM server (PACs). Depending upon your PACs and its setup, images and functionalities may be different. This software is not provided by QUANTEL MEDICAL.

When the DICOM option is activated, several report functions become available in the Report screen:

> To send all images displayed in the report to the DICOM server, select:

Images are sent to the PACs separately:



> To send the exam report to the DICOM server in .pdf format, select:

> To send the exam report to the DICOM printer, select:

4.2.3 Exporting a cineloop to a DICOM server

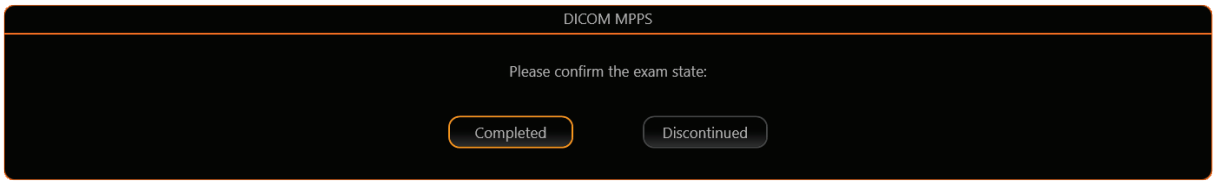
1. In the B mode acquisition screen, once the acquisition has been performed, select the Cineloop bar (it turns red):

2. Send the cineloop sequence to the DICOM server:

NOTE
Depending on the number of images sent and the connection, the transfer time can be several seconds or even minutes.

4.2.4 End session with MPPS configured

> When ending the session with MPPS, the **DICOM MPPS** message below appears. Click either **Completed** or **Discontinued** to set the status of the Modality Performed Procedure Step.



V – ABSolu General Setup & Maintenance

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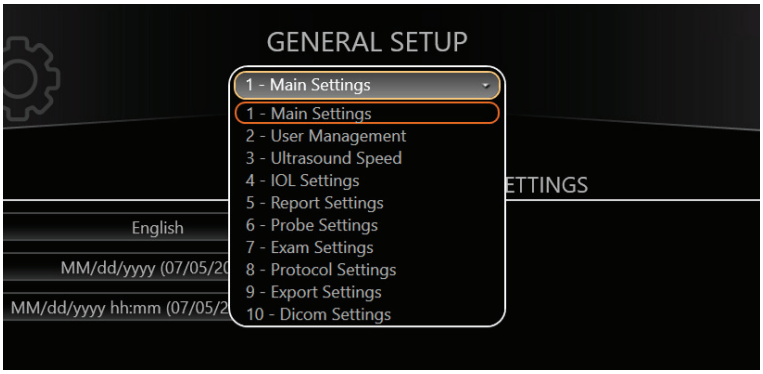
1. GENERAL SETUP SCREEN

> To set up the system, access the “General Setup screen” (from the “Patient Selection” screen) by pressing the following button:

NOTE
The “Patient Selection screen” is described in Section 1.2.

In the middle of the “General Setup screen”, a dropdown list enables to set up all system parameters:



1.1 Main Settings

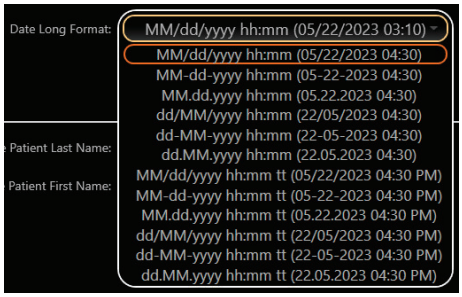
The ABSolu setup shortcut (“Absolu.Presentation.Main.Setup”) can be found under the following link: C:\Quantel\ABSolu

> Once opened, select Main Settings to adjust main system parameters.

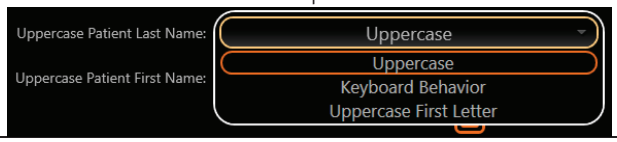
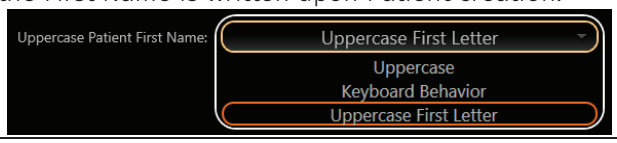
The following screen is displayed:

NOTE
These parameters are available only when launching the application with the "ABSolu - Setup.exe" file: **Patient Confidentiality**, **HIPAA compliance**, **Import Settings**, **General Setup Password**.

Default parameters

Parameter	Allows user to:
Language	Select the language to be displayed in the ABSolu application from the drop list: English / French / German / Spanish / Polish / Japanese / Chinese Restart the application to apply the changes.
Date Short Format	Select the date short format to be displayed in the ABSolu application from the drop list:  The list format depends on the selected language.
Date Long Format	Select the date long format to be displayed in the ABSolu application from the drop list:  The list format depends on the selected language.

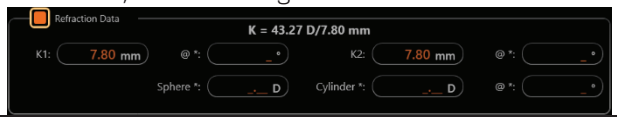
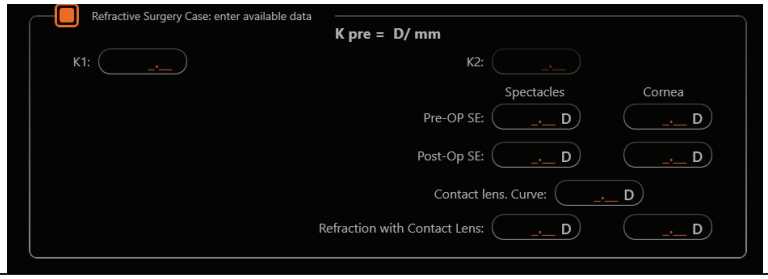
ID patient settings

Parameter	Allows user to:
Uppercase Patient Last Name	Select how the Last Name is written upon Patient creation: 
Uppercase Patient First Name	Select how the First Name is written upon Patient creation: 
Default ID Auto	Select the checkbox so that when a Patient is created, its ID is automatically generated by the system. Leave this box unchecked in case you want to be able to enter a different ID.

Default patient data

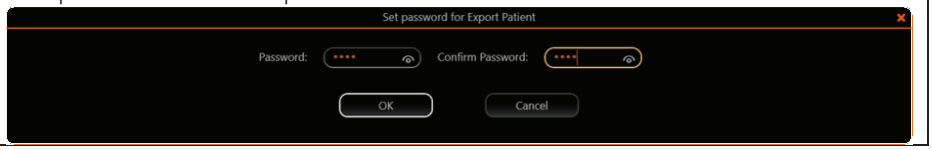
If these options are activated, some patient data is completed as well as additional data information fields are available when creating a new Patient.

See also ABSolu User Manual – Chapter III – Using the ABSolu Section 2.2.2. Selecting/Creating a new Patient.

Parameter	Allows user to:
Default Ame Value	Select an Ametropia value that will be displayed by default when creating a new Patient. The possible values have to be selected between -20 to +20 Diopters.
Default Refraction Data	Select the checkbox to display the Patient Refraction data information fields. When activated, the following refraction data can be entered: 
Default Refractive Surgery Case	Select the checkbox to display the Patient Refractive Surgery Case data information fields. When activated, the following refractive data can be entered: 

Export settings

NOTE
The export of patient data is only for the QUANTEL MEDICAL after-sales service in the context of after-sales diagnostics.

Parameter	Allows user to:
Activate Password to Export Patient File (Archives)	Set a password on an exported patient file. When the option is activated in the keycode, a password can be set on exported files. When reimporting a patient file that was exported before, this password must be provided. 

Import settings

NOTE
This option allows to import patient files in .xml format. Contact QUANTEL MEDICAL or the distributor for more information.

Parameter	Allows user to:
Activate the Patient File Icon in Welcome Screen	Select the checkbox to import Patient Files. When the option is activated in the keycode, the import settings are managed in the General Setup.
Import of Patient File	Browse and select the path from which to import patient files.

Printer settings

Parameter	Allows user to:
Activate USB Video Printer	Select the checkbox to use an USB video printer (A6 format). This option will then be available in the Exam screen when the user will select the "Print" function. NOTE: Only one image can be printed on the video printer.
By Default, Print Function (In Exam Screen) Allows To Print In A6 Format	Select the checkbox to print images in A6 format by default
Ink Saver (Print biometry curve in black on white background)	Ink saver option
Display Limited Information to Images	Select the checkbox to get clear images with minimum text information.

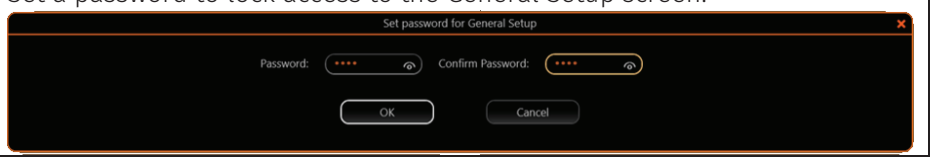
Patient confidentiality

Parameter	Allows user to:
Activate Hide Selection	Select this checkbox to hide Patient information
Activate Password Function	When this checkbox is selected, the Physician has the option of choosing a password. By setting up a password, the user can make sure that its Patient data remain confidential. The password is then required to visualize and save images or access Patient files

HIPAA compliance

Parameter	Allows user to:
Default Parameters for HIPAA Compliance	When this checkbox is selected: the following options are activated by default: • Disable OS/OD icon • Disable Save icon • New save Icon Displayed By Default
Disable OD/OS Icon	The OD/OS function allows the user to change eye on a saved exam in case the wrong eye was selected by error before the exam. This option may be disabled by selecting this checkbox.
Disable Save Icon	When this option is selected: it is impossible to save a new exam over an older one. It is only possible to save the exam as a new exam (e.g., with the "New Save" icon).
New Save Icon Displayed By Default	The "New Save" icon allows to save exams as new exams only.

General Setup password

Parameter	Allows user to:
Activate Password to Access General Setup	Set a password to lock access to the General Setup screen: 

1.2 User Management

> Select **User Management** to adjust the user parameters.

The following screen is displayed:

Physician list

Parameter	Allows user to:
Physician List	Enter Physician's Last Name and First Name.

Examiner list

Parameter	Allows user to:
Examiner List	Enter Examiner's Last Name and First Name.

Clinical information

Parameter	Allows user to:
Load Logo	Load a clinic Logo which can be displayed in exam reports.
Clinic Information	Enter Clinic Name, Address, Zip Code, City, Country, Phone, Fax, and E-mail. This information will be displayed in exam reports.

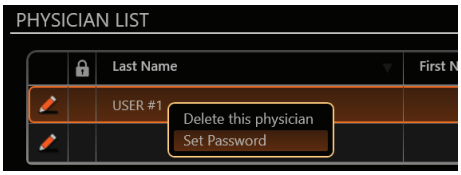
Physician password

If needed, a password can be set to secure Physician parameters.

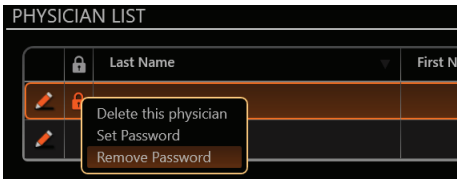
NOTE
This configuration is available only when launching the application with the "ABSolu -Setup.exe" file.

1. In the **Main Settings**, check the "Activate Password Function" parameter. When returning to User Management, a chain icon is displayed in the Physician List table:

2. Right-click a physician from the table and select “Set Password”:



3. Set and confirm the new password. Then click OK.
4. To delete a password, right-click the physician and select “Remove Password”. Then enter the password to confirm deletion.



1.3 Ultrasound Speed

> Select **Ultrasound Speed** to adjust the ultrasound speed parameters for Lens materials and Vitreous materials.

NOTE
The **Default Parameters** are available only when launching the application with the “ABSolu - Setup.exe” file.

The following screen is displayed:

Default parameters for axial length measurement

Select the Ultrasound Speeds of propagation displayed by default in the Exam screens:

- For the Cornea and for the Anterior Chamber, each value displayed in orange can be changed / adjusted.
- Select a Lens Material. New implant materials for Lens Materials and their corresponding Speeds can be created.
- Select a Vitreous Material. New Vitreous Materials and their corresponding Speeds can be created.

NOTE
The Cornea is available only when the standardized probe is installed and when the "Activate Axial Length" is selected. Refer to Section 1.6 Probe Settings.

Default parameters

Values in orange can be changed / adjusted.

The maximum number of segments for the Advanced Caliper tool is 7.

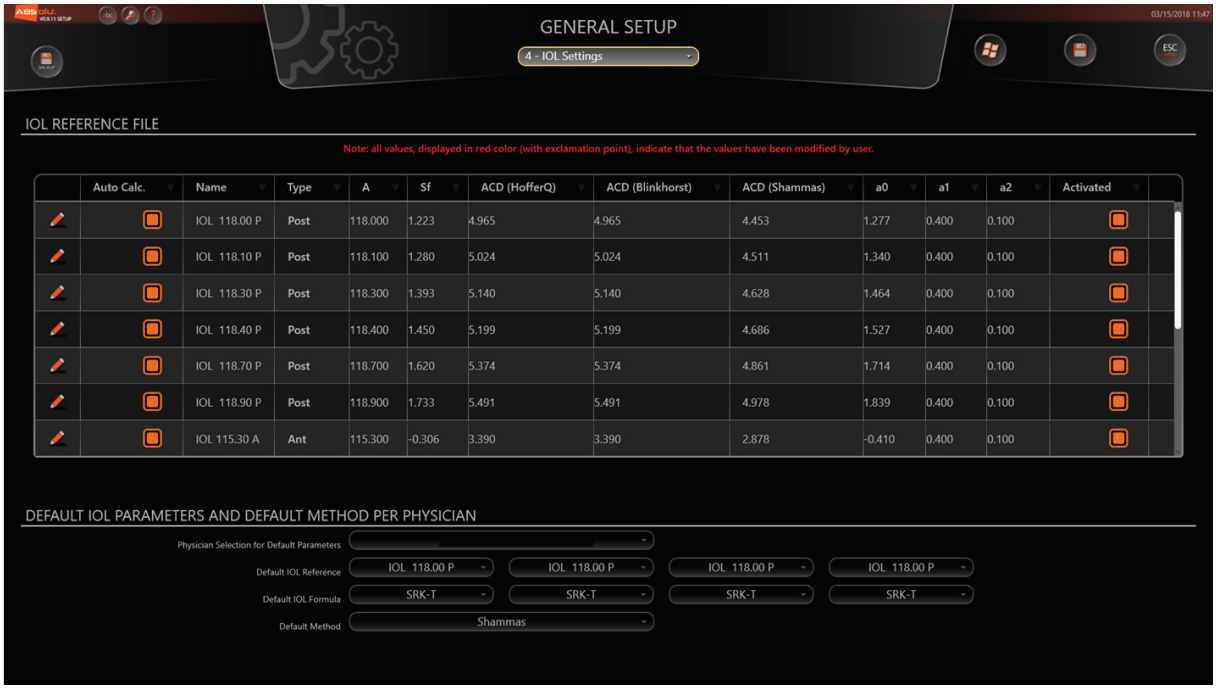
Default parameters for STS measurement

Values in orange can be changed / adjusted.

1.4 IOL Settings

> Select IOL Settings to set up the IOL parameters.

The following screen is displayed:



IOL reference file

The user can personalize the IOL reference file:

- Modify a name or an IOL value
- Delete or create a new IOL

The table displays the default values for IOLs constants.

When the “Auto calc.” checkbox is checked, the values are automatically calculated by using the A constant.

When the “Activated” checkbox is checked, the corresponding IOL reference is displayed in the Default IOL Reference List.

WARNING

All the parameters can be modified within the limits described in ABSolu User Manual – Chapter II – Technical Information Section 2.10.7.- Data entry limits.

The Haigis constants (a0, a1, a2) also have to be modified within the combined limits described in this same chapter.

- A, SF and ACD are linked together. Modifying one of them will impact the value of the others.
- The Haigis default values a0 is also calculated from the A constant.
- The ACDb constant is not calculated. It must be entered manually. The ACDb constant is used in the Binkhorst formula.

NOTE

It is recommended to make a backup of this IOL table prior to any modification or unit servicing. For more information concerning IOLs formulae, please refer to ABSolu User Manual – Chapter VI - Appendix: IOL formulae. All values, displayed in red color, indicate that the values have been modified by the user.

Default IOL parameters and default method per physician

The Physician can choose up to 4 IOLs and formulae that will be displayed / used by default in the IOL result screen as showed below:

1.5 Report Settings

> Select **Report Settings** to set up report parameters.

The following screen is displayed:

NOTE
Any template selections or font modifications will be visible under Preview in the right area of the Report screen.

Default header/footer and Comments font

> Select an available header/footer template (e.g., with or without editable report title or footer comment).

> Set the comments formatting (e.g., font, font size, text alignment).

Default templates

> Under “Available Templates”, select a template and drag it to “Favorite List”. Repeat this step for each template to be added. These templates will then be used by default in the Report screen.

> Load new templates:

> Delete a template:

1.6 Probe Settings

> Select **Probe Settings** to adjust probe parameters.

The following screen is displayed:

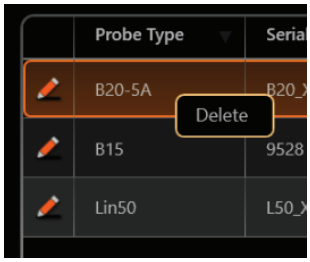
Each biometry and B probe has specific parameters. The list of all already installed probes parameters is displayed in the tables (see figure above):

- Biometry probe parameters table.
- B probe parameters table.

This list should correspond to the Serial Numbers of the probes currently in use on the ABSolu unit.

1.6.1 Delete a probe

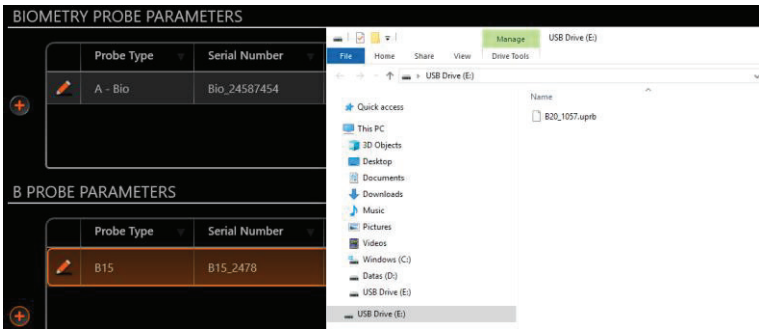
> To delete a probe, right-click on it and select “Delete”.



1.6.2 Install a probe

1. Insert the matching USB flash drive in one of the USB-ports on the ABSolu unit.
2. Add a new probe:

3. In the “Select the probe parameters” dialog box, select the probe parameters file. It corresponds to the probe’s Serial Number that must be installed. The probe will consequently be added to the probe list.

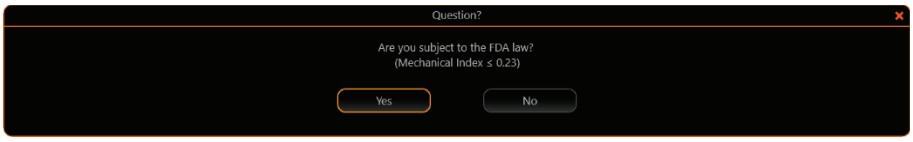


The message below appears when the B20-5A probe parameters are installed.

> Click on **Yes** for USA only.

> Click on **No** for the Rest of the world.

> Click the **X** to close the dialog box temporarily. The message will reappear at the next launch.



WARNING
Carefully read these warnings when installing probes:

- The serial numbers of the listed probes should correspond (and only correspond) to the serial numbers of the probes actually connected or used on the unit!
- Two probes of the same type must not appear in the list. If this is the case (e.g., their parameters are installed), then the ABSolu may use the wrong calibration and measurements. The probe not currently in use on the unit must be removed from the list.
- When a new biometry probe is installed, it is necessary to follow the calibration procedure as described below (Measurement test / A mode calibration)
- When a LIN 50MHz probe (BHF-50LIN) is installed, it is necessary to check the probe calibration as described in Chapter 2 Linear calibration check.

1.6.3 Biometry probe parameters

Parameter	Allows user to:
Default Technique Immersion	Select the technique displayed by default in the biometry exam screen: Contact or Immersion ABSolu User Manual – Chapter III – Using the ABSolu Section 4.2. Biometry techniques and precaution of use **NOTE**: Contact technique is only available when D1 is selected
Default Acquisition Auto + Save	Select the acquisition mode displayed by default in the biometry exam screen: Auto + Save / Auto or Manual ABSolu User Manual – Chapter III – Using the ABSolu Section 4.4.2. Automatic mode acquisition

Default Biometry Mode D1	Select the biometry mode displayed by default in the biometry exam screen: D1 or D2 ABSolu User Manual – Chapter III – Using the ABSolu Section 4.3. Biometry display modes NOTE: In the D2 mode, only the immersion technique is available.

Default Dyn 35 dB	Dynamic displayed by default in the biometry exam screen. NOTE: 35 dB is recommended for D1. 20 dB is recommended for D2.

Axial Length parameters (A-Std probe)

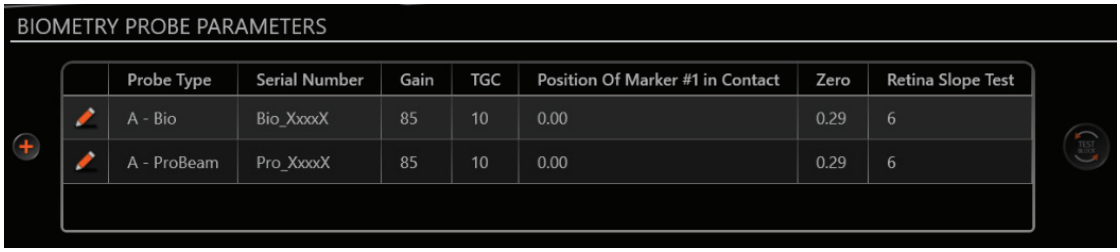
Parameter	Allows user to:
Default Technique Immersion	Select the technique displayed by default in the exam screen: Immersion or Immersion basic NOTE: Contact is not available in axial length.

Measurement test / A-mode calibration

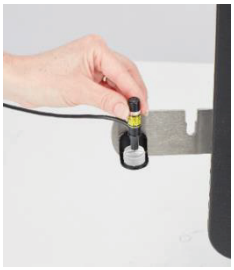
The Test-Block is located on the probe holder on the side of the ABSolu unit.

It is a plastic block used to test and calibrate the A-Scan measurements. This block has an equivalent distance of 10 mm at a velocity of 1550 m/s.

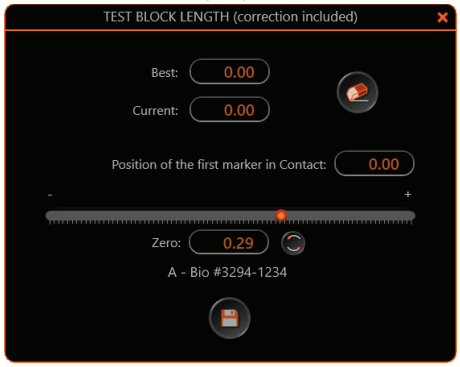
1. Select the probe for which the calibration has to be performed.



2. Select the “Test Block” icon.
3. Put a drop of water on the Test-Block.
4. Position the probe on the test block to be as much perpendicular and well centered as possible. The test-block has a rounded shape that matches the concave tip of the probe.
   A tracking starts. The purpose is to record the measurement with the highest posterior face echo. This measurement will correspond to the best probe position, well perpendicular to the posterior face.



Two values are displayed:



- "Best =" is the measurement corresponding to the best image.
- "Current =" is the measurement corresponding to the current position of the probe.

For a good calibration, the probe should measure a thickness situated in between 10.00 and 10.11mm. If the measurement is not within these range (best and current), the "position of Marker #1 in contact" cursor should be adjusted.

5. Select how to continue:
   - Save the calibration:

   - Erase "Best" and "Current" fields and start a new measurement:

   - Reset the "Zero" value and apply the correction of the position of the first marker in contact:

WARNING
When the probe is replaced, the calibration has to be checked and adjusted if necessary.

If both (Biometry and ProBeam probes) are in use, the calibration for both probes must be done. Also, the appropriate probe has to be selected in the biometry screen when performing an exam in order to have the calibration corresponding to the connected probe!.

NOTE
This correction is affecting the Anterior Chamber depth measurement when doing the acquisition in CONTACT technique only! With the IMMERSION technique, this correction does not apply. With the IMMERSION technique, the first marker is set on the corneal echo, far from the emission spike.

1.6.4 B probe parameters

Parameter	Allows user to:
Activate Probe Detection	Adjust the probe position on the patient eye before acquiring measurements in the Exam screen.
Light Icon On	Set the light option to On by default.
STS Check	Perform the STS probe check when the Lin50 probe is selected.

1.6.5 S probe parameters

> Select the depth of field for LESION Q-I, Retina A1, Retina QII, Musc. Profile and Axial Length parameters (when activated).

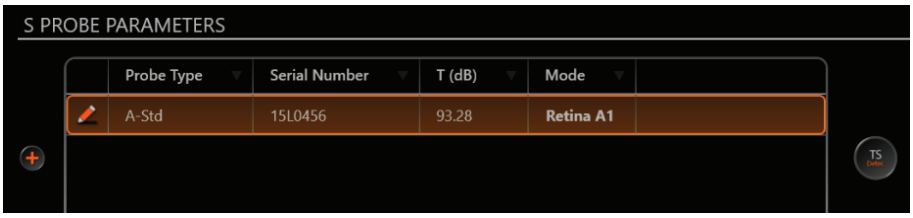
Other Standardized mode parameters can be adjusted in this screen:

- "Activate Threshold Line" enables to display the threshold line in the Lesion Q-I mode.
- "Quant-I Offset".
- "Activate Optic Nerve Table" enables to display the Optic Nerve Table in the Musc. Profile mode.

- "Axial Length" enables to perform axial length measurements with the A-Std probe. The acquisition technique (Immersion or Immersion Basic) can be selected by default.

Tissue Sensitivity determination

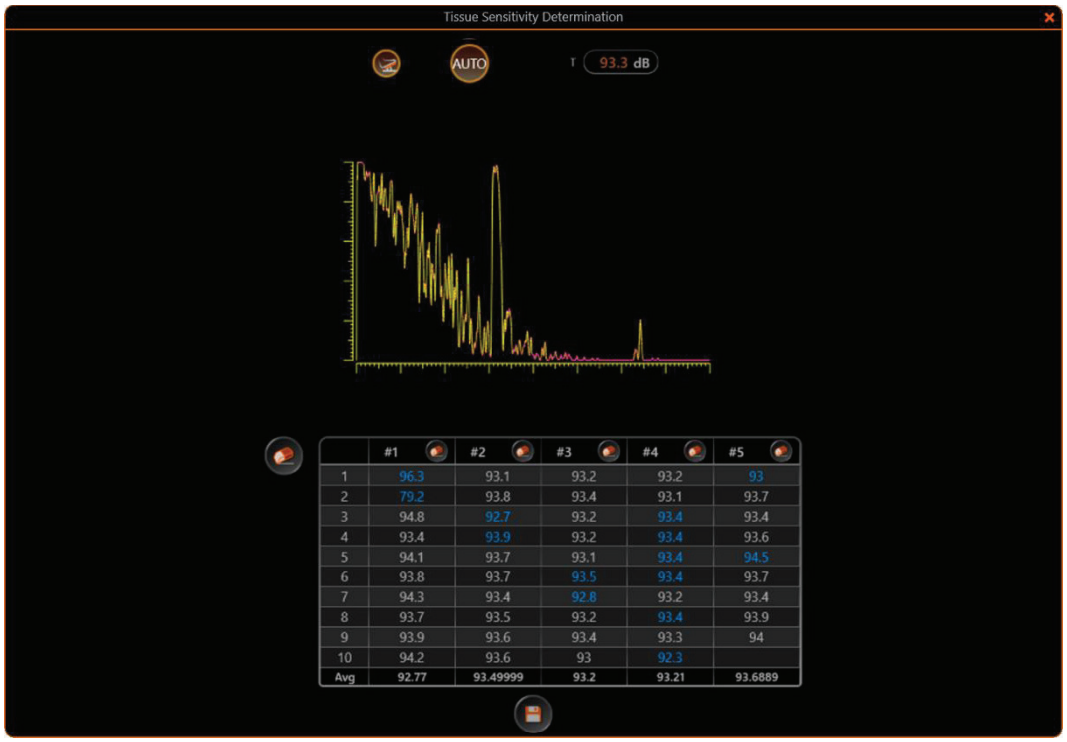
1. Select the A-Std probe for which the Tissue Sensitivity determination has to be performed.



2. Select the "TS Determination" option:

3. Put a drop of water on the surface of the Tissue Model.
4. Position the probe vertically in contact with the Tissue Model.

5. Select the footswitch to activate the probe
6. Select "Auto" (or press the space bar) to automatically fill the result table.



This procedure can be repeated five times (five columns). The T gain value (average over all measured values) is displayed at the top of the screen (T).

7. At the end of the automatic tissue sensitivity determination procedure:
   - Save the results.

OR

   - Erase data and start a new acquisition.

NOTE

The Tissue Sensitivity has to be determined for the whole system: ABSolu and Standardized A-probe (using the tissue model). Another probe with the same ABSolu unit may have a different T Gain.

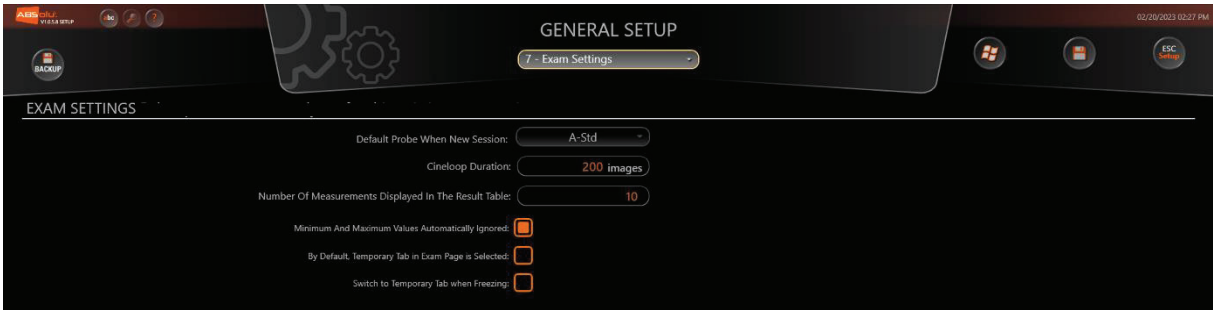
The T Gain result value should be comprised within the following range:

75 dB ≤ T ≤ 101 dB.

1.7 Exam Settings

> Select **Exam Settings** to adjust exam parameters.

The following screen is displayed:



The table below lists the exam parameters:

Parameter	Allows user to:
Default Probe When New Session	Select the Probe (and thus the Exam Screen) that will be displayed by default when opening a New Session.
Cineloop Duration	Select Cineloop duration (from 10 to 400 images).
Number Of Measurements Displayed In The Result Table	Set the number of measurements (from 5 to 10).
Minimum And Maximum Values Automatically Ignored	By default, the Min. and Max. values of the arrow of measurements will be ignored (barred lines).
By Default, Temporary Tab in Exam Page is Selected	Activate the option to display the temporary tab by default in the Exam screen.
Switch to Temporary Tab when Freezing	Activate the option to automatically switch to the temporary tab when freezing.

1.8 Protocol Settings

> Select Protocol Settings to adjust protocol parameters.

The following screen is displayed:

Probe orientation settings

Parameter	Allows user to:
Probe orientation Displayed by Default	Select this checkbox to pre-select the probe orientation for Posterior / Anterior Pole.
Probe orientation Order for Posterior Pole (as B10, B20-5A probes)	Select the Probe orientation Order to be displayed by default in the probe selection tool for Posterior / Anterior Pole 
Probe orientation Order for Anterior Pole (as LIN50 Probe)	

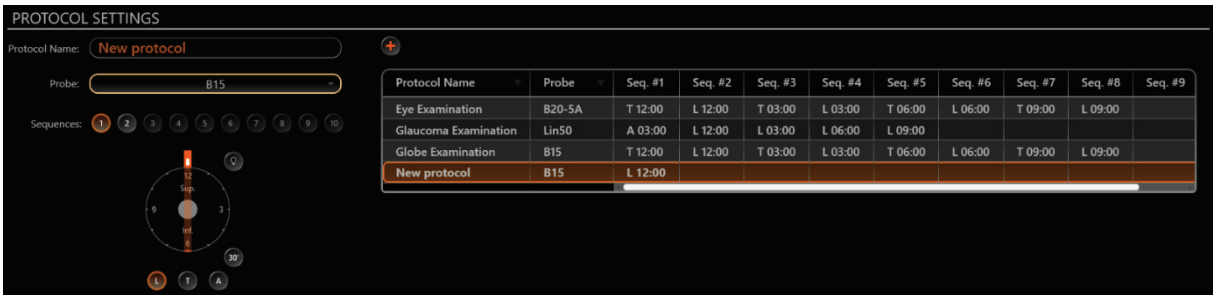
Protocol settings

To create a new protocol:

1. Select (+) to add a new protocol line in the Protocol table (the line lights up in orange).

2. Enter the new Protocol name.
3. Select the probe type.

4. Select the protocol sequence. For each sequence step 1 to 10: select a position on the clock.



1.9 Export Settings

> Select **Export Settings** to adjust export and archiving parameters.

The following screen is displayed:

Export folder

> To display the PDF/EMR/JPEG/Word icon in the Report screen, activate each option:

NOTE
The layout in Word may be altered depending on the version installed on the ABSolu.

> Browse and select the default export location for each file format (e.g., PDF, EMR etc.).:

NOTE
For JPEG, AVI, and MP4 files, select the Default Resolution: Full (1600 x 1200) / High (1280 x 960) / Medium (800 x 600) / Low (640 x 480).

Archive database

The “Archive Database” function allows the user to automatically copy the database files under a chosen path:

NOTE
Be sure that Cobian software is correctly set in function of user needs. For more information, please contact your QUANTEL MEDICAL local distributor or QUANTEL MEDICAL.

1.10 Keyboard shortcuts

Key(s)	Action
Esc	• Escape from IOL page → back to the probe previously selected: either Bio, or Bio B, or Axial Length. • Escape from report page → back to exam page. • Close windows: like Shortcut. • Close scroll down menus.
CTRL + N or CTRL + (+)	• Create a patient from Welcome screen.
F1	• New session.
SHIFT + F1	• Open the “?” (Help) menu.
F2	• Eye switching: OD/OS.
F3	• N/A.
F4	• A-Std and S-Mode probe (Toggle function).
F5	• Bio and/or ProBeam probe (toggle function Bio → ProBeam → Bio).
F6	• 15MHz probe (B1).
F7	• 20MHz 5A probe (B20-5A).
F8	• LIN 50MHz probe (BHF-50LIN).
F9	• Mode (depending on the probe. E.g., for B20-5A: Eye, Vitreous, Retina).
F10	• Save.
F11	• Print.
F12	• End Session.
WINDOWS + D	• Access desktop without closing or reopening tabs.
Alt + Tab	• Switch from one tab to the other without resizing or closing tabs.
Alt + F4	• Close the software or the document.
Ctrl + T	• Put Tags in Cineloop.

Probe functions	
Horizontal arrows	• Modify the marker position in an alphanumerical box. • Change the image zoom.
Vertical Arrows	• Increase / Decrease the value in an alphanumerical box. • Increase or decrease the gain in the image.
Ctrl + Horizontal arrows	• Modify image position into central zone: to the left and to the right.
Ctrl + Vertical Arrows	• Modify image position into central zone: upward and downward.
Ctrl + Space Barr	• Display the zoom by default.
Shift + Horizontal arrows	• N/A
Shift + Vertical Arrows	• N/A

Probe letter functions	
C	• Play and Stop Cineloop
B	• Select the previous image in the Cineloop
N	• Select the next image in the Cineloop
SHIFT + B	• Decrease the Cineloop selection to save
SHIFT + N	• Increase the Cineloop selection to save
Ctrl + X	• Cut text in the field
Ctrl + C	• Copy text in the field
Ctrl + V	• Paste text in the field
Ctrl + S	• Save the image
Ctrl + F	• Search

A-Std functions	
T	• Select T / T+9 / T modified
Space Barr	• Select T / T+9 / T modified

Lesion Q-I functions	
K	• Kappa angle
I	• Kappa angle + curve
M	• Display or delete markers

Retina A1 – Retina Q-II functions (only in Acquisition)	
Shift + Horizontal arrows	• Modify the segment position (right and left)
Shift + Vertical Arrows	• Increase or decrease the segment size

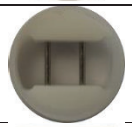
Retina Q-II functions (only in Acquisition)	
SHIFT + (+) (on numerical keypad only)	• Increase the segment limit
SHIFT + (-) (on numerical keypad only)	• Decrease the segment limit

2. LINEAR CALIBRATION CHECK

WARNING
To use the probe for sizing: the probe calibration should systematically be checked.

2.1 Calibration tool

The LIN 50MHz probe (BHF-50LIN) is delivered with a calibration tool that has been checked against a master tool.

Description	Visual
The probe type is engraved on the tool border.	
Two metallic pins which distance is used for calibration are located inside the tool.	
A label indicating the distance D (between the pins) is stuck on the tool border.	

2.2 Calibration check

2.2.1 Equipment

- 1 calibration tool corresponding to the probe type.
- Demineralized water at temperature between 20°C and 25°C.

2.2.2 Setting up the probe for calibration check

CAUTION
Carefully read these cautions for calibration check:

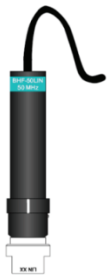
- It is very important to stop the probe scanning motion while setting up the calibration procedure (freeze the image using the footswitch).
- Place the removable window on the probe.

To set up the probe:

1. Fill up the calibration tool with demineralized water.
2. Position the probe on the calibration tool.

The probe is now ready to be checked.

3. Perform the checking procedure as described in the following section.

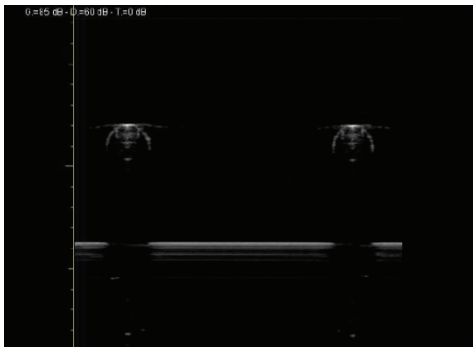


NOTE
Never immerse the probe tip over 3 cm.

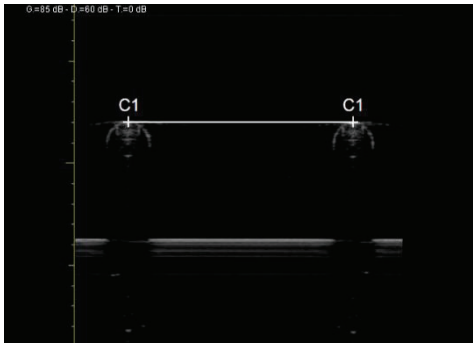
2.3 Checking up the LINEAR probe calibration

1. In the Exam Screen, select the LIN 50MHz probe (BHF-50LIN).
2. Press the footswitch to activate the probe's motion. The image that follows is now displayed on the screen:

3. Adjust the gain to get the best image quality (clear and precise).
4. Press the footswitch to freeze the image.



5. Place calipers as follows:
   C1: Measure of the distance between the calibration tool pins



Check the C1 measurement result (measure of the distance between the calibration tool pins). This result should correspond to the D value (with its tolerance) written on the label slicked on the calibration tool border.
For example:

LIN 50
D= 11 mm (± 0,06 mm) i.e., 10,94 mm < D < 11,06 mm

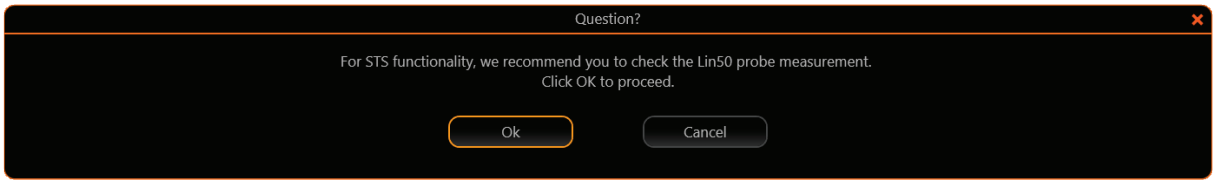
WARNING
In case the measurement result is out of range: the probe can be used for diagnosis only BUT NOT for sizing. Contact your local distributor or the Quantel Medical Service Department.

3. STS PROBE CHECK

To use the STS functionality, it is recommended to check the probe measurement of the LIN 50MHz probe. Once the STS probe check is completed, it is valid for 24 hours for all users of the ABSolu unit on which the procedure was performed.

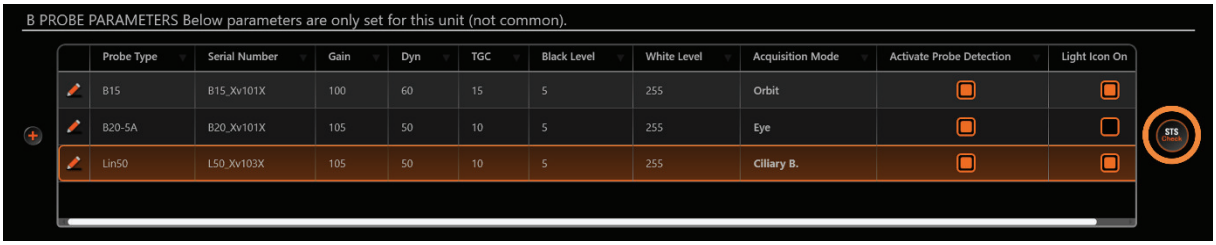
The selection of the STS probe verification can be made from several screens:

- When launching the ABSolu application.



NOTE
When the STS probe check is not performed upon login (e.g., user clicks Cancel or (x)), this message will reappear when another user logs in to the ABSolu unit.

- When selecting the Lin50 probe in the **Probe Settings** of the General Setup, the STS Check option is available.

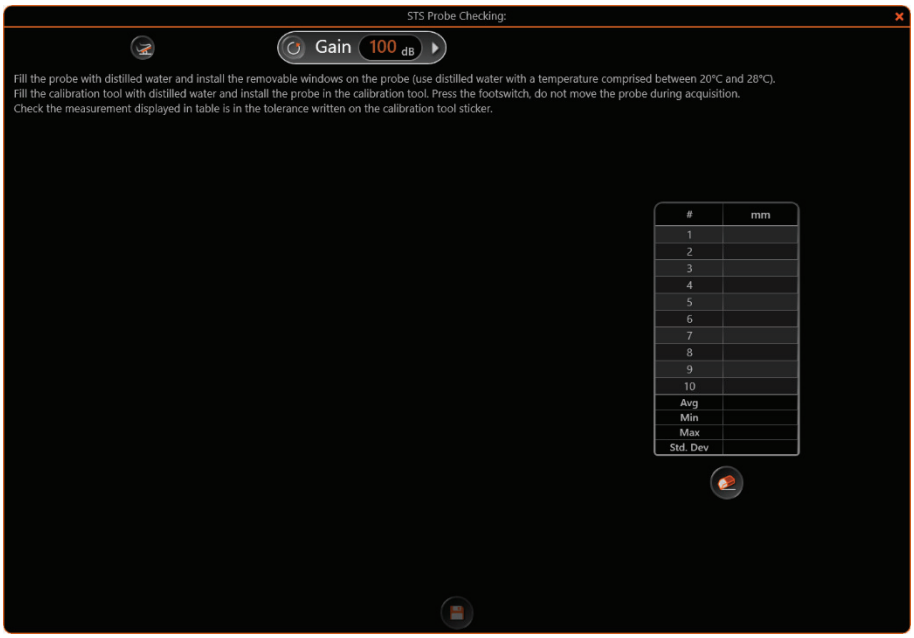


- When selecting the STS mode in the Exam screen, the STS Check option is available:

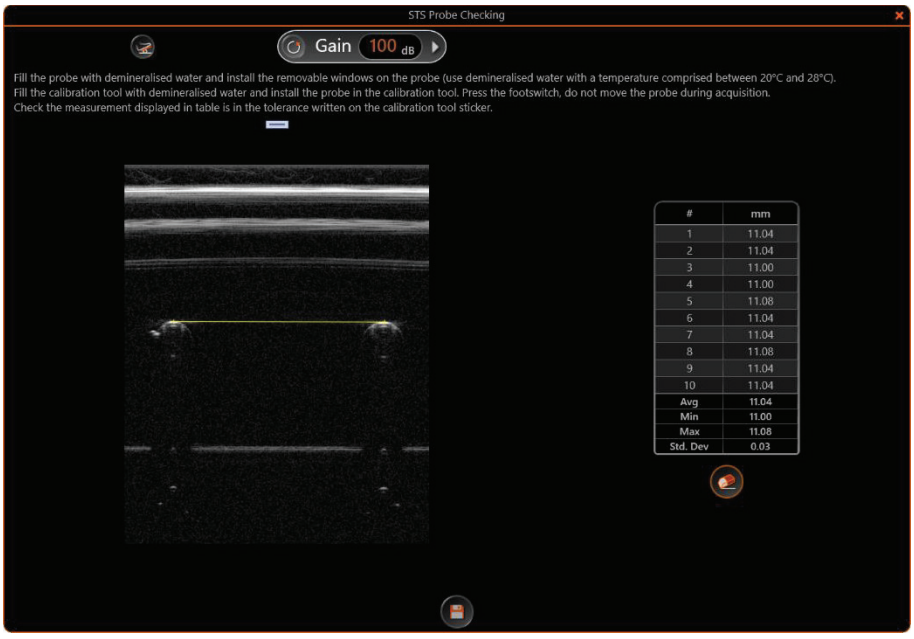
NOTE
A warning message (“Probe Checking NOT Approved”) is displayed when the check has not yet been performed.

Procedure:

1. Proceed with STS check from one of the above-mentioned screens. The STS Probe Checking window appears:



2. Fill the probe with distilled water (between 20° and 28°C).
3. Install the removable window on the probe.
4. Fill the calibration tool with distilled water. Then install the probe in the calibration tool.
5. Press the footswitch. Do not move the probe during acquisition.
6. Check that the measurement displayed in the table is within the tolerance indicated on the calibration tool sticker.



7. At the end of the STS probe check procedure:
   - Save the results.

OR
   - Erase data and start a new acquisition.

NOTE
The Probe Checking NOT Approved message will be displayed again if the recorded calibration is not within the tolerances of the checking tool or if the calibration has not been recorded (e.g., when measurements were erased and then saved or when closing the STS Probe Checking dialog box).

4. SERVICING THE UNIT

4.1 ABSolu unit and fuse replacement

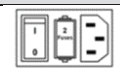
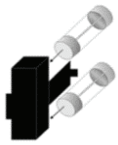
It is recommended to periodically inspect the unit once a year (image check and calibration). Contact QUANTEL MEDICAL Service Department or your local distributor.

WARNING
Some people may be extremely allergic to isopropyl alcohol.

CAUTION
Carefully read these cautions concerning unit maintenance:

- Disconnect the power cord before cleaning the unit case.
- Only use a damp cloth for cleaning.
- Do not use any solvent or alcohol.

Fuse replacement:

Fuse specifications:	
The fuse type is engraved on the tool border.	
Two metallic pins which distance is used for calibration are located inside the tool.	
A label indicating the distance D (between the pins) is stuck on the tool border.	

4.2 Probes care

For safety and regulatory information on probes care, refer to ABSolu User Manual – Chapter I – Regulatory & safety information Chapter 2 – Safety information and precautions.

Storage of linear probes:

LIN 50	
1	Remove and throw away the white removable window.
2	Drain out the water from the probe.
3	Place the black cap on the probe aperture to avoid dust penetration.
4	Store the probe inside its box.

WARNING
Carefully read these warnings concerning probes care:

- In the B mode acquisition screen, the “The probe is not connected” error message is displayed in case the probe is not detected or does not work. Refer to: ABSolu User Manual – Chapter III – Using the ABSolu - Chapter 5 – B-SCAN Exam screen
- If this is the case: check that the probe is correctly connected to the unit. Refer to ABSolu User Manual – Chapter II – Technical information - Chapter 5 – Installation: technical information
- For further information, please contact your QUANTEL MEDICAL local distributor or QUANTEL MEDICAL.

CAUTION
For the LIN 50 disinfection procedure, replace the probe black cap before disinfecting the probe, in order to protect the transducer.

VI – Appendix: IOL formulae

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2018 CE 0459
Directive 93/42/EEC

TABLE OF CONTENTS

1. IOL FORMULAE

1.1 Used variables

Used Variables for all formulae:

AL:	Axial length.
K:	Averaged dioptric power of the cornea = (K1 + K2) / 2.
R:	Corneal curvature in mm = 337.5 / K (K in Diopters).
ACD:	Post-Operative Anterior Chamber Depth.

1.2 S.R.K.-II

Emmetropic Power: P = A - 2.5AL - 0.9K + C

C = Correction to the first S.R.K. formula where C=0.

C values depending on the measured axial length:

If AL < 20 mm then C = + 3
If 20 ≤AL < 21 then C = + 2
If 21 ≤ AL < 22 then C = + 1
If 22 ≤ AL < 24.5 then C = 0
If AL ≥ 24.5 then C = - 0.5
If AL < 20 mm then C = + 3

SRK-II Ametropic Powers:

With:

P:	Emmetropic power
I:	Desired implant power
Rt:	Target Refraction
Rf:	Refraction factor

Refraction = Vs (I):

Rt = (P-I) / Rf where Rf = 1.25 if P > 14

Rf = 1 if P ≤ 14

IOL= Vs (Rt):

I = P - (Rt.Rf) where Rf = 1.25 if P > 14

Rf = 1 if P≤ 14

1.3 S.R.K. – T

Retinal thickness: Rethick = 0.65696 - 0.02029 x AL

Lc = AL except if AL > 24.2 Lc = -3.446 + (1.716 x AL) - (0.0237 x AL^2)

Kd = 337.5 / Rmm
Rmm = 337.5 / Kd

C1 = -5.40948 + 0.58412 x Lc + 0.098 x Kd

Rc = [Rmm^2 - $(C1)^2$ / 4]
If Rc < 0 then Rc = 0

C2 = Rmm - SQRT [Rc]

ACD = 0.62467 x A - 68.74709 where A = SRK Constant

ACDE = C2 + ACD - 3.3357

n1 = 1.336
n2 = 0.333

L0 = AL + Rethick = 0.97971 x AL + 0.65696

S1 = L0 - ACDE

S2 = n1 x Rmm - n2 x ACDE
S3 = n1 x Rmm - n2 x L0
S4 = 12 x S3 + L0 x Rmm
S5 = 12 x S2 + ACDE x Rmm

$$\text{REF\_X} = \frac{(1336 \text{ x } S3 \ - \ \text{IOL x } S1 \text{ x } S2)}{(1.336 \text{ x } S4 \ - \ 0{,}001 \text{ x IOL x } S1 \text{ x } S5)}$$

$$\text{IOL\_FOR\_TGT} = \frac{[1336 \text{ x } (S3 \ - \ 0.001 \text{ x REFt x } S4)]}{[S1 \text{ x } (S2 \ - \ 0.001 \text{ x REFt x } S5)]}$$

1.4 Double K / SRK-T (From Dr Jaime Aramberri)

Correction Axial Length: Lcor
Lcor = AL except if AL > 24.2 Lcor = -3.446 + (1.716 x AL) - (0.0237 x AL²)

Corneal curvatures, 2 Keratometry values are used:

- Pre corneal refractive surgery:
  Rpre = 337.5 / Kpre = 337.5 / Rpre
- Post corneal refractive surgery:
  Rpost = 337.5 / Kpost = 337.5 / Rpost

Calculations with Kpre or Rpre:

Computed corneal width: CW
CW = -5.40948 + 0.58412 x Lcor + 0.098 x Kpre

Corneal Height: H
Rc = [Rpre² - (CW) ² / 4] If Rc < 0 then Rc = 0

H = Rpre - SQRT [Rc]

Anterior Chamber Depth Constant: ACDconst
ACDconst = 0.62467 x A - 68.74709 where A = SRK Constant

Estimated Post-operatice ACD: ACDest
ACDest = H + Offset where Offset = ACDconst - 3.3357

Constants: na = 1.336 V = 12 nc = 1.333 C2 = nc - 1

Retinal thickness: Rethick = 0.65696 - 0.02029 x AL

Optical Axial Length: L0PT = AL + Rethick = 0.97971 x AL + 0.65696

Calculations with Kpost or Rpost:

S1 = L0PT – ACDest
S2 = na x Rpost - C2 x ACDest
S3 = na x Rpost - C2 x L0PT
S4 = V x S3 + L0PT x Rpost
S5 = V x S2 + ACDest x Rpost

$$\text{IOL emme} = \frac{1336 \text{ x } S3}{(S1 \text{ x } S2)}$$

$$\text{REF\_X} = \frac{(1336 \text{ x } S3 - \text{IOL x } S1 \text{ x } S2)}{(1.336 \text{ x } S4 - 0{,}001 \text{ x IOL x } S1 \text{ x } S5)}$$

$$\text{IOL\_FOR\_TGT} = \frac{[1336 \text{ x } (S3 - 0.001 \text{ x REFt x } S4)]}{[S1 \text{ x } (S2 - 0.001 \text{ x REFt x } S5)]}$$

1.5 Binkhorst

Used Variables:

- Lb: Axial length corrected for Binkhorst II.
  Lb = LA + 0.1984 mm
- ACD-b: Anterior chamber corrected only for POSTERIOR CHAMBERS.

  If Lb < 26 then ACD-b = ACD x (LA / 23.45)
  If Lb ≥ 26 then ACD-b = ACD x (26 / 23.45)
  So ACD-b = 1.1087 x ACD

R:	Cornea curvature in mm = 337.5 / K (K in Diopters)
Ref:	Target Refraction.
Lb:	Corrected Axial length.
AC:	Post-operative Anterior Chamber. AC = ACD for Anterior Chamber IOLs AC = ACD-b for Posterior Chamber IOLs.

FORMULA GIVING THE IMPLANT VALUE VERSUS THE DESIRED REFRACTION: REF

IOL = Vs (Ref) if Ref =0 IOL= IOLem (emmetropia)

$$IOL = \frac{1336\,[\,1.336R - 0.3333Lb - 0.001Ref\,(16{,}032R - 4Lb + Lb.R)]}{(Lb - AC)\,[\,1.336R - 0.3333AC - 0.001Ref\,(16.032R - 4AC + AC.R\,]}$$

FORMULA GIVING THE REFRACTION VERSUS THE DESIRED IMPLANT: IOLAM

Ref = Vs (IOL)

$$Ref = \frac{1336(1.336R - 0.3333Lb) - IOL.(Lb - AC)(1.336R - 0.3333AC)}{1.336(16.032R - 4Lb + LbR) - 0.001IOL(Lb - AC)(16.032R - 4AC + AC.R)}$$

1.6 Holladay

Used variables:

R:	Cornea curvature in mm = 337.5 / K (K in Diopters)
Ref	Target Refraction.

Lh: Axial length corrected for HOLLADAY.

Lh = AL + 0.200 mm

SF: Surgeon Factor: specific for Holladay formula.

SF = (A x 0.5663) - 65.60 where A is the SRK Constant

ACh: Anterior Chamber corrected for HOLLADAY.

Rag = R except if R < 7mm then Rag = 7 mm

AG = (12.5 / 23.45) AL so: AG = 0.533.AL

except if AG > 13.5 then AG = 13.5 mm

ACD = 0.56 + Rag - [SQRT (Rag^2 - AG^2 /4)]

ACh = ACD + SF

FORMULA GIVING THE IMPLANT VALUE VERSUS THE DESIRED REFRACTION (OR AMETROPIA): REF

IOLam = Vs (Ref)

If Ref =0 IOLam = IOLem (emmetropia)

$$\text{IOLam} = \frac{1336\,[1.336.\text{R} - 0.3333\text{Lh} - 0.001\text{Ref}\,(16.032\text{R} - 4\text{Lh} + \text{Lh.R})]}{(\text{Lh} - \text{ACh})\,[1.336\text{R} - 0.3333\text{ACh} - 0.001\text{Ref}\,(16.032\text{R} - 4\text{ACh} + \text{ACh.R}]}$$

FORMULA GIVING THE REFRACTION VERSUS THE DESIRED IMPLANT: IOLam

Ref = vs (IOLam)

$$\text{Ref} = \frac{1336\,(1.336\text{R} - 0.3333\text{Lh}) - \text{IOLam}(\text{Lh} - \text{ACh})(1.336\text{R} - 0.3333\text{ACh})}{1.336\,(16.032\text{R} - 4\text{Lh} + \text{Lh.R}) - 0.001\,\text{IOLam}\,(\text{Lh} - \text{ACh})(16.032\text{R} - 4\text{ACh} + \text{ACh.R})}$$

1.7 Hoffer-Q

Used variables:

P:	Implant POWER (D)
R:	Refractive error at corneal plane (D).
Rx:	Desired ametropia: Refractive error at spectacle (D).
K:	Average Keratometry (D)
CD:	Corrected Chamber Depth (mm).
ACD:	Anterior chamber depth from the personalized IOL User file.
AL:	Axial Length (mm)

CORRECTED CHAMBER DEPTH:

If AL ≤ 23 M = +1 and G = 28
If AL > 23 M = -1 and G = 23.5

If AL > 31 AL = 31
If AL < 18.5 AL = 18.5

CD = ACD + 0.3(AL - 23.5) + (tan K) 2 + 0.1M (23.5 - AL) 2 tan [0.1(G - AL) 2] - 0.99166

EMMETROPIA POWER:

R = Rx / (1 - 0.012Rx)

P = [1336 / (AL - CD - 0.05)] - {1.336 / [(1.336 / (K + R)) - ((CD + 0.05) / 1000)]}

FORMULA GIVING THE REFRACTION (RX) VERSUS THE DESIRED IMPLANT: IOLAM

Rx = vs (IOLam)

$$R = [\frac{1.336}{[1.336 / (1336 / (AL - CD - 0.05) - IOLam) + (CD + 0.05) / 1000]}] - K$$

Rx = R / (1 + 0.012R)

1.8 Shammas

KERATOMETRY CORRECTION:

KS = 1.14 Kpost – 6.8
Where Kpost is the measurement of the Keratometry by classical means.

IOL CALCULATION FOR EMMETROPIA

$$\text{IOLemm} = \frac{1336}{\text{L} - 0.1(\text{L} - 23) - \text{C} - 0.05} - \frac{1}{\frac{1.0125}{\text{K}} - \frac{\text{C} + 0.05}{1336}}$$

Where:
- L= Axial Length in mm
- K = Keratometry in Diopters
- C = ACD (Shammas) = 0.5835.A - 64.40

FORMULA TO CALCULATE THE IMPLANT CORRESPONDING TO THE DESIRED REFRACTION (R):

IOL Am = Vs (R)

$$\text{IOLAm} = \frac{1336}{\text{L} - 0.1(\text{L} - 23) - \text{C} - 0.05} - \frac{1}{\frac{1.0125}{\text{K} + \text{R}} - \frac{\text{C} + 0.05}{1336}}$$

FORMULA TO CALCULATE THE REFRACTION CORRESPONDING TO THE IOL VALUE:

Refr. = Vs (IOL)

$$\text{R} = \frac{1336 - \text{IOL}\,(\text{L} - 0.1(\text{L} - 23) - \text{C} - 0.05)}{\frac{\text{L} - 0.1(\text{L} - 23)}{1.0125} - \frac{(\text{IOL}\,(\text{C} + 0.05)\,(\text{L} - 0.1(\text{L} - 23) - \text{C} - 0.05)}{1352.7}} - K$$

1.9 Haigis

Formulas for the IOL calculation according to HAIGIS (W. Haigis)

1. IOL power for given refraction Dl:

   All calculations are based on the "Thin-lens-formula":

$$Dl = \frac{n}{L - d} - \frac{n}{n/z - d} \quad (1)$$

   With:

$$z = Dc + \frac{Rx}{1 - Rx \cdot dx} \quad (2)$$

   Where:

$$Dc = \frac{Nc - 1}{R}$$

   And:

Dl	IOL power
Dc	corneal power
Rx	desired refraction
n	refractive index of aqueous and vitreous (=1.366)
Nc	fictitious refractive index of cornea (=1.3315)
Dx	vertex distance between cornea and spectacles (=12 mm)
R	corneal radius
L	axial length (as measured by ultrasound)
d	optical ACD

2. Refraction Rx for given IOL power:

   From (1), the following equation for the resultant refraction Rx for an IOL power Dl and an optical ACD d:

$$Rx = \frac{q - Dc}{1 + dx \cdot (q + Dc)} \quad (3)$$

   Where:

$$q = \frac{n \cdot [n - Dl \cdot (L - d)]}{n \cdot (L - d) + d \cdot [n - Dl \cdot (L - d)]}$$

3. Optical ACD: d

   The optical ACD: d is given by the following expressions:

   If AC=0 then $d = (a0 + u \cdot a1) + (a2 + v \cdot a1) \cdot L$ (4)
   else $d = a0 + a1 \cdot AC + a2 \cdot L$ (5)

   with AC: preoperative acoustical anterior chamber depth, as measured by ultrasound
   L:preoperative axial length, as measured by ultrasound

   and u: -0.241
   v: 0.139
   The parameters a0, a1 and a2 are constants describing the IOL.

4. IOL constants a0, a1, a2:

In standard or default mode, the constants a0, a1 and a2 are given by:
a1 = 0.400
a2 = 0.100
a0=0.62467 x A – 72.434 (6)

with A: Lens constant provided by the manufacturer.

In optimized mode, the constants a_0, a_1 and a_2 are obtained by a separate optimization process. For each patient, the actual post-op refraction is used to calculate the corresponding optical ACD. For all patients, these values are then correlated with the pre-op ultrasound measurements of the (acoustical) ACD and the axial length. Double linear regression analysis yields the constants a_0, a_1 and a_2.

Global limitations: $-2 < a_0 + 3.37a_1 + 23.39a_2 < 12$

$-2 < a_0 + 2.53a_1 + 20.00a_2 < 12$

$-2 < a_0 + 3.50a_1 + 27.00a_2 < 12$

5. Examples:

A-constant A=118.0

> a0 = 1.277; a1 = 0.400; a2 = 0.100;

1) L = 21.44; AC = 2.69; R = 7.45;
target refr. R_X= -0.250
> d = 4.497; D_L= 26.862

2) L = 23.27; AC = 3.14; R = 7.69;
IOL implanted D_L= 22.000
> d = 4.860; R_X= -0.398

3) L=27.09; AC = 3.48; R = 7.76;
target refr. R_X = 2.730
> d = 5.378; D_L= 5.768

6. Copyright notice:

Würzburg, Jan.25th, 2000; Dr.W. Haigis

2. IOL CALCULATION FOR POST REFRACTIVE SURGERY

IOL calculations by classical means turned out to be wrong for a lot of patients who got a cataract few years after refractive surgery (RK, PRK or Lasik), indeed:

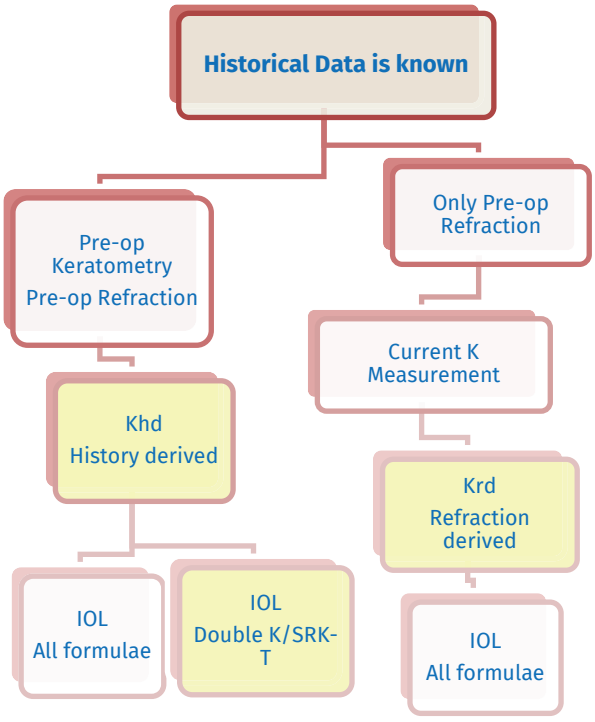
- The keratometry measured by classical means was over estimated.
- Using this K value, the calculated IOL power was underestimated and the patient then got hyperopia after implantation.

The goal of the "Post-refractive surgery cases" program is to:

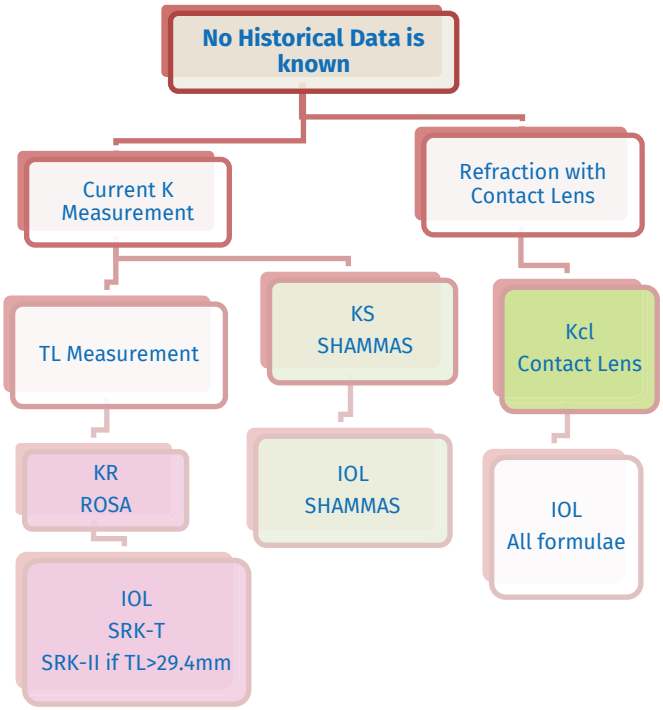
- Estimate the real curvature of the cornea.
- Calculate the correct IOL value.

Different methods and formulas are available depending on the available patient information such as:

Keratometry information:	Pre-op Keratometry Or actual Keratometry only
Refraction information:	Pre-op & post-op Refraction Or post-op Refraction only



Available methods & formulae when historical patient data is known.



Available methods & formulae when historical patient data is NOT known.

NOTE
The post-op refraction can easily be determined using the last spectacles correction information.

NOTE
A cataract may affect refraction, so that a direct evaluation may be altered.

2.1 HISTORY DERIVED / DOUBLE K – SRKT METHODS (Case 1: when all patient history is known)

All the historical data of the Right Eye is available:

Pre-Op Keratometry: 49.25D
Pre-Op Spect. Refraction: -10.00D
Post-Op Spect. Refraction: -1.00D

Correction on Corneal Plan = (Post-Op Refr) - (Pre-Op Refr) = 0.99-(8.93) =7.94D

A History derived method:

Formula:
Khd = (Pre-Op K) - (Correction)
Khd = 49.25-7.94=41.31D
The "**Calculated Khd = 41.31D**" is displayed in the IOL Calculation screen.

B Double K/SRK-T method:

The formulae: SRK-T; Holladay; Hoffer-Q calculate the Effective Lens Position (ELP) from the keratometry value. The refractive surgery is not modifying the natural anterior chamber of the eye, so the ELP calculated with a post-op K will be incorrect and underestimated. Hoffer-Q usually gives a stronger value. To solve this issue: the "Double K / SRK-T" formula from Dr. Aramberri applies the SRK-T formula using both keratometry values:

- The pre-op K for the Effective Lens Position
- The history-derived post-op K value for the final IOL power.

2.2 REFRACTION DERIVED METHOD (Case 2: Only the refractions are known)

Pre-Op & Post-Op Refractions are known:

Pre-Op Refraction: -10.00D
Post-Op Refraction: -1.00D

Correction at Corneal Plan= (Post-Op Refr) – (Pre-Op Refr) = 0.99-(-8.93) = 7.94D

We measure the present Keratometry by classical means:
K = 44.25D

Refraction Derived method:

Formula:
Krd = 44.25-0.23x7.94
Krd = 44.42D

The “Corrected Krd = 44.42D” is displayed in the IOL Calculation screen.

2.3 ROSA / SHAMMAS (Case 3: Unknown patient history: corrected K value)

We measure the present Keratometry by classical means:
Example: K = 44.25D
This value is then corrected.

2 regression formulas exist:

A ROSA

Formula:
Rr = R(0.0276TL+0.3635)

Where:
*TL is the total length
*R = 337.5/K
KR = 337.5/Rr

Example:

TL = 25.5mm
R = 337.5/44.25 = 7.6271
Rr = 7.6271x(0.7038+0.3635)
Rr = 8.14
KR = 337,5 / 8.14
Then KR = 41.46

The "Corrected KR = 41.46D" is displayed in the IOL Calculation

NOTE
The Rosa method uses only the SRK formulas.

SRK-T is selected if TL≤ 29.4mm
SRK-II is selected if TL > 29.4 mm.

B SHAMMAS

Formula:
KS = 1.14K-6.8

KS = 1.14x44.25-6.8
KS = 50.45-6.8
KS = 43.65D

The "Corrected KS = 43.65D" is displayed in the IOL Calculation screen.

NOTE
The Shammas method uses only the Shammas formula.

2.4 CONTACT LENS METHOD (Case 4: Unknown patient history: evaluated Post-Op K)

Contact Lens method:
We evaluate the Post-Op Keratometry with a Hard Contact Lens in PMMA:

Post-Op Refraction: Post-Op Spectacles Refr = -1.00D
Spectacles Refraction with the Contact Lens: CLRefr = +1.00D

The following calculation is done in the IOL Calculation screen:

Contact Lens method:
Base Curve = BC = 40.00D

DRefr = CLRefr- (Post-Op Refr)
DRefr = +1-(-1.00) = +2

Formula:
Kcl = BC+DRefr
Kcl = 40.00+2 = 42.00D

The "Calculated Kcl = 42.00D" is displayed in the IOL Calculation screen.