clarius

Clarius Ultrasound Scanner

HD3 Scanners User Manual

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About This Manual

To obtain a printed copy of this manual at no additional cost, go to clarius.com/contact and contact Clarius.

This manual provides instructions for use on the Clarius Ultrasound Scanner - HD3 Scanners family of ultrasound scanners. For models that are not HD3, refer to the appropriate user manual at clarius.com/manuals.

This document is licensed as part of the purchase of the Clarius Ultrasound Scanner and meets applicable regulatory requirements. Use of this document by unauthorized persons is strictly prohibited.

This document contains the following information:

- About the Clarius Ultrasound Scanner: Describes the product, and lists technical specifications, and its intended use.
- Using the Clarius Ultrasound Scanner: Shows you how to get started and begin scanning, introduces you to the features and concepts, and helps you set up your system.
- Accessories: Describes additional accessories you can purchase for use with your Clarius Ultrasound Scanner- HD3 Scanners.
- Cleaning & Disinfecting: Explains how to clean and disinfect your scanner and its accessories.
- Safety: Outlines important safety standards, principles, and policies to follow when using the product.
- References: Offers information such as product standards and regulatory requirements.
- Measurement Accuracy Tables: Displays the measurement accuracy and Doppler sensitivity of each scanner and mode.
- Acoustic Output Tables: Displays acoustic data for each scanner and mode.
- Revision History: Displays a historic list of changes made to this document.

Access to user documentation may be affected by: Internet availability and accessibility, website availability, and local electromagnetic interference.

Intended Users

This user manual is written for trained medical professionals who use the Clarius Ultrasound Scanner. It contains instructions and reference material pertaining to the usage and maintenance of the device.

This document does not provide training in sonography, ultrasound, or clinical practices.

Document Conventions

Icons

Icon	Title of Icon	Description
	Alert	Possible risks beyond the reasonable control of Clarius.
	Do not do this	This icon indicates actions to avoid.
	Note	This icon indicates informative material or helpful suggestions.

Symbols Glossary

The symbols shown in this document and on the Clarius Ultrasound Scanner are compliant with current versions of the following standards: ISO 7000, ISO 7010, IEC 60417, and (EN) ISO 15223-1.

STANDARD: ISO 15223-1 — GRAPHICAL SYMBOLS FOR USE ON EQUIPMENT — REGISTERED SYMBOLS

Symbol	Reference	Title	Description
	3082	Manufacturer	Indicates the medical device manufacturer.
	2497	Date of manufacture	Indicates the date when the medical device was manufactured.

STANDARD: ISO 15223-1 — GRAPHICAL SYMBOLS FOR USE ON EQUIPMENT — REGISTERED SYMBOLS

Symbol	Reference	Title	Description
	2493	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	2609	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
	0621	Fragile; handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.
	0626	Keep dry	Indicates a medical device that needs to be protected from moisture.
	0632	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.
	0224	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.
	1641	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use.
	0434A	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequence.
	1135	General symbol for recovery/recyclable	To indicate that the marked item or its material is part of a recovery or recycling process.

You may see some of these standard symbols on your Clarius Scanner HD3, accessories, and packaging:

OTHER STANDARDS — GRAPHICAL SYMBOLS FOR USE ON EQUIPMENT — REGISTERED SYMBOLS

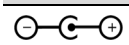
Symbol	Standard	Reference	Title	Description
	ISO 7010	M002	Refer to instruction manual/booklet	Indicates to read the instruction manual/booklet before starting work or before operating equipment or machinery. Note: The symbols presented in this manual may appear in black-and-white on the medical device. The meaning and application of each symbol remain the same, regardless of color variation. 

OTHER STANDARDS—GRAPHICAL SYMBOLS FOR USE ON EQUIPMENT—REGISTERED SYMBOLS

Symbol	Standard	Reference	Title	Description
	IEC 60417	5172	Class II equipment	To identify equipment meeting the safety requirements specified for Class II equipment according to IEC 60536.
	IEC 60417	5957	For indoor use only	To identify electrical equipment designed primarily for indoor use.
	IEC 60417	5333	Type BF applied part	To identify a type BF applied part complying with IEC 60601-1.

You may see these other symbols on your Clarius Scanner HD3, accessories, and packaging:

OTHER GRAPHICAL SYMBOLS FOR USE ON EQUIPMENT

Symbol	Title	Description
	Power connector	Indicates a barrel-type power connector.
	RoHS compliant	Identifies electrical and electronic equipment that meets the Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU.
	European Conformity	Conforms to European Medical Device Regulation 2017/745.
	FCC	Conforms to US Federal Communications Commission.
	CSA certification	Certified by the Canadian Standards Association. The number below this symbol indicates the contract number.
	Waste Electrical and Electronic Equipment	Requires separate collection for electrical and electronic equipment in compliance with the Waste Electrical and Electronic Equipment (WEEE) Directive. When accompanied by Pb or Hg, components of the device may contain lead or mercury, respectively, which must be recycled or disposed of in accordance with local, state, or federal laws. The backlight lamps in an LCD system monitor contain mercury.
IP67	Ingress protection rating	The equipment inside the enclosure is protected from tools and wires greater than 1.0 millimeters, is dust-tight, and is also protected from immersion up to 1 meter in depth for 30 minutes.
	DC	Direct current.
GS1	GS1 DataMatrix	Identifies GS1 encoded DataMatrix.
GMDN	Global Medical Device Nomenclature Code	A system of internationally agreed generic descriptors used to identify all medical device products.
EC REP	Authorized representative in the European Community	Indicates the Authorized representative in the European Community.

OTHER GRAPHICAL SYMBOLS FOR USE ON EQUIPMENT

Symbol	Title	Description
CH REP	Authorized representative in Switzerland	Indicates the authorized representative in Switzerland.
	n/a	Do not stack boxes.
	n/a	Do not use knife to open.
 Li-ion	n/a	Recycle scanner in accordance with local, state, and federal regulation.
MD	Medical Device	European Medical Device Regulation 2017/745.
Rx only	Rx Only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

1 About the Clarius Ultrasound Scanner

Install, operate, and maintain this product according to the safety and operating procedures in this manual, and only for its intended purpose. Always use the information in this user manual in conjunction with sound clinical judgment and standard POCUS practices.

This product is subject to the law in the jurisdiction that the product is used. Install, use, and operate the product only in ways that adhere to applicable laws or regulations, which have the force of law.

This device complies with part 15 of the FCC rules and Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.[1]

- Product package must be maintained with medical device. Do not dispose.
- Using the product incorrectly, or for purposes other than those intended and expressly stated by Clarius, may relieve Clarius or its agents from all or some responsibility for resultant noncompliance, damage, or injury.
- Using portable and mobile radio frequency (RF) communications equipment can affect the operation of medical equipment.
- Operating this system in the presence of flammable gases or anesthetics can cause an explosion.

1. Le présent appareil est conforme avec la section 15 des règlementations FCC ainsi qu'aux standards CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire d'interférence, et (2) l'appareil doit accepter toute interférence radioélectrique subi, même si l'interférence est susceptible d'en compromettre le fonctionnement.

- Install and operate medical equipment according to electromagnetic compatibility (EMC) guidelines.
- Users are responsible for image quality and diagnosis.
- This product has demonstrated EMC compliance under conditions that included the use of compliant peripheral devices. It is important that you use compliant peripheral devices to reduce the possibility of causing interference to radios, televisions, and other electronic devices.

- Circumstances in the patient's environment may negatively impact the scanner and the exam. For example: (1) Chemicals and gases in the operating room. (2) Altitudes below -382 m or above 4000 m.
- Vulnerable patients, such as children and pregnant/nursing women, may be more prone to the exposure of acoustic energy when the scanner is used for prolonged periods.
- Biological incompatibility may exist between the scanner materials used and the biological tissues, cells, and body fluids of the patient/user, taking account of the intended purpose of the scanner.
- Using the scanner in the patient environment may be unsafe if the following conditions exist: (1) Extremes in humidity (RH<15% and RH>95%). (2) Ambient temperatures that are excessively high (>40°C / 104°F) or excessively low (<-20°C /-4°F).
- Unqualified/untrained personnel purchasing and using the Clarius Scanner HD3 may be unable to attain quality images.
- Each Clarius Scanner HD3 contains a Li-ion battery. Treat the battery with precaution.

Users should be trained medical professionals (e.g., doctors, nurses, technicians) with previous training in ultrasound. Images produced by the scanner are transmitted wirelessly to the user's smart device (tablet or smart phone).

Device Description

For regulatory information in e-labeling format, open the Clarius App and go to the About page.

The Clarius Ultrasound Scanner is a portable, general-purpose, software-controlled, diagnostic ultrasound system used to acquire and display high-resolution, real-time ultrasound data through a commercial off-the-shelf (COTS) Apple iOS or Android™ device. The Clarius Ultrasound Scanners are Bluetooth and wireless, and communicate with traditional tablets/ smartphones via direct Wi-Fi to allow users to export ultrasound images and display in different modes of operation. The Clarius Scanner HD3 houses a battery and internal power supplies, multichannel beamformer, prescan converter, and Wi-Fi components. The Clarius Scanner HD3 is supplied with a charger.

The system is a transportable ultrasound system intended for use in rotary-wing air ambulances, road ambulances, and emergency medical service (EMS) environments where

healthcare is provided by trained healthcare professionals. The EC7 HD3[1] and the Clarius Charger HD3[1] should be used in a stationary setting.

Product Dimension

Item	Length (in/mm)	Width (in/mm)	Thickness (in/mm)	Weight (oz/g)
Clarius Scanner C3 HD3 (CIDN 99-13-00018)	5.7/146	3.0/76	1.3/32	10.9/308
Clarius Scanner C7 HD3 (CIDN 99-13-00019)	5.9/151	3.0/76	1.3/32	10.2/289
Clarius Scanner EC7 HD3 (CIDN 99-13-00024)	12.2/310	3.0/76	1.3/32	11.5/326
Clarius Scanner L7 HD3 (CIDN 99-13-00020)	5.8/147	3.0/76	1.3/32	10.2/288
Clarius Scanner L15 HD3 (CIDN 99-13-00021)	5.8/147	3.0/76	1.3/32	10.2/290
Clarius Scanner L20 HD3 (CIDN 99-13-00022)	5.8/147	3.0/76	1.3/32	10.2/290
Clarius Scanner PA HD3 (CIDN 99-13-00023)	5.8/148	3.0/76	1.3/32	10.3/292
Clarius Scanner PAL HD3 (CIDN 99-13-00029)	5.8/148	3.0/76	1.3/32	10.8/307

Product Usage

Indications for Use

The Clarius Ultrasound Scanner is a software-based ultrasound imaging system and accessories, intended for diagnostic imaging. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: ophthalmic[2] , fetal, abdominal, intra-operative (non-neurological), pediatric, small organ, cephalic (adult), trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), urology, gynecology, cardiac (adult, pediatric), peripheral vessel, carotid, and procedural guidance of needles into the body.

The system is a transportable ultrasound system intended for use in environments where healthcare is provided by trained healthcare professionals.

1. Not intended for EMS environment.
2. Only applicable to the L7 HD3, L15 HD3, L20 HD3, & PAL HD3 scanners.

Intended Patient Population

The system is intended for use for diagnostic ultrasound imaging and fluid flow analysis of anatomical structures and fluids of adult and pediatric patients.

Indications for Use Tables

Clarius Ultrasound Scanner HD3

SYSTEM: CLARIUS ULTRASOUND SCANNER HD3
INDICATION FOR USE: DIAGNOSTIC ULTRASOUND IMAGING OR FLUID FLOW ANALYSIS OF THE HUMAN BODY AS FOLLOWS:

Clinical Application		**Mode of Operation**						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**Color Doppler**	**Power Doppler**	**PW Doppler**	**Combined (Specify)**	**Other***
Ophthalmic	Ophthalmic	✔						
Fetal Imaging & Other	Fetal	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Abdominal	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Intra-operative (Abdominal organs & vascular)	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Laparoscopic							
	Pediatric	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Small Organ (Thyroid, Prostate, Scrotum, Breast)	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Neonatal Cephalic	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Adult Cephalic	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Trans-rectal	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	
	Trans-vaginal	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	
	Trans-urethral							
	Trans-esophageal (non-Cardiac)							
	Musculo-skeletal (Conventional)	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Musculo-skeletal (Superficial)	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Intravascular							
	Other (Urology, Gynecology)	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	
Cardiac	Cardiac Adult	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Cardiac Pediatric	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Intravascular (Cardiac)							
	Trans-esophageal (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel	Peripheral Vessel	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Other (Carotid)	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
Note 1: Needle Enhancement in B-Mode.								

Clarius Scanner C3 HD3

DEVICE NAME: CLARIUS SCANNER C3 HD3
INDICATION FOR USE: DIAGNOSTIC ULTRASOUND IMAGING OR FLUID FLOW ANALYSIS OF THE HUMAN BODY AS FOLLOWS:

Clinical Application		**Mode of Operation**						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**Color Doppler**	**Power Doppler**	**PW Doppler**	**Combined (Specify)**	**Other***
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	
	Abdominal	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	
	Intra-operative (Abdominal organs & vascular)	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	
	Laparoscopic							
	Pediatric	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	
	Small Organ (Thyroid, Prostate, Scrotum, Breast)							
	Neonatal Cephalic							
	Adult Cephalic	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esophageal (non-Cardiac)							
	Musculo-skeletal (Conventional)	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Urology, Gynecology)	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	
Cardiac	Cardiac Adult	✔	✔	✔		✔	B+M; B+CD; B+PWD	
	Cardiac Pediatric	✔	✔	✔		✔	B+M; B+CD; B+PWD	
	Intravascular (Cardiac)							
	Trans-esophageal (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel	Peripheral Vessel	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	
	Other (Carotid)							

Clarius Scanner C7 HD3

DEVICE NAME: CLARIUS SCANNER C7 HD3
INDICATION FOR USE: DIAGNOSTIC ULTRASOUND IMAGING OR FLUID FLOW ANALYSIS OF THE HUMAN BODY AS FOLLOWS:

Clinical Application		**Mode of Operation**						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**Color Doppler**	**Power Doppler**	**PW Doppler**	**Combined (Specify)**	**Other***
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	
	Abdominal	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	
	Intra-operative (Abdominal organs & vascular)	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	
	Laparoscopic							
	Pediatric	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	
	Small Organ (Thyroid, Prostate, Scrotum, Breast)	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esophageal (non-Cardiac)							
	Musculo-skeletal (Conventional)	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Urology, Gynecology)	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	
Cardiac	Cardiac Adult	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	
	Cardiac Pediatric	✔	✔	✔		✔	B+M; B+CD; B+PWD	
	Intravascular (Cardiac)							
	Trans-esophageal (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel	Peripheral Vessel	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	
	Other (Carotid)							

Clarius Scanner EC7 HD3

DEVICE NAME: CLARIUS SCANNER EC7 HD3
INDICATION FOR USE: DIAGNOSTIC ULTRASOUND IMAGING OR FLUID FLOW ANALYSIS OF THE HUMAN BODY AS FOLLOWS:

Clinical Application		**Mode of Operation**						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**Color Doppler**	**Power Doppler**	**PW Doppler**	**Combined (Specify)**	**Other***
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	
	Abdominal	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	
	Intra-operative (Abdominal organs & vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Prostate, Scrotum, Breast)	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	
	Trans-vaginal	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	
	Trans-urethral							
	Trans-esophageal (non-Cardiac)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Urology, Gynecology)	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esophageal (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel	Peripheral Vessel							
	Other (Carotid)							

Clarius Scanner L7 HD3

DEVICE NAME: CLARIUS SCANNER L7 HD3
INDICATION FOR USE: DIAGNOSTIC ULTRASOUND IMAGING OR FLUID FLOW ANALYSIS OF THE HUMAN BODY AS FOLLOWS:

Clinical Application		**Mode of Operation**						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**Color Doppler**	**Power Doppler**	**PW Doppler**	**Combined (Specify)**	**Other***
Ophthalmic	Ophthalmic	✔						
Fetal Imaging & Other	Fetal							
	Abdominal	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Intra-operative (Abdominal organs & vascular)	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Laparoscopic							
	Pediatric	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Small Organ (Thyroid, Prostate, Scrotum, Breast)	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esophageal (non-Cardiac)							
	Musculo-skeletal (Conventional)	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Musculo-skeletal (Superficial)	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Intravascular							
	Other (Urology, Gynecology)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esophageal (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel	Peripheral Vessel	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Other (Carotid)	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
Note 1: Needle Enhancement in B-Mode.								

Clarius Scanner L15 HD3

DEVICE NAME: CLARIUS SCANNER L15 HD3
INDICATION FOR USE: DIAGNOSTIC ULTRASOUND IMAGING OR FLUID FLOW ANALYSIS OF THE HUMAN BODY AS FOLLOWS:

Clinical Application		**Mode of Operation**						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**Color Doppler**	**Power Doppler**	**PW Doppler**	**Combined (Specify)**	**Other***
Ophthalmic	Ophthalmic	✔						
Fetal Imaging & Other	Fetal							
	Abdominal	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Intra-operative (Abdominal organs & vascular)	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Laparoscopic							
	Pediatric	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Small Organ (Thyroid, Prostate, Scrotum, Breast)	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esophageal (non-Cardiac)							
	Musculo-skeletal (Conventional)	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Musculo-skeletal (Superficial)	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Intravascular							
	Other (Urology, Gynecology)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esophageal (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel	Peripheral Vessel	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Other (Carotid)	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
Note 1: Needle Enhancement in B-Mode.								

Clarius Scanner L20 HD3

DEVICE NAME: CLARIUS SCANNER L20 HD3
INDICATION FOR USE: DIAGNOSTIC ULTRASOUND IMAGING OR FLUID FLOW ANALYSIS OF THE HUMAN BODY AS FOLLOWS:

Clinical Application		**Mode of Operation**						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**Color Doppler**	**Power Doppler**	**PW Doppler**	**Combined (Specify)**	**Other***
Ophthalmic	Ophthalmic	✔						
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Abdominal organs & vascular)	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Laparoscopic							
	Pediatric	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Small Organ (Thyroid, Prostate, Scrotum, Breast)	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esophageal (non-Cardiac)							
	Musculo-skeletal (Conventional)	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Musculo-skeletal (Superficial)	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Intravascular							
	Other (Urology, Gynecology)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esophageal (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel	Peripheral Vessel	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Other (Carotid)	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
Note 1: Needle Enhancement in B-Mode.								

Clarius Scanner PA HD3

DEVICE NAME: CLARIUS SCANNER PA HD3
INDICATION FOR USE: DIAGNOSTIC ULTRASOUND IMAGING OR FLUID FLOW ANALYSIS OF THE HUMAN BODY AS FOLLOWS:

Clinical Application		**Mode of Operation**						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**Color Doppler**	**Power Doppler**	**PW Doppler**	**Combined (Specify)**	**Other***
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Abdominal	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Intra-operative (Abdominal organs & vascular)	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Laparoscopic							
	Pediatric	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Small Organ (Thyroid, Prostate, Scrotum, Breast)							
	Neonatal Cephalic	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Adult Cephalic	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esophageal (non-Cardiac)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Urology, Gynecology)							
Cardiac	Cardiac Adult	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Cardiac Pediatric	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Intravascular (Cardiac)							
	Trans-esophageal (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel	Peripheral Vessel							
	Other (Carotid)							
Note 1: Needle Enhancement in B-Mode.								

Clarius Scanner PAL HD3

DEVICE NAME: CLARIUS SCANNER PAL HD3
INDICATION FOR USE: DIAGNOSTIC ULTRASOUND IMAGING OR FLUID FLOW ANALYSIS OF THE HUMAN BODY AS FOLLOWS:

Clinical Application		**Mode of Operation**						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**Color Doppler**	**Power Doppler**	**PW Doppler**	**Combined (Specify)**	**Other***
Ophthalmic	Ophthalmic	✔						
Fetal Imaging & Other	Fetal	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Abdominal	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Intra-operative (Abdominal organs & vascular)	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Laparoscopic							
	Pediatric	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Small Organ (Thyroid, Prostate, Scrotum, Breast)	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esophageal (non-Cardiac)							
	Musculo-skeletal (Conventional)	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Musculo-skeletal (Superficial)	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Intravascular							
	Other (Urology, Gynecology)							
Cardiac	Cardiac Adult	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Cardiac Pediatric	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Intravascular (Cardiac)							
	Trans-esophageal (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel	Peripheral Vessel	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
	Other (Carotid)	✔	✔	✔	✔	✔	B+M; B+CD; B+PD; B+PWD	Note 1
Note 1: Needle Enhancement in B-Mode.								

Precautions

For Use in Surgical Environments

Before you use the Clarius Scanner HD3 for intra-operative procedures or in a surgical environment, follow the instructions for high-level disinfection (for instructions see ***High-Level Disinfection*** on page 40), then cover the Clarius Scanner HD3 with an approved third-party manufactured sheath (according to the regulatory jurisdiction where it is available, such as but not limited to the US, Canada, and the EU), following the usage instructions provided by the manufacturer.

When you have finished using the Clarius Scanner HD3, immediately clean it (for instructions see ***Cleaning the Clarius Scanner HD3*** on page 38), followed by another high-level disinfection.

If the sheath breaks during the intra-operative procedure, dispose the sheath and follow the same cleaning and high-level disinfecting process as above, then cover the Clarius Scanner HD3 with a new sheath before continuing to use it.

For Use in Endocavitary Procedures

Before using the Clarius Scanner HD3 for endocavitary procedures (trans-vaginal and/or trans-rectal), inspect the probe for any rough surfaces, sharp edges, or sharp corners that may cause harm to the patient. Next, perform a high-level disinfection (for instructions see ***High-Level Disinfection*** on page 40). The EC7 HD3 scanner shall be covered with an approved third-party manufactured probe cover/sheath (according to the regulatory jurisdiction where it is available, such as but not limited to the US, Canada, and the EU), following the usage instructions provided by the manufacturer. Ensure the entire length of the end piece is protected/covered by the sheath prior to use.

When you have finished using the Clarius Scanner EC7 HD3, immediately clean it (for instructions see ***Cleaning the Clarius Scanner HD3*** on page 38), followed by another high-level disinfection. If a Clarius Power Fan HD3 (CIDN 50-02-00077) was used, remove the fan prior to the high-level disinfection and follow the instructions for an intermediate-level disinfection (for instructions see ***Disinfecting the Clarius Power Fan HD3*** on page 41).

If the sheath breaks during an endocavitary procedure, dispose the sheath and follow the same cleaning and high-level disinfecting process as above, then cover the Clarius Scanner HD3 with a new sheath before continuing use.

When using a biopsy guide, use one of the following recommended products:

- Civco Reusable Endocavity Needle Guide (Product Number 613-198)
- Civco Disposable Endocavity Needle Guide (Product Numbers 667-089 and 667-090)

Follow the usage instructions provided by the manufacturer.

Do not reuse biopsy guides unless instructed by the manufacturer.

For Use in Ophthalmic Procedures

Using the Clarius Ultrasound Scanner - HD3 Scanners for ocular (ophthalmic) indications is restricted to the Clarius Scanner L7 HD3, L15 HD3, L20 HD3, and PAL HD3 (all in B-Mode). No other model should be used for this indication or for any use causing the acoustic beam to pass through the eye. Doing so may result in serious and irreversible harm to the eye of the patient.

Hardware

Warranty

Your Clarius Scanner HD3 includes a standard three-year warranty.

- For full warranty details, go to clarius.com/ca/hd3-warranty-terms/
- To purchase extended warranty, go to clarius.com/contact and contact Clarius.

Disposal

Clarius is an active participant in the protection of the natural environment. The equipment and its accessories are designed and manufactured according to environmental protection guidelines, and the disposal of this equipment is intended to follow the same principles. The equipment materials that are essential for functionality are also harmful to the natural environment, therefore, you must dispose these materials appropriately.

For proper disposal of the Clarius Scanner HD3 or any of its accessories, dispose it in accordance with local, state, and federal regulations. Alternatively, you can return it to Clarius.

The improper disposal of the Clarius Scanner HD3 or any of its accessories adds hazardous materials to our landfills.

Security

Information Security

When entering data using the Clarius App, it is your responsibility to protect your security credentials (e.g., passwords) and the personal information of patients (e.g., names). You are responsible for ensuring that patient health information is protected when using features in the Clarius App that may expose identifying information to other viewers (e.g., Clarius Live).

Network Security

When connecting your smart device, use a network that supports Wi-Fi 802.11n. We recommend that you secure this network using WPA (Wi-Fi Protected Access) or WPA2 (Wi-Fi Protected Access II) as your security protocol.

For information on setting up your wireless network security, refer to your network equipment’s documentation.

You may run into situations where no wireless access point is available. Using an untrusted wireless access point may allow malicious parties to see your Wi-Fi signals, perform harmful actions, and view communications between the two smart devices. When no secure access point is available, operate the Clarius App in Wi-Fi Direct mode, and it will automatically set up encryption.

For security purposes:

- Use secure passwords.
- Use secure wireless equipment using the latest firmware and software, and secure protocols.
- Lock your smart devices.
- Go to Apple App Store or Google Play Store and update the Clarius App to the latest version.
- Ensure your mobile device is running the latest version of Android™ or iOS . The Clarius App supports the latest three versions of Android™ and iOS.
- Do not run the Clarius App on devices that are rooted or jailbroken.

The following actions could introduce new risks to patients, operators, and third parties. It is your organization's responsibility to identify, analyze, evaluate, and control these risks:

- Changing network configurations.
- Connecting to additional networks or disconnecting from existing networks.
- Upgrading to new equipment or updating existing equipment.

Confidentiality

Confidentiality of information is assured as follows:

- The scanner contains no patient-identifying information.
- When the scanner connects to a wireless network, it encrypts and stores the Wi-Fi password.
- The data transferred between the Clarius Scanner HD3 and the Clarius App is encrypted.

- Image data contains no patient- or user-identifying information and is transmitted in unencrypted form. If you want this data encrypted, connect to a:
    - Wi-Fi network where only trusted parties are permitted. The Wi-Fi network encrypts all image data sent from other Wi-Fi networks.
    - Wi-Fi Direct network. The Wi-Fi Direct network encrypts all image data, and because no other users are on the Wi-Fi Direct network, the image data is confidential.
- If no images are exported to Clarius Cloud or DICOM, the Clarius App stores them indefinitely. If images are exported, these images will be deleted from the device 10 days after export by default. You can change this default in the Clarius App's Settings page.

Integrity

Integrity of the data transmitted between the Clarius Scanner HD3 and the Clarius App is assured as follows:

- Authenticated encryption prevents malicious users from intercepting and modifying data.
- Integrity checks ensure completion and validity of data received. If any data is incomplete or invalid, it is discarded.
- TCP channels used over Wi-Fi ensures that data is delivered correctly. For transmitting image data, a UDP channel is used.

Availability

If Wi-Fi connection is unattainable (e.g., Wi-Fi access points are unavailable, or the network is down), use Wi-Fi Direct network, which is managed by the smart device. Because Wi-Fi Direct network is a peer-to-peer connection using the Wi-Fi protocol, it disallows other users from connecting, thereby reducing DDOS (Distributed Denial of Service) attacks.

If the Wi-Fi Direct network is disrupted, the Clarius Scanner HD3 continues to monitor itself, and shuts down after a period of inactivity. This reduces acoustic energy transmission and battery usage.

Accountability

The concept of accountability does not apply to the Clarius Ultrasound Scanner. However, ownership (i.e., the active user) of a smart device is assigned to one user at a time. Once you begin using the smart device, no other user can connect to the same smart device. All data transmitted between the smart device and the Clarius App is owned by the active user.

System Requirements

Using the Clarius Ultrasound Scanner on a smart device that does not meet the minimum requirements may result in low-quality images, unexpected results, and possible misdiagnoses.

To run the Clarius App, a smart device must meet or exceed the following minimum specifications:

Technical Features:

- Supports Bluetooth LE v4.0+
- Supports Wi-Fi 802.11n and Wi-Fi Direct
- 8 GB of storage (on-board)
- 1 GB of memory

Operating System:

- Two versions prior to the latest iOS or Android™-stable release build

Display:

- Resolution (in pixels) of at least 960x640 (or 640x960)
- Contrast ratio of at least 800:1
- Supports OpenGL ES 2.0

- Some sections of this User Manual may not apply to earlier versions of the Clarius Ultrasound Scanner. Make sure you have the latest version of the Clarius App.
- Using a smart device that is too small may not have the necessary resolution for viewing small structures.

Using the Clarius Ultrasound Scanner

2

This chapter explains how to install and use your Clarius Ultrasound Scanner safely and effectively.

Refer to ***Safety*** on page 43 before handling the Clarius Ultrasound Scanner.

Your Clarius Scanner HD3 is already activated and ready for use. Just download the Clarius App on an Apple iOS device or an Android™-based device.

Downloading the Clarius App

Whether you are using Apple iOS or Android™, you must have an account and password set up with them.

Before installing the Clarius App, make sure your smart device meets the minimum requirements. See ***System Requirements*** on page 23.

▼To download the Clarius App:

1. Go to the Apple App Store or Google Play Store.
2. Search for the Clarius App.

   If you cannot find the Clarius App, your smart device may not be meeting minimum specifications.

3. Tap the Install button and follow the instructions on your screen.

   This downloads the application.

4. Tap the Open button.

   This opens the Clarius App.

Turning the System on & off

Starting the Clarius App

Before you begin using the Clarius Ultrasound Scanner, make sure you have the Clarius Scanner HD3 and also your smart device with the Clarius App installed on it.

▼To open the Clarius App on your smart device:

Go to your smart device's home screen and tap .

The Clarius App opens to the sign-in screen.

For information on using the Clarius App and scanner, go to support.clarius.com/hc/en-us.

Exiting the Clarius App

▼To close the Clarius App:

Refer to your smart device's user manual.

Imaging

Start Scanning

Scanner Buttons	Description
Up	Press this button while scanning to capture an image (default setting).
Down	Press this button to turn on the scanner. Press this button while scanning to freeze or unfreeze an image (default setting).

The Clarius Scanner HD3 can take up to 30 seconds to power up and prepare for imaging. If you turn on the Clarius Scanner HD3 and leave it untouched, it will go through the following modes to help reduce battery power and temperature:

1. After three seconds, it decreases frame rate.
2. After 30 seconds of decreased frame rate, it freezes.
3. After 10 seconds in freeze mode, it goes idle.
4. After 15 minutes of idle time, it shuts down.

When scanning for more than 15 consecutive minutes, with any Clarius Scanner HD3, the fan must be used. For information on the fan, see ***Clarius Power Fan HD3*** on page 34.

When you go to the image acquisition page to begin an exam, the Clarius Scanner HD3 automatically switches from standby mode to scanning mode. For instructions on using the imaging tools, go to support.clarius.com/hc/en-us.

A typical use of the Clarius Scanner HD3 is described as five continuous scanning minutes followed by 10 minutes in standby mode (or turned off).

- Notifications and alerts from third-party applications may interrupt you or the Clarius App, thereby interfering with the exam. Configure your smart device in accordance with your institution's security policies.
- Vibration range that is too high for the scanner may cause the scanner to malfunction during an exam.
- Using improper gel type or combining different gel types may expose patients to risks and produce poor-quality images.
- When using PAL HD3 with dual array technology, there will be an offset on the transducer physical placement in the elevation axis. Due to the side-by-side physical arrangement of the transducers, refer to the transducer elevation width center line for the linear array when doing ultrasound guided injection procedure.
- When using PAL HD3 with dual array technology, the preset selection will determine array utilization. Care must be taken to avoid using the wrong preset when doing Ophthalmic imaging (low MI/TI limit). Ensure appropriate preset has been selected before imaging begins.

For proper transmission of the acoustic beam, use only ultrasound transmission gel or coupler intended to be used in ultrasound examination, and use it only before expiry date. Download the usage instructions from the manufacturer website and read all the information before operating the device. Clarius Ultrasound Scanner has been tested and known to work well with below ultrasound gel or coupler:

- Parkerlabs, Aquasonic 100
- Eccospray

Do not use:

- Lotion-based products or gels that contain mineral oil.
- Hand-sanitizing gels.
- Scanners left soaking in gel.

Scanner Notifications

The Clarius Ultrasound Scanner displays no error messages. Instead, the Clarius Scanner HD3 presents visual notifications in the form of status lights, and audible notifications in the form of status alerts.

Status Lights

The following table defines the Clarius Scanner HD3's status lights:

Color	Display	Meaning
Blue	Flashing	Scanner is booting up.
Blue	Solid	Scanner is ready for a Wi-Fi connection.
Green	Flashing	Scanner is imaging and live ultrasound image is displayed via Clarius App (has ultrasound output).
Green	Solid	Scanner is connected to the Clarius App via Wi-Fi and is ready to start imaging.
Orange	Flashing	Battery is low.
Orange	Solid	Scanner error (software or hardware).
Purple	Flashing	Software/firmware is updating.

Audible Notifications

The following table defines the audible indicators the Clarius Scanner HD3 emits:

Sounds	Meaning
2 quick beeps	Scanner components are ready
3 quick beeps	Bluetooth is ready
2 tone-increasing pitches	Power on

Sounds	Meaning
2 tone-decreasing pitches	Power off
1 beep every few seconds	Battery is critically low
Ringing	Find my scanner

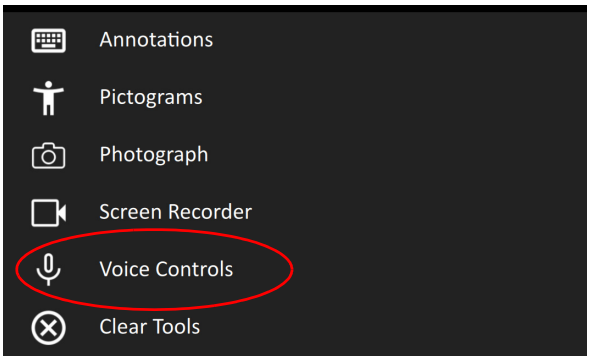
Voice Controls

The Voice Controls feature shall be used in a reasonably quiet clinic or medical office setting. Users can be masked or unmasked and should speak the Voice Commands clearly. Excessive noise will affect the device's ability to hear the commands correctly.

Start Voice Controls

Set your mobile device (phone or tablet) on a surface that is from 1-3 feet/ less than 1 meter away from you. If you typically have your phone or tablet further away, it is recommended to use an earbud with a mic or external microphone.

1. Click the Tool & Measurements icon: 
2. Click the Voice Controls option.



3. Confirm that you see a flashing microphone icon at the top of the screen.

All Voice Controls commands shall be verified by the user. Manual commands can always be used.

Turn off Voice Controls

1. Click the Tool & Measurements icon: 
2. Click the Voice Controls option.

   The flashing microphone no longer appears.

Voice Command Dictionary

You can find the Voice Command dictionary at clarius.com/voice-commands.

Updating the Clarius Ultrasound Scanner

Software Updates

▼To update the software:

Go to the Apple App Store or the Google Play store.

Firmware Updates

If a Clarius Scanner HD3 software update is required, the Clarius App will notify you.

▼To update the firmware:

Tap **Update**.

During the update, the Clarius Scanner HD3 emits a purple flashing light. Also, a purple indicator displays at the top right of the screen. Once the update is complete, the Clarius Scanner HD3 light turns blue.

Maintenance

The scanner routinely performs automated maintenance of the scanner itself. Prior to and after use, you must clean and disinfect the Clarius Scanner HD3 according to the instructions in this User Manual.

Perform maintenance regularly and as needed. The system must be serviced by trained personnel only.

Failing to regularly maintain or verify the Clarius Ultrasound Scanner may lead to undetected performance errors.

Hardware Maintenance

Testing Scanners

When you turn on the system, the scanner powers up and automatically tests its internal components. The Clarius Scanner HD3's LED will light up and you will hear a two-tone beep. For a list of status lights and audible notifications, see ***Scanner Notifications*** on page 27.

Also, the system runs a series of tests in the background. If your smart device is not connected to a wireless or cellular network, the logs are queued until you have network connectivity. For more information, go to clarius.com/contact and contact Clarius.

Storing Scanners

To protect your Clarius Scanner HD3:

- Dry thoroughly before storage.
- Avoid storing in extreme temperatures.
- Avoid placing under direct sunlight for prolonged periods of time. This will not impact the Clarius Scanner HD3's safety and performance but may discolor the housing's finish.
- Store separately from other equipment.

The scanner may degrade in performance or become unusable if stored or transported in ambient temperatures below-20°C (-4°F) or above 50°C (122°F).

System Maintenance

To send activity logs, select the Support menu option to go to the Support page and select the Submit Logs button. This downloads logs from the Clarius Scanner HD3, then combines them

with the logs from the Clarius App. This bundle is then sent to Clarius Cloud where they can be retrieved by a Clarius Support staff. The log files contain diagnostic information.

If the log files grow too large, you may want to delete them to save space on your smart device. To delete the log files, go to the Settings menu.

Accessories

3

To order these additional accessories, go to clarius.com/contact:

- Clarius Charger HD3
- Clarius Power Fan HD3

Clarius Charger HD3

The Clarius App displays the scanner's battery level on your smart device. Because the Clarius Scanner HD3 is battery-operated, you must recharge its battery when necessary. An empty battery takes approximately 1 ½ hours to fully charge.

A fully charged battery gives you approximately 45 minutes of typical scanning time. Scanners in sleep mode will send battery warning notifications, via BLE, using your smart device's standard notification services.

About the Clarius Charger HD3

The Clarius Charger HD3 is included with your Clarius Ultrasound Scanner. It is designed to be used with the following products:

- Clarius Scanner C3 HD3 (CIDN 99-13-00018)
- Clarius Scanner C7 HD3 (CIDN 99-13-00019)
- Clarius Scanner EC7 HD3 (CIDN 99-13-00024)
- Clarius Scanner L7 HD3 (CIDN 99-13-00020)
- Clarius Scanner L15 HD3 (CIDN 99-13-00021)
- Clarius Scanner L20 HD3 (CIDN 99-13-00022)
- Clarius Scanner PA HD3 (CIDN 99-13-00023)
- Clarius Scanner PAL HD3 (CIDN 99-13-00029)

The Clarius Charger HD3 is designed for use in professional healthcare facilities. The device is not intended to come in contact with the patient during normal use.

For regular maintenance, clean and disinfect the Clarius Charger HD3. For cleaning instructions, see ***Cleaning the Clarius Charger HD3*** on page 39. For disinfecting instructions, see ***Disinfecting the Clarius Charger HD3*** on page 42.

The charger supports various USB-dedicated adapters and USB ports; however, these products may cause the charger to fail or vary in charge time.

Do not use the Clarius Charger HD3 in air ambulances, regular ambulances, or the EMS environment in general (including patient transportation and home healthcare).

- If the AC power cord is damaged, contact Clarius for a replacement.

- Charging the scanner in a rotary-wing airborne ambulance may cause the charger's power supply to interfere with the aircraft's electrical system, causing a malfunction that could lead to failure of control, instrumentation, and communication systems.
- Connecting the charger to a power supply that is not manufactured by Clarius may have the incorrect voltage/current, which could damage the charger.

Components

The Clarius Charger HD3 is made of the following components:

- A fully assembled Clarius Charger HD3 (CIDN 50-02-00069).
- A power supply (CIDN 10-21-00006/Globtek GTM46161) with an adapter compatible with your country's socket and voltage.
- A removable cable (CIDN 10-18-000026).

Technical Specifications

- Input:
  - wall power supply: 100-240 VAC, 50-60 Hz, 0.45 A
  - Clarius Charger HD3: 5 VDC, 3.2 A
- Output:
  - wall power supply: 5 VDC, 3.2 A
  - Clarius Charger HD3: 5 VDC, 3.2 A
- Protection Against Electric Shock: Class II / double insulated
- Applied Part: None

- Ingress Protection: IP00
- Mode of Operation: Continuous

Setting Up the Clarius Charger HD3

▼To use the Clarius Charger HD3:

1. Clean and disinfect the scanners before placing them in the Clarius Charger HD3.

   For cleaning instructions, see ***Cleaning the Clarius Scanner HD3*** on page 38. For disinfecting instructions, see ***Disinfecting the Clarius Scanner HD3*** on page 40.

2. Connect the Clarius Micro USB Cable to the Clarius Charger HD3.
3. Connect the USB A to the power supply.
4. Insert the AC male plug into a power source.

   The Clarius Charger HD3 is now ready to use.

Clarius Power Fan HD3

Attach the Clarius Power Fan HD3 to the built-in heatsink of the Clarius Scanner HD3 to extend scanning time.

▼To attach the Clarius Power Fan HD3:

1. Align the top of the fan with the top of the scanner.

   Make sure the fan's logo is facing towards you. The logo on the fan and the logo on the scanner should align on top of each other.

2. Press the top of the fan onto the top of the scanner until the fan snaps into place.

   When the scanner reaches a temperature of 35°C (95°F), the fan automatically activates.

▼To remove the Clarius Power Fan HD3:

1. Pull on the latch located on either side of the fan.

   This loosens the fan from the scanner.

2. Lift the fan off the scanner.

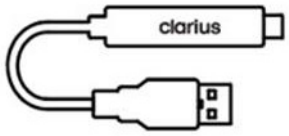
Clean and disinfect the Clarius Power Fan HD3 after each use. For cleaning instructions, see ***Cleaning the Clarius Power Fan HD3*** on page 39. For disinfecting instructions, see ***Disinfecting the Clarius Power Fan HD3*** on page 41.

About the Clarius Power Fan HD3

Components

The Clarius Power Fan HD3 is made of the following components:

- A fully assembled Clarius Power Fan HD3 (CIDN 50-02-00077).
- A removable cable (CIDN 10-18-00039).



Technical Specifications

- Input:
    - wall power supply: 100-240 VAC, 50-60 Hz, 0.45 A
    - Clarius Power Fan HD3: 5 VDC, 3.2 A
- Output:
    - wall power supply: 5 VDC, 3.2 A
    - Clarius Power Fan HD3: 5 VDC, 3.2 A
- Protection Against Electric Shock: Class II / double insulated
- Applied Part: None

Charging the Clarius Scanner HD3

Charge the Clarius Scanner HD3 using only the Clarius Charger HD3 or the Clarius Power Fan HD3.

▼To charge the scanner:

Place the scanner into the Clarius Charger HD3.

▼To charge the scanner using the Clarius Power Fan HD3:

1. Clean and disinfect the Clarius Power Fan HD3.

   For cleaning instructions, see ***Cleaning the Clarius Power Fan HD3*** on page 39. For disinfecting instructions, see ***Disinfecting the Clarius Power Fan HD3*** on page 41.

2. Attach the Clarius Power Fan HD3 to the scanner.

   For instruction on attaching the Clarius Power Fan HD3 to the scanner, see ***Clarius Power Fan HD3*** on page 34.

3. Connect the Clarius Micro USB Cable provided with the Clarius Power Fan HD3 to the Clarius Power Fan HD3.
4. Connect the USB A to a power supply.
5. Insert the AC male plug into a power source.

   The scanner will begin charging.

The scanner LED indicates the charge level of the battery in the scanner:

- Orange: 0 – 64%
- Blue: 65 – 89%
- Green: 90 – 100%

You can continue scanning patients while the scanner charges via the Clarius Power Fan HD3. Use only power supplies recommended by Clarius when plugging into an AC power outlet.

Do not charge the scanner via the Clarius Power Fan HD3 in air ambulances, regular ambulances, or the EMS environment in general (including patient transportation and home healthcare).

Cleaning & Disinfecting

4

It is important to clean and disinfect the Clarius Scanner HD3 immediately after use. This chapter will guide you through the cleaning and disinfecting process.

The classification of cleaning and disinfecting you select will depend on the type of tissue the Clarius Scanner HD3 comes into contact with. To find the correct classification, refer to ***Spaulding Classification*** on page 42.

All compatible accessories may be cleaned using CaviWipes. For a full list of accessories that are compatible with the system, visit clarius.com/products/accessories.

When cleaning and disinfecting:

- Follow the procedures in the order they are described in this guide, without skipping steps.
- Use only solutions approved by Clarius Mobile Health. Other solutions may be incompatible with the system and could damage the scanner.
- Follow the manufacturer's instructions, recommendations, and guidelines for cleaners and disinfectants, as well as your regional regulations.
- Check expiry dates, concentration, and efficacy of the chemicals used.
- Wear the appropriate personal protective equipment (PPE), such as eyewear and gloves, as recommended by the chemical manufacturer.

- Due to repeated use and cleaning, the cleanliness and sterility of the hardware deteriorates over its service life (five years for the scanner, charger, and fan).

- Using incompatible solutions to clean the scanner may damage its surface.
- Cleaning or disinfecting the scanner using IPA (isopropyl alcohol) may damage it.

During an emergency where the scanner is used to examine multiple patients in a short period of time, the lack of proper cleaning and disinfecting between patients may spread infections to other patients and users.

Cleaning

Cleaning the Clarius Scanner HD3

Before cleaning, visually inspect the scanner to determine that it is free of any unacceptable deterioration, such as corrosion, discoloration, pitting, or cracked seals. If damage is evident, discontinue use and contact Clarius Mobile Health.

To ensure proper cleaning and/or disinfection, make sure there is no particulate matter (for example, biological agents, ultrasound gel, and dirt) in the scanner's crevasses, openings, and/or cavities.

Cleaning the scanner requires that you select the proper cleaning level. Before you begin, determine the level of cleaning by referring to ***Spaulding Classification*** on page 42. Once you have determined the level, have the cleaning solution ready and follow the procedure below.

▼To clean the Clarius Scanner HD3:

1. Make sure the Clarius Scanner HD3 is turned off.
2. Remove the fan from the scanner.
3. To clean the scanner, dampen a soft cloth using a compatible cleaner. Alternatively, use a premoistened disinfectant wipe. Use a swab for unreachable areas.

   For a list of compatible cleaners, see ***Cleaners & Disinfectants*** on page 76.

4. Start at the top of the scanner and wipe toward the scan head. Be sure to remove any gels or particulate matter. Dispose the cloth.
5. Verify that all gel, particulate matter, and bodily fluids have been removed. Where applicable, remove sterile sheaths and covers.
6. Repeat with new cleaning material if necessary.

Cleaning the Clarius Power Fan HD3

▼To clean the Clarius Power Fan HD3:

1. Remove the fan from the Clarius Scanner HD3.
2. Wipe down all surfaces using a premoistened disinfectant wipe.

   For a list of compatible cleaners, see ***Cleaners & Disinfectants*** on page 76.
3. Repeat with new cleaning material if necessary.
4. Air-dry the fan. Alternatively, use a non-linting cloth.

   When you are done, keep the two components separate. You will be disinfecting them individually.

Cleaning the Clarius Micro USB Cable

▼To clean the Clarius Micro USB Cable:

1. Detach the USB A to from the power supply.
2. Detach the Clarius Micro USB Cable from the Clarius Power Fan HD3.
3. Wipe down all surfaces using a premoistened disinfectant wipe for one minute until visibly clean.

   For a list of compatible cleaners, see ***Cleaners & Disinfectants*** on page 76.
4. Repeat with new cleaning material if necessary.
5. Air-dry the Clarius Micro USB Cable. Alternatively, use a non-linting cloth.

   When you are done, keep the two components separate. You will be disinfecting them individually.

Cleaning the Clarius Charger HD3

▼To clean the Clarius Charger HD3:

1. Unplug the Clarius Charger HD3 from the power source.
2. Disconnect the Clarius Micro USB Cable from the Clarius Charger HD3.
3. Wipe down all surfaces using a premoistened disinfectant wipe. Do not submerge the Clarius Charger HD3 in any liquid.

For a list of compatible cleaners, see ***Cleaners & Disinfectants*** on page 76.

4. Repeat with new cleaning material if necessary.
5. Air-dry the Clarius Charger HD3. Alternatively, use a non-linting cloth.

Disinfecting

Disinfecting the Clarius Scanner HD3

Before you begin disinfecting, make sure you have cleaned the scanner (see ***Cleaning the Clarius Scanner HD3*** on page 38).

Disinfecting requires that you choose the proper disinfecting level. Determine the necessary disinfection level by referring to ***Spaulding Classification*** on page 42. Once you have determined the required disinfecting level, have the disinfectant ready and follow one of the appropriate procedures below. Note that different levels of disinfection require different steps, not just different solutions.

Intermediate Disinfection

Refer to ***Cleaners & Disinfectants*** on page 76 for a list of disinfectants recommended for intermediate disinfection of the scanner.

If the scanner has come into contact with broken skin, mucosal membranes, or blood, it is classified as semi-critical, and you must perform a high-level disinfection. See ***High-Level Disinfection*** on page 40 for steps.

▼To disinfect your scanner (intermediate):

1. Make sure the fan is still detached from the scanner.
2. Disinfect the scanner by wiping with a cloth moistened with a compatible disinfectant. Alternatively, use a premoistened disinfectant wipe. Use a swab for unreachable areas.
3. Air-dry. Alternatively, use a non-linting cloth.
4. Examine the scanner for damage, such as cracks or splitting where fluid can enter. If damage is evident, do not use the scanner and contact Clarius Mobile Health.

High-Level Disinfection

Refer to ***Cleaners & Disinfectants*** on page 76 for a list of disinfectants recommended for high-level disinfection of the scanner.

▼To disinfect your scanner (high-level):

1. Make sure the fan is still detached from the scanner.
2. Mix the disinfectant solution by following the disinfectant label instructions for solution strength and disinfectant contact duration.
3. Ensure the disinfection process temperature is within the scanner temperature limit. For information on the scanner temperature limit, see ***Scanner Specifications*** on page 72. Using a compatible disinfectant, immerse the scanner in the disinfectant solution as per the recommendation provided within the disinfectant instructions.
4. Using the instructions on the disinfectant label, rinse the scanner.
5. Air-dry. Alternatively, use a non-linting cloth.
6. Examine the components for damage, such as cracks or splitting where fluid can enter. If damage is evident, do not use the scanner and contact Clarius Mobile Health.

Disinfecting the Clarius Power Fan HD3

Before you begin disinfecting, make sure you have cleaned the fan (see ***Cleaning the Clarius Power Fan HD3*** on page 39).

Because the Clarius Power Fan HD3 cannot be submerged in liquid, never use high-level disinfectants. Always use intermediate-level disinfectants. For a list of disinfectants recommended for intermediate disinfection of the Clarius Power Fan HD3, refer to ***Cleaners & Disinfectants*** on page 76.

▼To disinfect the Clarius Power Fan HD3:

1. Make sure that the fan is detached from the scanner.
2. Disinfect the fan by wiping with a cloth moistened with a compatible disinfectant. Alternatively, use a premoistened disinfectant wipe.
3. Air-dry. Alternatively, use a non-linting cloth.
4. Examine the fan for damage, such as cracks or splitting. If damage is evident, do not use the fan and contact Clarius Mobile Health.

Disinfecting the Clarius Micro USB Cable

▼To disinfect the Clarius Micro USB Cable:

1. Make sure the Clarius Micro USB Cable is detached from the power supply and the Clarius Power Fan HD3.
2. Disinfect the Clarius Micro USB Cable by wiping with a cloth moistened with a compatible disinfectant. Alternatively, use a premoistened disinfectant wipe.

3. Air-dry. Alternatively, use a non-linting cloth.
4. Examine for damages, such as cracks or splits. If damage is evident, do not use the Clarius Micro USB Cable and contact Clarius Mobile Health.

Disinfecting the Clarius Charger HD3

Before you begin disinfecting, make sure you have cleaned the charger (see ***Cleaning the Clarius Charger HD3*** on page 39).

Because the Clarius Charger HD3 cannot be submerged in liquid, never use high-level disinfectants. Always use intermediate-level disinfectants. For a list of disinfectants recommended for intermediate disinfection of the Clarius Charger HD3, refer to ***Cleaners & Disinfectants*** on page 76.

▼To disinfect the Clarius Charger HD3:

1. Disinfect the charger by wiping with a cloth moistened with a compatible disinfectant. Alternatively, use a premoistened disinfectant wipe.
2. Air-dry. Alternatively, use a non-linting cloth.
3. Examine for damages, such as cracks or splits. If damage is evident, do not use the charger and contact Clarius Mobile Health.

Spaulding Classification

The level of cleaning and disinfecting required for your Clarius Scanner HD3 is based on the Spaulding classification system. Following the correct classification will help reduce cross-contamination and infection.

Each Spaulding classification mandates a specific level of cleaning and disinfecting of the equipment before it can be used in the next exam. Determine the Spaulding classification based on your scanner's usage.

Class	Use	Method
Non-Critical Class	Touches intact skin	Cleaning followed by intermediate disinfection
Semi-Critical Class	Touches mucous membranes and non-intact skin	Cleaning followed by high-level disinfection (HLD)

Safety

5

This chapter provides instructions on the product's safe usage and offers information on safety guidelines. Pay special attention to warnings and cautions, and follow them before, during, and after operating the product:

- Warnings indicate information vital to the safety of you, the operator, and the patient.
- Cautions highlight possible damages to the product that may void your warranty or service contract or lose patient or system data.

About Diagnostic Ultrasounds

Interactions with Matter

When using diagnostic ultrasound, the sound waves are directed towards an area of interest, which then interacts with any matter along its path. This interaction is determined by the characteristics of the ultrasound wave, as well as the physical properties of the matter through which the sound wave passes. Diagnostic ultrasound frequencies range from 2 MHz to 15 MHz.

Studies

Exposure-effect studies have been performed at intensity levels much higher than those in diagnostic ultrasound practice, which revealed two mechanisms known to alter biological systems:

- Thermal mechanism: Heating of soft tissue and bone.
- Non-thermal mechanism: Mechanical phenomena, such as cavitation.

These mechanisms are discussed later.

Benefits & Risks

Ultrasound is widely used because it provides many clinical benefits to the patient and has an outstanding safety record. In more than three decades of use, there has been no known long-term negative side-effects associated to this technology.

More questions of safety are being discussed because more applications are being discovered, and the industry is producing technically sophisticated scanners that provide more diagnostic information. Dialogue among the medical community, manufacturers, and the FDA has resulted in a standard that allows higher outputs for greater diagnostic capability.

Ultrasound benefits:

- Multiple diagnostic uses
- Immediate results with high-quality information
- Replacement or complimentary or used with other procedures
- Cost-effectiveness
- Portability
- Patient acceptance
- Safety record

Ultrasound risks:

The potential for adverse bioeffects caused by heating or cavitation.

"… the benefits to patients of the prudent use of diagnostic ultrasound outweigh the risks, if any, that may be present."-- AIUM

Safety Topics

Use the Clarius Ultrasound Scanner only if you have read and understood all the information in this section. Operating the system without proper safety awareness could lead to fatal or serious personal injury.

This section covers general safety information. Safety information applicable to specific tasks are noted in the procedure. The Clarius Ultrasound Scanner is intended for use by a trained medical professional, or by the direction and supervision of a licensed physician qualified to instruct its usage.

"Diagnostic ultrasound is recognized as a safe, effective, and highly flexible imaging modality capable of providing clinically relevant information about most parts of the body in a rapid and cost-effective fashion." -- WHO (World Health Organization)

Product Safety

Clarius is responsible for the safety of the scanners. The safety of your smart device is your responsibility. Always follow the safety guidelines provided with your smart device before, during, and after use.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Product Warnings

The following actions may cause fatal or other serious injury:

- Using the system without adequate training on its safe and effective operation. If you are unsure of your ability to operate the system safely and effectively, do not use it.
- Attempting to remove, modify, override, or frustrate any safety provisions on the system.
- Using the system with any product that Clarius does not recognize as compatible with the system or operate the product for unintended purposes.

- If the system and scanner appears to be malfunctioning, stop use immediately. Go to clarius.com/contact and contact Clarius.
- To avoid exposing you and the patient to safety hazards, if any part of the system is known or suspected to be defective or incorrectly adjusted, do not use the system until it is repaired.
- To avoid compromising the effectiveness of the system and the safety of the patient, yourself, and others, do not operate the system with patients unless you have an adequate understanding of its capabilities and functions.
- Configure your smart device in compliance with your institution's security policies. For example, notifications and alerts from third-party applications may interfere with an exam.

- Selecting an incorrect or hazardous imaging mode may deliver excessive acoustic energy to the patient during the exam.
- Heat dissipates through the heatsink and the metal portion of the scanner enclosure. Do not touch these components or apply them against the patient for longer than one minute. Hold the scanner using the black rubber handle.

Product Compatibility

The Clarius Ultrasound Scanner - HD3 Scanners are supplied with the Clarius Charger HD3 and a power supply for the charger. Components and accessories of HD3 models are not compatible with non-HD3 models and are not interchangeable. Do not use your system in combination with other products or components not made by Clarius, unless Clarius expressly recognizes those other products or components as compatible.

Changes and additions to the system can be made only by Clarius or by third parties expressly authorized by Clarius to do so. Such changes and additions must comply with all applicable laws and regulations that have the force of law within the jurisdictions concerned, and best engineering practices. System changes and additions that are made without the appropriate training or by using unapproved spare components may carry risks of system damage and personal injury.

Battery Safety

- If the scanner fails to fully charge, contact Clarius for battery replacement options.
- Keep the scanner away from heat sources. For example, do not charge the scanner near a fire or heater.
- Do not discard the scanner in fire.
- Do not open, crush, or puncture scanner.
- If the scanner leaks or emits an odor, contact Clarius Technical Support.
- If the scanner emits an odor or heat, is deformed or discolored, or in any way appears abnormal during use, recharging, or storage, stop using it immediately. If you have any questions about the scanner, go to clarius.com/contact and contact Clarius.
- If the scanner is to remain unused for over a month, keep the charge level between 40% and 50% to prolong its life, and store it in temperatures between-20°C (-4°F) and 20°C (68°F).

The following actions may damage the battery:

- Returning a scanner without instructions from Clarius Technical Support.
- Using the scanner in temperatures below 0°C (32°F) or above 40°C (104°F).
- Charging the scanner using non-Clarius equipment. Always charge the scanner using the charger provided by Clarius.

Cleaning Safety

It is important to clean and maintain the ultrasound system and peripherals. Thorough cleaning is particularly important for pieces of peripheral equipment because they contain

electromechanical components. If exposed to constant and excessive sunlight and humidity, the scanner will suffer in both performance and reliability.

It is your responsibility to clean and disinfect your scanner in accordance with the cleaning and disinfecting instructions in this manual. For instructions on cleaning and disinfecting the Clarius Scanner HD3, refer to ***Cleaning*** on page 38.

Cleaners & Disinfectants

- Use only cleaners and disinfectants recommended by Clarius. Avoid acetone, Methyl ethyl ketone (MEK), paint thinner, or other strong solvents and abrasive cleaners.
- Always use protective eyewear and gloves when cleaning and disinfecting equipment.
- Disinfectants are recommended based on their chemical compatibility (not their biological effectiveness) with product materials. For the biological effectiveness of a disinfectant, see the guidelines and recommendations of the disinfectant manufacturer, the U.S. Food and Drug Administration, and the U.S. Centers for Disease Control.
- If a pre-mixed solution is used, check the expiry date.
- The level of disinfection required for a scanner is determined by the type of tissue it contacts. Ensure the disinfectant is appropriate for the scanner and its application. Also, read the disinfectant label instructions and the recommendations of the Association for Professionals in Infection Control, the U.S. Food and Drug Administration, and the U.S. Centers for Disease Control.
- Clean the scanner after each use. This is an essential step before disinfection.
- When disinfecting the scanner, ensure that the solution's strength and duration of contact are appropriate for disinfection.
- Selecting a non-recommended solution, using an incorrect solution strength, or immersing a scanner deeper or longer than recommended can damage the scanner and will void warranty.
- Follow the manufacturer's recommendations and instructions when using cleaners and disinfectants.

Minimizing the Effects of Residual Disinfectant

If you use an OPA-based disinfectant, residual solution may remain on your scanners if you do not carefully follow the manufacturer's instructions.

To minimize the effects from residual OPA, or any other disinfectant, Clarius recommends the following:

- Follow the disinfectant manufacturer's instructions very carefully.
- Limit the time that scanners are soaked in the disinfectant solution to the minimum time recommended by the disinfectant manufacturer.

Factors Affecting Disinfectant Efficacy

The following factors will affect the efficacy of a disinfectant solution:

- Number and location of microorganisms
- Innate resistance of microorganisms
- Concentration and potency of disinfectants
- Physical and chemical factors
- Organic and inorganic matter
- Duration of exposure
- Biofilms

Scanner Care

Lint, dust, and light (including sunlight) have no effect on the scanner's basic safety and essential performance.

- Avoid sharp objects, such as scissors, scalpels, or cauterizing knives, from touching the scanners.
- Avoid bumping the scanner on hard surfaces.
- Avoid surgeon's brushes when cleaning scanners. Even soft brushes can damage scanners.
- Before storing scanners, make sure they are completely dry. If it is necessary to dry the scanner lens or acoustic window, apply a soft cloth to the area, and blot rather than wipe.
- Use only liquid solutions to disinfect scanners.
- Regularly check the lens of the scanner's acoustic window for degradation, as described in ***Cleaning*** on page 38, to prevent degradation of image quality and abrasions to the patient's skin.

The following actions may damage your scanner:

- Cleaning or disinfecting a scanner using methods unapproved by Clarius.
- Using paper or abrasive products. They damage the soft lens of the scanner's acoustic window. If the lens is damaged to the point that the scanner elements are exposed, stop using the scanner. Go to clarius.com/contact and contact Clarius immediately. Exposed scanner elements may cause burns or electric shock to the patient.
- Soaking the scanner for extended periods. Use soaking time and depth recommended by the disinfectant manufacturer.

Clinical Safety

Syringe Safety

Needle Enhance Mode

- If the needle is not visible, do not perform the needle procedure.
- Verify the location of the needle tip in the image. The Clarius Scanner HD3 cannot visualize a needle that is out of plane.
- Thin needles can bend when entering tissue. Verify the needle's position by identifying the echoes from the needle.
- Make sure you are not using a false needle image to locate the needle. False needle images caused by reverberation or other tissue artifacts can misguide you.

Needle X Mode

- Needle X Mode is designed for detecting subtle tissue movements when a needle is inserted into the human body. It is not intended to provide direct visualization of the needle.
- Out-of-plane needles location can be detected based on movement information when the needle tip or shaft is entering the plane of imaging due to the needle pushing tissue.
- Users must not rely solely on Needle X Mode for needle positioning. Always use additional verification methods to confirm the needle's location for safety and accuracy.

Defibrillator Safety

If you are using the Clarius Ultrasound Scanner and defibrillation is required, use defibrillators that do not have grounded patient circuits. To determine whether a defibrillator patient circuit is grounded, see the defibrillator service guide, or consult a biomedical engineer.

Before defibrillation, remove any part of the system that is in contact with the patient.

Biological Safety

- Do not use a system that exhibits erratic or inconsistent image updates. This indicates a hardware failure that must be corrected before continuing use.
- Perform ultrasound procedures prudently. Use the ALARA (as low as reasonably achievable) principle. For information on ALARA, see ***ALARA Principle*** on page 52.
- Clean and disinfect the Clarius Ultrasound Scanner immediately after use. Do not use Clarius Ultrasound Scanners on animals. Veterinary models of the Clarius Ultrasound Scanners are available.

Latex

The Clarius Scanners do not contain natural rubber latex.

The sheaths and biopsy guides that you select to use with the Clarius Ultrasound Scanner may contain latex. Check with the manufacturer's safety information.

The following are FDA recommendations on latex awareness:

- When taking general histories of patients, include questions about latex sensitivity. For surgical and radiology patients, spina bifida patients and health care workers, this recommendation is especially important. Questions about itching, rashes, or wheezing after wearing latex gloves or inflating a toy balloon may be useful. For patients with positive histories, flag their charts.
- If latex sensitivity is suspected, consider wearing a non-latex glove over the latex glove if the patient is sensitive. If both the health professional and the patient are sensitive, a latex middle glove could be used. (Latex gloves labeled “Hypoallergenic” may not always prevent adverse reactions.)
- Whenever latex comes in contact with mucous membranes, be alert to the possibility of an allergic reaction.
- If an allergic reaction does occur and latex is suspected, advise the patient of a possible latex sensitivity, and consider an immunologic evaluation.
- Advise the patient to tell health professionals and emergency personnel about any known latex sensitivity before undergoing medical procedures. Consider advising patients with severe latex sensitivity to wear a medical identification bracelet.

Bioeffects

Thermal

Thermal bioeffects refers to heat generated whenever ultrasound energy is absorbed. The amount of heat produced depends on the ultrasound's intensity, exposure time, and the tissue's absorption characteristics.

Tissue absorbs ultrasound energy to varying degrees depending on the tissue's absorption characteristics. Absorption characteristics are quantified by the absorption coefficient:

- Fluids: Their absorption coefficient is almost zero. Fluids such as amniotic fluid, blood, and urine absorb very little ultrasonic energy. That means the ultrasound goes through the fluid with very little decrease. And there's little temperature elevation in the fluid.

- Bone: Its absorption coefficient is very high. Dense bone absorbs the energy very quickly and causes the temperature to rise rapidly. Adult bone absorbs nearly all acoustic energy impinging on it. Fetal bone absorption coefficients vary greatly depending on the degree of ossification.

- Soft tissue: Soft tissue varies in density depending on the organ, but the density does not vary much within an organ. We call it soft tissue to distinguish it from hard tissue such as

bone. Also, the tissue density within a particular organ is not always the same. But for our purposes, we assume that attenuation is uniform throughout the organ. We call this a homogeneous soft tissue model.

Attenuation is caused by:

- Absorption: Energy converted to heat.
- Scattering: Redirection of ultrasound.

Mechanical (Non-Thermal)

Mechanical bioeffects are threshold phenomena, such as cavitation, that occur when the output exceeds a certain level. This threshold varies by tissue type.

Cavitation is the interaction of ultrasound with gas bubbles, causing rapid and potentially large changes in bubble size. These bubbles originate within materials at locations termed nucleation sites, the exact nature and source of which are not well understood in a complex medium such as tissue or blood. The change in bubble size may increase temperature and pressure within the bubble, causing mechanical stress on surrounding tissues, precipitate fluid microjet formation, and generate free radicals. Gas-containing structures, such as lungs, are most susceptible to the effects of acoustic cavitation; however, such higher frequency ultrasounds do not provide sufficient time for significant bubble growth; therefore, cavitation is unlikely to occur under these circumstances. Factors that produce cavitation include pressure (compressional, rarefactional), frequency, focused/unfocused beam, pulsed/ continuous waves, degree of standing waves, boundaries, and the nature and state of material.

Scientific evidence suggests that the onset of transient cavitation is a threshold phenomenon. There's a combination of rarefactional pressure values, ultrasonic frequency, and cavitation nuclei that are required for inertial cavitation to occur. If inertial cavitation is a threshold phenomenon, then exposure to pressure levels below the threshold will never induce such events, regardless of the length of exposure.

There are two categories of cavitation:

- Stable: Stable cavitation is associated with vibrating gas bodies. In stable cavitation, a gas body oscillates or pulsates continuously around its equilibrium size. As the oscillations become established, the liquid-like medium around the gas body begins to flow or stream; we call this microstreaming. Microstreaming has been shown to produce stress sufficient to disrupt cell membranes.
- Inertial: During inertial (transient) cavitation, pre-existing bubbles or cavitation nuclei expand because of the rarefactional pressure of the ultrasonic field and then collapse in a violent implosion. The whole process takes place in a time span on the order of microseconds. The implosion can produce huge local temperature rises that may be thousands of degrees Celsius and pressures equal to hundreds of atmospheres, all in a volume of less than 1 μm^3. The implosion can damage cells and tissue, ultimately leading to cell death. In addition, bubble implosion can generate highly reactive chemical species. All of these effects, microstreaming, implosion, and generation of reactive chemicals, occur in a very small space around the bubble, affecting only a few cells.

Exposure of the lung can produce small, localized hemorrhages under some conditions in laboratory animals. These lesions resolve naturally and are without lasting effects in normal subjects, but their possible significance in compromised individuals has not been studied.

ALARA Principle

The guiding principle for the use of diagnostic ultrasound is defined by the ALARA (as low as reasonably achievable) principle. The threshold for diagnostic ultrasound bioeffects is undetermined, and the definition of “reasonable” is left to the judgment and insight of qualified personnel. No set of rules can be formulated that would be sufficiently complete to dictate the correct response to every circumstance. By keeping ultrasound exposure as low as reasonably achievable as you obtain diagnostic images, you can minimize ultrasonic bioeffects.

Output display indices are designed to provide more quality information, to help guide the sonographers using ultrasound technology, in applying the ALARA principle. Some variables that affect the way output display indices can be used to implement the ALARA principle:

- index values
- body size
- location of the bone relative to the focal point
- attenuation in the body
- ultrasound exposure time (an especially useful variable, as it is controlled by you)

Applying ALARA

The system's imaging mode you select depends on the information needed. Understanding the nature of the imaging mode used, the scanner frequency, system setup values, scanning techniques, exposure time, system and scanner capabilities, and operator experience allows the sonographer to apply the ALARA principle with informed judgment and meet the definition of the ALARA principle.

The amount of acoustic output is up to the system operator. This decision must be based on the following factors: type of patient, type of exam, patient history, ease or difficulty of obtaining diagnostically useful information, and the potential localized heating of the patient due to scanner surface temperatures. The objective is to limit patient exposure to the lowest index reading for the shortest amount of time achieving acceptable diagnostic results.

A high index reading does not necessarily indicate the occurrence of a bioeffect; however, it must be taken seriously. It is your responsibility to make every effort to reduce the possible effects of a high index reading by limiting exposure time.

System controls (direct, indirect, and receiver) can be used to adjust the image quality and limit the acoustic intensity and are related to the techniques that an operator could use to implement ALARA.

Using System Controls to Implement ALARA

Direct Controls

The system has no direct control for output; therefore, the sonographer must control exposure time and scanning technique to implement the ALARA principle. To ensure that acoustic and thermal limits are not exceeded for all imaging modes, the Clarius Ultrasound Scanner is designed to automatically adjust output.

The system does not exceed a spatial peak temporal average intensity (I_{SPTA}) of 720 mW/cm^2 for all imaging modes. The system follows the Output Display Standard (IEC 60601-2-37) and falls within the Track 3 acoustic output limits.

Indirect Controls

Controls affecting imaging mode, freeze, and depth indirectly affect output. The imaging mode determines the nature of the ultrasound beam. Because freeze stops all ultrasound output but keeps the last image displayed on screen, you can use it to limit exposure time while studying an image and maintaining scanner position during a scan. Some controls, such as depth, show a rough correspondence with output, and may be used as a general means for indirectly reducing MI or TI.

Controls indirectly affecting intensity:

- Pulse repetition frequency: The higher the PRF, the more output pulses per second, increasing the temporal-average intensity.
- Focusing depth: Setting the scanner focus at the proper depth improves the resolution of that structure, without the need to increase intensity to see it better.
- Pulse length: Generally, the longer the pulse, the greater the temporal-average intensity value, which both raises the temperature in the tissue and slightly increases the likelihood for cavitation.
- Dwell time: Scanned modes, such as B-Mode imaging, distribute the energy over a large volume. In scanned modes (equipment keeps the beam stationary), the highest temperature is frequently at the surface where the ultrasound enters the body.

Receiver Controls

The receiver controls have no output effect. The following receiver controls affect images only:

- Gain or time-gain control (TGC)
- Dynamic range
- Post-processing

User Responsibility

The various operating modes and output levels mean that more responsibility must be assumed by the users. This is a point that is very often neglected: many assume that if an instrument is "FDA cleared," then there is no risk of bioeffects. This notion is inaccurate because changing the mode of operation or manipulating controls has the potential to cause major changes in output and hence in exposure. In other words, there is a shift in responsibility for patient safety from the manufacturer to the user.

To obtain good diagnostic information, a high return signal amplitude is needed. This can be attained either by higher output, similar to talking louder, or by higher receiver gain, similar to a hearing aid with a volume control. You must attain the best diagnostic information with minimal exposure to the patient. The threshold at which ultrasound energy causes bioeffects for each individual patient is unknown, therefore, you must get the most information at the lowest possible output level by adjusting the output intensity of the equipment.

As a general guideline:

1. Select the correct scanner frequency and application.
2. Start with a low output level.
3. Optimize the image by using focus, receiver gain, and other imaging controls.
4. If the image is still not diagnostically useful, increase output.

Additional considerations:

- Minimize scan time by performing only medically required ones.
- Use diagnostic ultrasounds efficiently and effectively, as all other medical tools.
- Compromising the exam's quality by rushing the exam could result in a poor exam, which could require follow-up exams, which then adds exposure time.
- Select the appropriate TI and MI range for the task at hand.
- Note that output is affected by frequency, focus, pulse length, and dwell time.

Output Display

The output display provides an indication of the potential for bioeffects that might be caused by the ultrasound energy being emitted. With this information, users can better control the diagnostic ultrasound equipment and examination to ensure that needed diagnostic information is obtained with a minimum of risk to the patient.

Display Standards

The system output display consists of the following exposure indices to indicate the potential thermal and mechanical effects:

- TI: This is continuously displayed over the range of 0.0 to maximum output, based on the scanner and application, in increments of 0.1, and consists of the following indices:
    - thermal index for soft tissue (TIS)
    - thermal index for bone (TIB)
    - thermal index for cranial bone (TIC)

    Keep output display indices to a minimum. Select a TI based on:

    - Approximate index for the application: TIS is used for imaging soft tissue, TIB for a focus at or near bone, and TIC for imaging through bone near the surface (for example, a cranial exam).
    - Mitigating factors that might create artificially high or low TI readings: Location of fluid or bone, or blood flow. For example, is there a highly attenuating tissue path so that the actual potential for local zone heating is less than the TI displays?
    - Scanned modes versus unscanned modes of operation that affect the TI: For scanned modes (such as B-Mode), heating tends to be near the surface. For unscanned modes (such as M-Mode or Doppler-type modes), the potential for heating tends to be deeper in the focal zone.
- MI: This is continuously displayed over the range of 0.0 to 1.9, in increments of 0.1.

TI Display

The TI indicates any conditions that may lead to temperature increase on the surface of the body, within the body tissue, or at the point of focus of the ultrasound beam on bone. TI informs you of a potential rise in temperature of body tissue, by estimating temperature increases in those body tissue with specific properties. The actual temperature increase is influenced by factors such as tissue type, vascularity, and mode of operation. Use the TI as a guide for implementing the ALARA principle.

You can choose to display one of the following types of TI indices:

- TIS: Indicates potential for heating within soft homogeneous tissue.
- TIB: Indicates potential for heating at or near the focus after the ultrasound beam has passed through soft tissue or fluid. For example, at or near second- or third-trimester fetal bone.
- TIC: Indicates potential for heating of bone at or near the surface. For example, cranial bone.

MI Display

The higher the MI value, the greater the likelihood of mechanical bioeffects occurring. The potential for mechanical bioeffects varies by peak rarefactional pressure and ultrasound frequency. The MI accounts for these two factors. There is no specific MI value that indicates the occurrence of a mechanical effect. Use the MI as a guide for implementing the ALARA principle.

When interpreting the MI, remember that it is intended to estimate the potential for mechanical bioeffects. The higher the index reading, the greater the potential. However, neither MI = 1 nor any other level indicates that a bioeffect is actually occurring. We should not be alarmed by the reading, but we should use it to implement the ALARA principle.

Display Accuracy

The MI and TI have a precision of 0.1 unit on the system.

Estimates of the MI and TI display accuracies are shown in the Acoustic Output Tables. The following factors are considered when estimating the accuracy of the displayed values:

- hardware variations

  Variability among scanners and systems is a result of piezoelectric crystal efficiencies, process-related impedance differences, and sensitive lens-focusing parameter variations.

- estimation algorithm accuracy

  Differences in system pulser voltage control and efficiencies are also contributors to variability. There are inherent uncertainties in the algorithms used to estimate acoustic output values over the range of possible system operating conditions and pulser voltages.

- measurement variability

  Inaccuracies in laboratory measurements can be caused by hydrophone calibration and performance, positioning, alignment, and digitization tolerances, and variability among test operators.

Controls Affecting Display Indices

Use system controls to change the TI and MI values.

Power Controls

Two real-time output values are on the display: TI and MI. These change as the system responds to power-control adjustments. TI and/or MI values will be displayed whenever the Index values exceeds 0.4 (dimensionless).

B-Mode Controls

- Focus:

  When the focal depth is near the natural focus of the scanner, the MI may be higher.

Other Control Effects

- B-Mode Depth:

  An increase in two-dimensional depth will automatically decrease the B-Mode frame rate, thereby decreasing the TI. The system may also automatically choose a deeper two-dimensional focal depth. A change of focal depth may change the MI. The MI displayed is that of the zone with the largest MI value.

- Application:

  Acoustic output defaults are set when you select an application. Factory defaults vary with scanner, application, and mode. Defaults have been chosen below the FDA limits for intended use.

- Imaging Mode Controls:

  When a new imaging mode is selected, both the TI and MI may change to default settings. Each mode has a corresponding pulse repetition frequency and maximum intensity point. In combined or simultaneous modes, the TI is the sum of the contribution from the modes enabled, and the displayed MI is the largest of the MI values associated with each mode and focal zone enabled. The system will return to the previously selected state if a mode is turned off and then reselected.

- Scanner:

  Each scanner type has unique specifications for contact area, beam shape, and center frequency. Selecting a scanner initializes its default settings, which varies by scanner, application, and selected mode. These defaults are set below the FDA limits for intended use.

Example of reducing output:

Imagine we are getting ready to do a liver scan. The first thing we need to do is select the appropriate scanner frequency. Next, we adjust the output intensity (or power) transmit setting. We check to make sure that it is positioned at the lowest possible setting to produce an image. We adjust the focus to the area of interest and then increase the receiver gain to produce a uniform representation of the tissue. If we can obtain a good image by increasing the gain, we can lower the output and continue to increase the gain. Only after making these adjustments and if tissue penetration or echo amplitude levels are inadequate should we increase the output to the next higher level.

Acoustics

The scanner is the most important factor in image quality. Optimal imaging cannot be obtained without the correct scanner. The system is optimized for use based on your scanner selection.

The system limits patient contact temperature to 43°C (109°F), and acoustic output values to their respective U.S. Food and Drug Administration limits. A power-protection circuit protects against over-current conditions. If the power monitor protection circuit senses an over-current condition, then the drive voltage to the scanner is shut off immediately, preventing overheating of the scanner surface and limiting acoustic output. Validation of the power protection circuit is done under normal system operation.

A temperature elevation of less than 1.5°C (2.7°F) is considered harmless to human tissue (including embryo or fetus). Temperatures in excess of this may cause harm, depending on the length of time maintained. A temperature elevation of 4°C (7.2°F), maintained for five minutes or more, is considered to be potentially hazardous to a fetus or embryo.

Acoustic Artifacts

An acoustic artifact is information, present or absent in an image, which does not properly indicate the structure or flow being imaged. Examples of acoustic artifacts that hinder proper interpretation:

- Added objects displayed as speckle, section thickness, reverberation, mirror image, comet tail, or ring down.
- Missing objects due to poor resolution.
- Incorrect object brightness due to shadowing or enhancement.
- Incorrect object location due to refraction, multi-path reflections, side lobes, grating lobes, speed error, or range ambiguity.
- Incorrect object size due to poor resolution, refraction, or speed error.
- Incorrect object shape due to poor resolution, refraction, or speed error.

Acoustic Output & Measurement

The acoustic output for this system has been measured and calculated in accordance with the “Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment” (Revision 3, AIUM, NEMA, 2004), the “Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment” (Revision 2, AIUM, NEMA, 2004), and the September 2008 FDA document “Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Scanners.”

In Situ, Derated, & Water Value Intensities

All intensity parameters are measured in water. Because water absorbs very little acoustic energy, these water measurements represent a worst-case value. Biological tissue does absorb acoustic energy. The true value of the intensity at any point depends on the amount and type

of tissue and the frequency of the ultrasound that passes through the tissue. The intensity value in the tissue, in situ, has been estimated by using the following formula:

In situ = Water [e-(0.23alf)] where:

Variable	Value
In Situ	In situ intensity value
Water	Water value intensity
e	2.7183
a	Attenuation factor
Tissue	a(dB/cm-MHz)
Amniotic Fluid	0.006
Brain	0.53
Heart	0.66
Kidney	0.79
Liver	0.43
Muscle	0.55
l	Skin line to measurement depth (cm)
f	Center frequency of the scanner/system/mode combination (MHz)

Because the ultrasonic path during an examination is likely to pass through varying lengths and types of tissue, it is difficult to estimate the true in situ intensity. An attenuation factor of 0.3 is used for general reporting purposes. Therefore, the in situ value which is commonly reported uses the formula:

In situ derated = Water [e-(0.069lf)]

Because this value is not the true in situ intensity, the term “derated” is used.

Mathematical derating of water-based measurements using the 0.3 dB/cm MHz coefficient may yield lower acoustic exposure values than would be measured in a homogenous 0.3 dB/ cm MHz tissue. This is true because nonlinearly propagating acoustic energy waveforms experience more distortion, saturation, and absorption in water than in tissue, where attenuation present all along the tissue path will dampen the buildup of nonlinear effects.

The maximum derated and the maximum water values do not always occur at the same operating conditions. Therefore, the reported maximum water and derated values may not be related by the in situ (derated) formula. For example: A multi-zone array scanner that has maximum water value intensities in its deepest zone may have its largest derated intensity in one of its shallowest focal zones.

Conclusions Regarding Tissue Models & Equipment Survey

Tissue models are necessary to estimate attenuation and acoustic exposure levels in situ from measurements of acoustic output made in water. Presently, available models may be limited in their accuracy because of varying tissue paths during diagnostic ultrasound exposures and uncertainties in acoustical properties of soft tissues. No single tissue model is adequate for predicting exposures in all situations from measurements made in water, and continued improvement and verification of these models is necessary for making exposure assessments for specific applications.

A homogeneous tissue model with an attenuation coefficient of 0.3 dB/cm MHz throughout the beam path is commonly used when estimating exposure levels. The model is conservative in that it overestimates the in situ acoustic exposure when the path between the scanner and the site of interest is composed entirely of soft tissue, because the attenuation coefficient of soft tissue is generally higher than 0.3 dB/cm MHz. When the path contains significant amounts of fluid, as in many first- and second-trimester pregnancies scanned transabdominally, this model may underestimate the in situ acoustical exposure. The amount of underestimation depends on each specific situation. For example, when the beam path is longer than 3 cm and the propagation medium is predominantly fluid (conditions that may exist during transabdominal OB scans), a more accurate value for the derating term is 0.1 dB/cm MHz.

Fixed-path tissue models, in which soft tissue thickness is held constant, sometimes are used to estimate in situ acoustical exposures when the beam path is longer than 3 cm and consists largely of fluid. When this model is used to estimate maximum exposure to the fetus during transabdominal scans, a value of 1 dB/cm MHz may be used during all trimesters.

The maximum acoustic output levels of diagnostic ultrasound scanners extend over a broad range of values:

- A survey of 1990-equipment models yielded MI values between 0.1 and 1 at their highest output settings. Maximum MI values of approximately 2 are known to occur for currently available equipment. Maximum MI values are similar for real-time B-Mode, M-mode, and PW Doppler.
- Computed estimates of upper limits to temperature elevations during transabdominal scans were obtained in a survey of 1988 and 1990 Doppler equipment. The vast majority of models yielded upper limits less than 1°C and 4°C (1.8°F and 7.2°F) for exposures of first-trimester fetal tissue and second-trimester fetal bone, respectively. The largest values obtained were approximately 1.5°C (2.7°F) for first-trimester fetal tissue and 7°C (12.6°F) for second-trimester fetal bone. Estimated maximum temperature elevations given here are for a “fixed-path” tissue model and are for scanners having I_{spta} (derated) values greater than 500 mW/cm^2. The temperature elevations for fetal bone and tissue were computed based on calculation procedures given in Sections 4.3.2.1 through 4.3.2.6 in “Bioeffects and Safety of Diagnostic Ultrasound” (AIUM Report, January 28, 1993).

Acoustic Measurement Precision & Uncertainty

All table entries have been obtained at the same operating conditions that give rise to the maximum index value in the first column of the tables. Measurement precision and

uncertainty for power, pressure, intensity, and center frequency are listed in the following tables.

Measurement precision on the following quantities is determined by making repeated measurements and stating the standard deviation as a percentage.

ACOUSTIC MEASUREMENT PRECISION

Quantity	Precision (Percentage Standard Deviation)
Pr is the underated peak rarefactional pressure measured in megapascals (MPa)	Pr: 5.4%
Wo is the ultrasonic power in milliwatts (mW)	6.2%
f_c is the center frequency in megahertz (MHz) (NEMA UD-2 definition)	<1%
PII.3 is the derated spatial-peak pulse intensity integral in joules per square centimeter (J/cm^2)	PII.3: 3.2%

ACOUSTIC MEASUREMENT UNCERTAINTY

Quantity	Measurement Uncertainty (Percentage, 95% Confidence Value)
Pr is the underated peak rarefactional pressure measured in megapascals (MPa)	Pr: ±11.3%
Wo is the ultrasonic power in milliwatts (mW)	±10%

Fire & Electrical Safety

Fire Safety

Always have fire extinguishers available for both electrical and non-electrical fires.

In the event of an electrical or chemical fire, use only extinguishers that are specifically labeled for such purposes. Using water or other liquids can cause fatal or other serious personal injury. To reduce the risk of electrical shock, try isolating the product, if safe to do so.

Using electrical products in an environment for which they were not designed to be used can lead to fire or explosion. Apply, observe, and enforce appropriate fire regulations for the type of medical area being used.

Electrical Safety

- To reduce electrical shock hazards, inspect the scanner face and housing before use. Discontinue use if the housing is damaged, or if the face is cracked, chipped, or torn.
- All patient-contact scanners not specifically indicated as defibrillation-proof must be removed from the patient before applying high-voltage defibrillation pulse.
- High-frequency electrical signals from an ultrasound can interfere with pacemaker operation. Be alert to this unlikely but potential hazard and stop using the system if you notice it is interfering with a pacemaker.
- Connecting accessories not supplied or approved by Clarius could result in electrical shock.
- Electrosurgical units (ESUs) and other scanners intentionally introduce RF electromagnetic fields (currents) into patients. Because imaging ultrasound frequencies are within the RF range, ultrasound scanner circuits are susceptible to RF interference.
- A burn hazard may result from a surgical equipment with a defect in the high-frequency surgical neutral electrode connection. Do not use scanners with high-frequency surgical equipment.
- Using accessories other than those specified for use with the Clarius Ultrasound Scanner may result in increased emissions of the system.

Electromagnetic Safety

The Clarius Scanner HD3 uses wireless technology to communicate with your smart device. Wireless communication can be affected by severe weather conditions and radio frequency interference. Such environments will not cause the safety of the Clarius Ultrasound Scanner to deteriorate, but the captured image may show signs of unwanted noise and/or artifacts. The technology used in the Clarius Ultrasound Scanner is designed to minimize these affects but may not eliminate them entirely.

Electromagnetic Compatibility

The Clarius Ultrasound Scanner has been manufactured with existing electromagnetic compatibility requirements and have been tested and found to comply with electromagnetic compatibility standards to provide reasonable protection against harmful interference in a typical medical installation.

Use of this system in the presence of an electromagnetic field can cause momentarily degraded image quality. If this occurs frequently, review the environment surrounding the system and identify possible sources of radiated emissions. These emissions could be caused by other electrical equipment from:

- The same or adjacent room.
- Portable or mobile RF communications equipment (such as cellular phones and pagers).
- Radio, TV, or microwave transmission equipment located nearby.

The scanner's built-in radio operates in the 2.4 GHz and 5 GHz bands, and supports:

- Bluetooth 4.1 as well as CSA2.
- IEEE Std 802.11a, 802.11b/g, and IEEE Std 802.11n data rates with 20 MHz or 40 MHz SISO and 20 MHz MIMO.

Caution:

- Using components and accessories not recommended by Clarius may result in increased emissions or decreased immunity of the system. Use only accessories and peripherals recommended by Clarius.
- EMC precautions for medical equipment must be followed according to the EMC information provided in that system's accompanying documents.
- In Canada, the device for operation in the band 5150–5250 MHz is only for indoor use to reduce the potential for harmful interference to co-channel mobile satellite systems.

Note: Settings for channel band selection of Clarius Ultrasound Scanner is managed by Clarius Mobile Health Corp. as per local wireless regulation. Channel band being selected can be found under the App "Status" page. Users need to ensure channel band usage is in compliance with indoor and outdoor band allowance as per local wireless regulation.

Electrostatic Discharge Precautions

Electrostatic discharge (ESD), or static shock, results from the flow of an electrical charge from a person or object of a higher charge to that of a lower charge. ESD is most prevalent in low-humidity environments, often caused by heating or air-conditioning.

To reduce ESD:

- Use anti-static spray on carpets, linoleum, and mats. Or use a ground wire connection between the system and the patient table or bed.

Electromagnetic Emissions

Ensure that the Clarius Ultrasound Scanner is used only in those operating environments indicated in the following table. Operating the system in an environment that does not meet these conditions may degrade system performance.

Declaration of Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment
RF emissions, CISPR 11	Group 1	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

DECLARATION OF ELECTROMAGNETIC EMISSIONS

Emissions Test	Compliance	Electromagnetic Environment
RF emissions, CISPR 11	Class B	The system is suitable for use in all establishments, except domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions, IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions, IEC 61000-3-3	Complies	

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Electromagnetic Immunity

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level
ESD EN/IEC 61000-4-2	+/-2kV, +/-4kV, +/-8kV contact +/-2kV, +/-4kV, +/-8kV, +/-15kV Air	+/-2kV, +/-4kV, +/-8kV contact +/-2kV, +/-4kV, +/-8kV, +/-15kV Air
Radiated, radio frequency electromagnetic field immunity (1 kHz 80% AM for ETSI 301 489-1 and -17, 2 Hz modulation for IEC 60601-1-2)* EN/IEC 61000-4-3	3 V/M 2 Hz modulation 80% AM at 1 kHz modulation	3 V/M 2 Hz modulation 80% AM at 1 kHz modulation
Electrical fast transient IEC 61000-4-4	+/-0.5kV, +/-1.0kV, +/-2.0kV	+/-0.5kV, +/-1.0kV, +/-2.0kV
Immunity to surge IEC 61000-4-5	0.5kV, 1.0kV differential mode	0.5kV, 1.0kV differential mode
Conducted radio frequency electromagnetic immunity test IEC 61000-4-6	3 V RMS outside the ISM band, 6 V RMS in the ISM band, 80% AM at 1 kHz	3 V RMS outside the ISM band, 6 V RMS in the ISM band, 80% AM at 1 kHz

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level
Power frequency magnetic field immunity test IEC 61000-4-8	30A/M	30A/M
Voltage dips/ interruptions IEC 61000-4-11	0% for 0.5 cycle @ 0º, 45º, 90º, 135º, 180º, 225º, 270º, 315º 0% for 1 cycle @ 0º 70% for 25/30 cycles (50/60 Hz) @ 0º 0% for 250/300 cycles @ 0º	0% for 0.5 cycle @ 0º, 45º, 90º, 135º, 180º, 225º, 270º, 315º 0% for 1 cycle @ 0º 70% for 25/30 cycles (50/60 Hz) @ 0º 0% for 250/300 cycles @ 0º

*For ETSI 301 489-1 and ETSI 301 489-17: Tested in transmit mode only, no idle mode exists for this product.

Electromagnetic Interference

The way an electromagnetic interference (EMI) from other equipment affects the Clarius Ultrasound Scanner depends on the system's operation mode, image control settings, and the type and level of electromagnetic phenomena. Electromagnetic phenomena may be intermittent, making it difficult to identify the source.

If you experience EMI, use caution if you continue using the system, or consider relocating your system.

The following table describes typical interferences seen in imaging systems. It is impossible to describe all manifestations of interference because it depends on many parameters of the transmitting equipment, for example, the type of modulation used by the signal carrier, the source type, and the transmitted level. It is also possible for the interference to degrade the imaging system's performance and become invisible on the image. If the diagnostic results are suspicious, confirm the diagnosis using other methods.

Imaging Mode	ESD[1]	RF[2]	Power Line[3]
B-Mode	Change of operating mode, system settings, or system reset. Brief flashes in the displayed or recorded image.	For sector imaging scanners, white radial bands or flashes in the center lines of the image. For linear imaging scanners, white vertical bands, sometimes more pronounced on the sides of the image.	White dots, dashes, or diagonal lines near the center of the image.

1. Electrostatic discharge caused by discharging of electric charge buildup on insulated surfaces or persons.
2. Radio frequency energy from RF transmitting equipment such as portable phones, hand-held radios, wireless devices, commercial radio and TV stations, and so on.
3. Conducted interference on power lines or connected cables caused by other equipment, such as switching power supplies, electrical controls, and natural phenomena such as lightning.

Separation Distance

Recommended Separation Distance

The following table shows recommended separation distances for the system to be kept away from any RF-transmitting equipment. To reduce the risk of interference, when using portable and mobile RF communications equipment, follow the recommended separation distance (calculated from the equation applicable to the frequency of the transmitter). Ensure that field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, are less than the compliance level in each frequency range as noted in the table.

Field strength is difficult to predict theoretically with accuracy if they come from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast. To assess the electromagnetic environment from fixed RF transmitters, consider conducting an electromagnetic site survey. If the measured field strength in the location in which the system is used exceeds the applicable RF compliance level in the table, observe the system to verify normal operation. If abnormal performance is observed, apply additional measures, such as reorienting or relocating the system.

At 80 MHz and 800 MHz, the higher frequency range applies.

The recommended separation distance guidelines in the following table may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

The table here provides guidance on conducted and radiated interference from portable and fixed RF transmitting equipment.

RECOMMENDED SEPARATION DISTANCES BY TRANSMITTER FREQUENCY

Rated Maximum Output Power of Transmitter (Watts)	150 kHz to 80 MHz	80 to 800 MHz	800 MHz to 2.5 GHz
0.01	0.35 m (13.8 in)	0.12 m (4.7 in)	0.23 m (9.1 in)
0.1	1.1 m (3.6 ft)	0.38 m (15 in)	0.73 m (28.7 in)
1	3.5 m (11.5 ft)	1.2 m (3.9 ft)	2.3 m (7.5 ft)
10	11 m (36.1 ft)	3.8 m (12.5 ft)	7.3 m (24 ft)
100	35 m (114.8 ft)	12 m (39.4 ft)	23 m (75.5 ft)

For example, if a portable transmitter has a maximum radiated power of 1 W and an operating frequency of 156 MHz, it can be operated at distances greater than 1.2 m (3.9 ft) from the system. Similarly, a 0.01 W Bluetooth wireless LAN smart device operating at 2.4 GHz should be placed no closer than 0.24 m (9.5 in) from any part of the system.

Avoiding Electromagnetic Interference

An ultrasound system is designed to receive signals at radio frequencies, making them susceptible to interference generated by RF energy sources. Other examples of interference are medical equipment, information technology products, and radio and television transmission towers.

To locate the source, investigate whether the problem resides with the system or the scanning environment:

- Is the interference intermittent or constant?
- Does the interference show up only with one scanner or with several scanners?
- Do two different scanners operating at the same frequency have the same problem?
- Is the interference present if the system is moved to a different location in the facility?
- Can the EMC coupling path be attenuated? For example, placement of a scanner or printer close to an ECG cable can increase electromagnetic interference. Moving the cable or other medical equipment away from the location of the scanner or printer can result in reduced electromagnetic interference.

If you find the interference's source, go to clarius.com/contact and contact Clarius.

References

6

Compliance Statement

Clarius products comply with international and national standards and laws. Users are responsible for ensuring that the chosen smart device and scanner are compliant with the law in the jurisdiction where the product is used. Clarius meets all regulatory standards listed in this chapter.

The Clarius Ultrasound Scanner

Product Classification

Classification:

- Device with scanners (internally powered ME equipment):
    - Health Canada: Class III
    - US FDA: Class II
    - EU: Class IIa
- Scanners: Type BF applied parts, IP67
- Charger HD3: IP00
- Ordinary Equipment/Continuous Operation
- Non-AP/APG

Note:

- Compliance assessment of Clarius Ultrasound Scanner HD3 has been conducted by a Notified Body. The device is CE-marked followed by the 4-digit identification number (NB xxxx).
- Clarius Power Fan HD3 and Clarius Charger HD3 (accessories of Clarius Ultrasound Scanner HD3) are self-certified medical devices and do not require the oversight of a Notified Body. The devices are CE-marked without the NB xxxx.

Product Serial Number

Clarius has assigned a unique serial number on each scanner to track quality control.

Clarius Scanner HD3s uses the format STRRYYMMzXXXX. We will use the serial number L7HD3012112A0004 as an example to explain how to interpret this.

ST

Stack type and scanner model. In our example, the stack type is “L7”. The scanner model “HD3” does not change.

RR

Two-digit assembly revision number. In our example, this is “01”.

YY

Two-digit year of manufacture. In our example, this is “21” meaning the year 2021.

MM

Two-digit month of manufacture. In our example, this is “12” meaning the month of December.

z

Alphabetical counter, from A to Z. In our example, this is “A”.

XXXX

Four-digit numerical counter. In our example, this is “0004” meaning the fourth scanner manufactured in this series.

System Specifications

The Clarius Ultrasound Scanner conforms to the following specifications:

- Gray shades: 256 in B-Mode
- Scan lines: Up to 1,024 scan lines

- Pressure, humidity, and temperature limits: These limits apply only to the Clarius Scanner HD3, not to the smart device. It is your responsibility to select a Clarius-compatible smart device that meets the needs of your clinical environment.

To reach an operating temperature of 20°C (68°F), the Clarius Scanner HD3 requires approximately 30 minutes to:

- Warm up from a storage temperature of-20°C (-4°F).
- Cool down from a storage temperature of 50°C (122°F).

Maximum scanner surface temperatures[1] are:

- C3 HD3 = 31.69°C (89.04°F)
- C7 HD3 = 23.83°C (74.89°F)
- EC7 HD3 = 20.86°C (69.55°F)
- L7 HD3 = 23.51°C (74.32°F)
- L15 HD3 = 23.09°C (73.56°F)
- L20 HD3 = 26.51°C (79.72°F)
- PA HD3 = 24.42°C (75.96°F)
- PAL HD3 = 26.76°C (80.168°F)

If the scanner reaches its maximum surface temperature, it automatically shuts down.

To limit surface heating in the event of a single fault condition, the EC7 HD3 scanners automatically shut down.

This icon, when blue, indicates that the scanner is cool. When this icon is red, it indicates that the scanner is warm.

For information on storage temperatures see ***Storing Scanners*** on page 30.

1. Maximum scanner surface temperature is measured on the scanner scanning surface (lens) according to IEC 60601-2-37 Simulated Use.

Environmental Specifications

SCANNERS C3 HD3, C7 HD3, EC7 HD3, L7 HD3, L15 HD3, L20 HD3, PA HD3, PAL HD3, & CLARIUS POWER FAN HD3

	Operating Limits	Transient Operating Conditions[1,2]	Storage & Transportation Limits
Temperature	0°C (32°F) to 40°C (104°F)	-20°C (-4°F) to 35°C (95°F)	-20°C (-4°F) to 50°C (122°F)
Humidity	15% to 95% RH	15% to 95% RH	0% to 95% RH
Pressure	620 hPa to 1060 hPa	n/a	n/a

1. The conditions under which the scanner can operate for at least 20 minutes immediately after being removed from an environment of 20°C (60°F), by combining the Clarius Power Fan HD3, B-Mode, and Eco Mode (extends scanner time at reduced frame rate).
2. Charging the Clarius Scanner HD3 through the Clarius Power Fan HD3 is not rated for transient operating conditions or for use in EMS environments.

CLARIUS CHARGER HD3

	Operating Limits	Transient Operating Conditions	Storage & Transportation Limits
Temperature	0°C (32°F) to 40°C (104°F)	n/a	-20°C (-4°F) to 50°C (122°F)
Humidity	15% to 95% RH	n/a	0% to 95% RH
Pressure	620 hPa to 1060 hPa	n/a	n/a

Scanner Specifications

Scanner	Clinical Usage	Field of View	Frequency Range
Clarius Scanner C3 HD3	fetal, abdominal, intra-operative, pediatric, cephalic (adult), musculo-skeletal (conventional), urology, gynecology, cardiac (adult, pediatric), peripheral vessel	73°	2 – 6 MHz
Clarius Scanner C7 HD3	fetal, abdominal, intra-operative, pediatric, small organ (thyroid, prostate, scrotum, breast), musculo-skeletal (conventional), urology, gynecology, cardiac (adult, pediatric), peripheral vessel	112°	3 – 10 MHz
Clarius Scanner EC7 HD3	fetal, abdominal, small organ, trans-rectal, trans-vaginal, gynecology, urology	164°	3 – 10 MHz
Clarius Scanner L7 HD3	ophthalmic, abdominal, intra-operative, pediatric, small organ (thyroid, prostate, scrotum, breast), musculo-skeletal (conventional, superficial), peripheral vessel, carotid	38 mm	4 – 13 MHz
Clarius Scanner L15 HD3	ophthalmic, abdominal, intra-operative, pediatric, small organ (thyroid, prostate, scrotum, breast), musculo-skeletal (conventional, superficial), peripheral vessel, carotid	50 mm	5 – 15 MHz
Clarius Scanner L20 HD3	ophthalmic, intra-operative, pediatric, small organ (thyroid, prostate, scrotum, breast), musculo-skeletal (conventional, superficial), peripheral vessel, carotid	25 mm	8 – 20 MHz
Clarius Scanner PA HD3	fetal, abdominal, intra-operative, pediatric, cephalic (neonatal, adult), cardiac (adult, pediatric)	90°	1 – 5 MHz
Clarius Scanner PAL HD3 (Linear Array)	ophthalmic, abdominal, intra-operative, pediatric, small organ (thyroid, prostate, scrotum, breast), musculoskeletal (conventional, superficial), peripheral vessel, carotid	29 mm	5 – 15 MHz
Clarius Scanner PAL HD3 (Phased Array)	fetal, abdominal, intra-operative, pediatric, cardiac (adult, pediatric)	90°	1 – 5 MHz

Input: 5 VDC, 3.2 A

Battery: 3.6 VDC, 3.5Ah

Standards

Chemical

REACH 02006R1907-20181017 - REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency

The Clarius Ultrasound Scanner meets the minimum requirements for compliance with the European Union's Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU and its amendments.

Electrical Safety

Reference No.	Year	Title
IEC 61157	2013	Standard means for the reporting of the acoustic output of medical diagnostic ultrasonic equipment
IEC 62133	2012	Secondary cells and batteries containing alkaline or other non-acid electrolyte - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
ST/SG/AC.10/11/Rev.5	2009 UN38.3	Transport of Dangerous Goods.

Labeling

ISO 60417:2014 - Graphical symbols for use on equipment. See the Symbols Glossary in this User Manual.

Quality

Performance

Reference No.	Year	Title
AIUM/NEMA UD 2-2004	2009	NEMA Standards Publication UD 2-2004 (R2009) Acoustic Output Measurement Standard For Diagnostic Ultrasound Equipment, Revision 3. (Radiology)
AIUM/NEMA UD 3-2004	2009	NEMA Standards Publication UD 3-2004 (R2009) Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
ANSI/AAMI ES60601-1	2005/(R)2012 A1:2012 C1:2009(R)2012 A2:2010(R)2012	Medical electrical equipment-Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)

Reference No.	Year	Title
ANSI/AAMI/IEC 62304	2006 A1:2015	Medical device software – Software life cycle processes.
CAN/CSA-C22.2 No. 60601-1-6:11	2011	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (Adopted IEC 60601-1-6:2010, third edition, 2010-01)
CAN/CSA-C22.2 No. 60601-1:14	2014	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (Adopted IEC 60601-1:2005, third edition, 2005-12, including amendment 1:2012, with Canadian deviations)
IEC 60601-1	2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2	2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Capability - Requirements and tests
IEC 60601-1-6	2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
IEC 60601-1-12	2014	Medical electrical equipment - Part 1-12: Requirements for Medical Electrical Equipment and Medical Electrical Systems Intended For Use in the Emergency Medical Services Environment
IEC 60601-2-37+ AMD1	2015	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

Risk, Product Specification, Design Review, & Verification/Validation

Reference No.	Year	Title
21 CFR 11	2014	Part 11 Electronics Records and Electronic Signatures
21 CFR 801	2014	Part 801 Labeling
21 CFR 820	2014	Part 820 Quality System Regulation
21 CFR 821	2014	Part 821 Medical Device Tracking Requirements
21 CFR 822	2014	Part 822 Postmarket Surveillance
21 CFR 830	2014	Part 830 Unique Device Identification
CMDR SOR/98-282	2021	Canadian Medical Devices Regulations (CMDR): • Safety and Effectiveness Requirements (Sections 10-20) • Labeling Requirements (Sections 21-23)
EN ISO 13485 ISO 13485	2016 2016	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
EN ISO 14971 ISO 14971	2019 2019	Medical Devices - Application of Risk Management to Medical Devices

Reference No.	Year	Title
IEC 60529	2013	Degrees of protection provided by enclosures (IP Code)
IEC 62304	2006 A1:2015	Medical device software - Software life cycle processes
IEC 62366	2014	Medical devices - Application of usability engineering to medical devices
IEC/TR 80002-3	2014	Medical device software - Part 3: Process reference model of medical device software life cycle processes
IEEE 11073- 20601a	2010	Health informatics - Personal health device communication. Part 20601: Application profile - Optimized Exchange Protocols
ISO 10993-1	2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 15223-1	2021	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied
ISO 20417	2021	Information supplied by the manufacturer of medical devices
EU MDR	2017	European Medical Device Regulation 2017/745

Security & Privacy

IEC TR 80002-3:2014 - Medical device software - Part 3: Process reference model of medical device software life cycle processes.

Wireless

U.S.

- FCC Part 15/C 15.247; Part 15/E 15.407

Canada

- ISED RSS-Gen; RSS-247; RSS-210

Europe

- ETSI EN 300 328:V2.1.1- Electromagnetic compatibility and Radio spectrum Matters (ERM)
- ETSI EN 301 489-1:V2.1.1- Electromagnetic compatibility and Radio spectrum Matters (ERM)
- ETSI EN 301 489-17:V3.1.1- Electromagnetic compatibility and Radio spectrum Matters (ERM)

Cleaners & Disinfectants

Cleaner & Disinfectant Usage

The following table lists the cleaners and disinfectants compatible with your Clarius Ultrasound Scanner and accessories. The products listed in the following table are chemically compatible and have been tested for efficacy.

Product	Qualified Use[1]	Clarius Scanner HD3	Clarius Power Fan HD3	Clarius Charger HD3	Clarius Micro USB Cable
Accel® PREVention™ Wipes	LLD, ILD	✓	✓	✓	✓
CaviWipes	LLD, ILD	✓	✓	✓	✓
CIDEX® OPA	HLD	✓			
McKesson OPA/ 28 High-Level Disinfectant Solution	HLD	✓			
MetriCide™ OPA Plus High-Level Disinfectant Solution	HLD	✓			
Sani-Cloth® AF3 Germicidal Disposable Wipe	LLD, ILD	✓	✓	✓	✓
Sani-Cloth® Plus Germicidal Disposable Cloth	LLD, ILD	✓	✓	✓	✓
Tristel Trio Wipes System	HLD[2]	✓	✓		✓

1. CL = Cleaner, HLD = High-level disinfectant, ILD = Intermediate-level disinfectant, LLD = Low-level disinfectant, S = Sterilant
2. EU only.

You may also use products not specifically listed in the compatibility table but with similar active ingredients, as indicated in this list, and marketed for medical use.

Because of the large number of available cleaners and disinfectants, it is impossible to have an all-inclusive list. If you are unsure of the suitability of a particular product, go to clarius.com/contact and contact Clarius for more information.

Cleaner & Disinfectant Details

Solution	Origin[1]	Usage	Active Ingredients
Accel® PREVention™ Wipes	CA	Wipe	Hydrogen Peroxide
CaviWipes	US	Wipe	Alcohol, Quaternary Ammonia
CIDEX® OPA	US	Soak	Ortho-phthalaldehyde
McKesson OPA/28 High-Level Disinfectant Solution	US	Soak	Ortho-phthalaldehyde
MetriCide™ OPA Plus High-Level Disinfectant Solution	US	Soak	Ortho-phthalaldehyde
Sani-Cloth® AF3 Germicidal Disposable Wipe	US	Wipe	n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chlorides 0.14% n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chlorides 0.14%
Sani-Cloth® Plus Germicidal Disposable Cloth	US	Wipe	Alcohol, Quaternary Ammonia
Tristel Trio Wipes System	UK	Pre-clean wipe, Sporicidal wipe, Rinse wipe	Enzymes, Chlorine Dioxide

1. AU = Australia, CA = Canada, US = United States, UK = United Kingdom

Glossary of Terms

For ultrasound terms, refer to Recommended Ultrasound Terminology, Third Edition, published by AIUM.

Known Issues

For a list of currently known issues with the Clarius Ultrasound Scanner, see support.clarius.com/hc/en-us/articles/360019807731.

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Measurement Accuracy Tables

The Clarius Ultrasound Scanner can be used to make measurements on ultrasound images. These measurements can then be used with other clinical data to make a diagnosis.

Never make a diagnosis based solely on measurements. When quantifying data, consider other factors. The accuracy of each measurement is highly dependent on image quality, which in turn is highly dependent on system design, operator scanning technique, familiarity with system controls, and patient echogenicity.

You are responsible for image quality and diagnosis. Ensure that the data used for inspection and diagnosis is sufficient, both spatially and temporally, for the measurement method.

Inaccurate measurements or misinterpretation of results taken from an exam may lead to misdiagnosis.

Clarius Scanner C3 HD3

Clarius Scanner C3 HD3: B-Mode

Measurement	Tolerance	Range
Axial Distance	≤ ± 2%	0 – 30.5 cm
Lateral Distance	≤ ± 2%	0 – 30.5 cm

Clarius Scanner C3 HD3: M-Mode

Measurement	Tolerance	Range
Distance	≤ ± 2%	0 – 30.5 cm
Time	≤ ± 2%	minimum = 0 ms maximum = variable[1]
Heart Rate	≤ ± 2%	minimum = ≤ 1 beat maximum = variable[1]

1. Range depends on the viewing device used and the amount of spectrum that can fit on the device's screen.

Clarius Scanner C3 HD3: PW-Mode

Measurement	Tolerance	Range
Velocity	≤ ± 2%	0 – 369.6 cm/s
Time	≤ ± 2%	minimum = 0 ms maximum = variable[1]
Heart Rate	≤ ± 2%	minimum = ≤ 1 beat maximum = variable[1]

1. Range depends on the viewing device used and the amount of spectrum that can fit on the device's screen.

Clarius Scanner C3 HD3: Doppler Sensitivity

Sensitivity	Depth (cm)	Flow (ml/sec)
PW Doppler flow sensitivity at depth	5.0	0.1
CFI Doppler flow sensitivity at depth	5.0	0.1
PDI Doppler flow sensitivity at depth	5.0	0.1
PW Doppler depth sensitivity	9.0	–
CFI Doppler depth sensitivity	9.0	–
PDI Doppler depth sensitivity	9.0	–

Clarius Scanner C7 HD3

Clarius Scanner C7 HD3: B-Mode

Measurement	Tolerance	Range
Axial Distance	≤ ± 2%	0 – 18.0 cm
Lateral Distance	≤ ± 2%	0 – 18.0 cm

Clarius Scanner C7 HD3: M-Mode

Measurement	Tolerance	Range
Distance	≤ ± 2%	0 – 18.0 cm
Time	≤ ± 2%	minimum = 0 ms maximum = variable[1]
Heart Rate	≤ ± 2%	minimum = ≤ 1 beat maximum = variable[1]

1. Range depends on the viewing device used and the amount of spectrum that can fit on the device's screen.

Clarius Scanner C7 HD3: PW-Mode

Measurement	Tolerance	Range
Velocity	≤ ± 2%	0 – 269.5 cm/s
Time	≤ ± 2%	minimum = 0 ms maximum = variable[1]
Heart Rate	≤ ± 2%	minimum = ≤ 1 beat maximum = variable[1]

1. Range depends on the viewing device used and the amount of spectrum that can fit on the device's screen.

Clarius Scanner C7 HD3: Doppler Sensitivity

Sensitivity	Depth (cm)	Flow (ml/sec)
PW Doppler flow sensitivity at depth	5.0	0.1
CFI Doppler flow sensitivity at depth	5.0	0.1
PDI Doppler flow sensitivity at depth	5.0	0.1
PW Doppler depth sensitivity	8.8	–
CFI Doppler depth sensitivity	8.4	–
PDI Doppler depth sensitivity	7.5	–

Clarius Scanner EC7 HD3

Clarius Scanner EC7 HD3: B-Mode

Measurement	Tolerance	Range
Axial Distance	≤ ± 2%	0 – 15.0 cm
Lateral Distance	≤ ± 2%	0 – 15.0 cm

Clarius Scanner EC7 HD3: M-Mode

Measurement	Tolerance	Range
Distance	≤ ± 2%	0 – 15.0 cm
Time	≤ ± 2%	minimum = 0 ms maximum = variable[1]
Heart Rate	≤ ± 2%	minimum = ≤ 1 beat maximum = variable[1]

1. Range depends on the viewing device used and the amount of spectrum that can fit on the device's screen.

Clarius Scanner EC7 HD3: PW-Mode

Measurement	Tolerance	Range
Velocity	≤ ± 2%	0 – 107.8 cm/s
Time	≤ ± 2%	minimum = 0 ms maximum = variable[1]
Heart Rate	≤ ± 2%	minimum = ≤ 1 beat maximum = variable[1]

1. Range depends on the viewing device used and the amount of spectrum that can fit on the device's screen.

Clarius Scanner EC7 HD3: Doppler Sensitivity

Sensitivity	Depth (cm)	Flow (ml/sec)
PW Doppler flow sensitivity at depth	5.0	0.1
CFI Doppler flow sensitivity at depth	5.0	0.1
PDI Doppler flow sensitivity at depth	5.0	0.1
PW Doppler depth sensitivity	7.6	–
CFI Doppler depth sensitivity	6.5	–
PDI Doppler depth sensitivity	5.9	–

Clarius Scanner L7 HD3

Clarius Scanner L7 HD3: B-Mode

Measurement	Tolerance	Range
Axial Distance	≤ ± 2%	0 – 15.0 cm
Lateral Distance	≤ ± 2%	0 – 15.0 cm

Clarius Scanner L7 HD3: M-Mode

Measurement	Tolerance	Range
Distance	≤ ± 2%	0 – 15.0 cm
Time	≤ ± 2%	minimum = 0 ms maximum = variable[1]
Heart Rate	≤ ± 2%	minimum = ≤ 1 beat maximum = variable[1]

1. Range depends on the viewing device used and the amount of spectrum that can fit on the device's screen.

Clarius Scanner L7 HD3: PW-Mode

Measurement	Tolerance	Range
Velocity	≤ ± 2%	0 – 246.4 cm/s
Time	≤ ± 2%	minimum = 0 ms maximum = variable[1]
Heart Rate	≤ ± 2%	minimum = ≤ 1 beat maximum = variable[1]

1. Range depends on the viewing device used and the amount of spectrum that can fit on the device's screen.

Clarius Scanner L7 HD3: Doppler Sensitivity

Sensitivity	Depth (cm)	Flow (ml/sec)
PW Doppler flow sensitivity at depth	5.0	0.1
CFI Doppler flow sensitivity at depth	5.0	0.1
PDI Doppler flow sensitivity at depth	5.0	0.1
PW Doppler depth sensitivity	8.0	–
CFI Doppler depth sensitivity	7.3	–
PDI Doppler depth sensitivity	6.5	–

Clarius Scanner L15 HD3

Clarius Scanner L15 HD3: B-Mode

Measurement	Tolerance	Range
Axial Distance	≤ ± 2%	0 – 7.0 cm
Lateral Distance	≤ ± 2%	0 – 7.0 cm

Clarius Scanner L15 HD3: M-Mode

Measurement	Tolerance	Range
Distance	≤ ± 2%	0 – 7.0 cm
Time	≤ ± 2%	minimum = 0 ms maximum = variable[1]
Heart Rate	≤ ± 2%	minimum = ≤ 1 beat maximum = variable[1]

1. Range depends on the viewing device used and the amount of spectrum that can fit on the device's screen.

Clarius Scanner L15 HD3: PW-Mode

Measurement	Tolerance	Range
Velocity	≤ ± 2%	0 – 176.0 cm/s
Time	≤ ± 2%	minimum = 0 ms maximum = variable[1]
Heart Rate	≤ ± 2%	minimum = ≤ 1 beat maximum = variable[1]

1. Range depends on the viewing device used and the amount of spectrum that can fit on the device's screen.

Clarius Scanner L15 HD3: Doppler Sensitivity

Sensitivity	Depth (cm)	Flow (ml/sec)
PW Doppler flow sensitivity at depth	5.0	0.1
CFI Doppler flow sensitivity at depth	5.0	0.1
PDI Doppler flow sensitivity at depth	5.0	0.1
PW Doppler depth sensitivity	5.9	–
CFI Doppler depth sensitivity	4.6	–
PDI Doppler depth sensitivity	6.1	–

Clarius Scanner L20 HD3

Clarius Scanner L20 HD3: B-Mode

Measurement	Tolerance	Range
Axial Distance	≤ ± 2%	0 – 6.0 cm
Lateral Distance	≤ ± 2%	0 – 6.0 cm

Clarius Scanner L20 HD3: M-Mode

Measurement	Tolerance	Range
Distance	≤ ± 2%	0 – 4.0 cm
Time	≤ ± 2%	minimum = 0 ms maximum = variable[1]
Heart Rate	≤ ± 2%	minimum = ≤ 1 beat maximum = variable[1]

1. Range depends on the viewing device used and the amount of spectrum that can fit on the device's screen.

Clarius Scanner L20 HD3: PW-Mode

Measurement	Tolerance	Range
Velocity	≤ ± 2%	0 – 77.0 cm/s
Time	≤ ± 2%	minimum = 0 ms maximum = variable[1]
Heart Rate	≤ ± 2%	minimum = ≤ 1 beat maximum = variable[1]

1. Range depends on the viewing device used and the amount of spectrum that can fit on the device's screen.

Clarius Scanner L20 HD3: Doppler Sensitivity

Sensitivity	Depth (cm)	Flow (ml/sec)
PW Doppler flow sensitivity at depth	2.0	0.1
CFI Doppler flow sensitivity at depth	2.0	0.1
PDI Doppler flow sensitivity at depth	2.0	0.1
PW Doppler depth sensitivity	1.9	–
CFI Doppler depth sensitivity	1.9	–
PDI Doppler depth sensitivity	2.0	–

Clarius Scanner PA HD3

Clarius Scanner PA HD3: B-Mode

Measurement	Tolerance	Range
Axial Distance	≤ ± 2%	0 – 30.5 cm
Lateral Distance	≤ ± 5%	0 – 30.5 cm

Clarius Scanner PA HD3: M-Mode

Measurement	Tolerance	Range
Distance	≤ ± 2%	0 – 30.5 cm
Time	≤ ± 2%	minimum = 0 ms maximum = variable[1]
Heart Rate	≤ ± 2%	minimum = ≤ 1 beat maximum = variable[1]

1. Range depends on the viewing device used and the amount of spectrum that can fit on the device's screen.

Clarius Scanner PA HD3: PW-Mode

Measurement	Tolerance	Range
Velocity	≤ ± 2%	0 – 653.3 cm/s
Time	≤ ± 2%	minimum = 0 ms maximum = variable[1]
Heart Rate	≤ ± 2%	minimum = ≤ 1 beat maximum = variable[1]

1. Range depends on the viewing device used and the amount of spectrum that can fit on the device's screen.

Clarius Scanner PA HD3: Doppler Sensitivity

Sensitivity	Depth (cm)	Flow (ml/sec)
PW Doppler flow sensitivity at depth	5.0	0.1
CFI Doppler flow sensitivity at depth	5.0	0.1
PDI Doppler flow sensitivity at depth	5.0	0.1
PW Doppler depth sensitivity	9.4	–
CFI Doppler depth sensitivity	9.7	–
PDI Doppler depth sensitivity	10.2	–

Clarius Scanner PAL HD3 (Linear Array)

Clarius Scanner PAL HD3: B-Mode, Linear Array

Measurement	Tolerance	Range
Axial Distance	≤ ± 2%	0 – 7.0 cm
Lateral Distance	≤ ± 2%	0 – 7.0 cm

Clarius Scanner PAL HD3: M-Mode, Linear Array

Measurement	Tolerance	Range
Distance	≤ ± 2%	0 – 7.0 cm
Time	≤ ± 2%	minimum = 0 ms maximum = variable[1]
Heart Rate	≤ ± 2%	minimum = ≤ 1 beat maximum = variable[1]

1. Range depends on the viewing device used and the amount of spectrum that can fit on the device's screen.

Clarius Scanner PAL HD3: PW-Mode, Linear Array

Measurement	Tolerance	Range
Velocity	≤ ± 2%	0 – 176.0 cm/s
Time	≤ ± 2%	minimum = 0 ms maximum = variable[1]
Heart Rate	≤ ± 2%	minimum = ≤ 1 beat maximum = variable[1]

1. Range depends on the viewing device used and the amount of spectrum that can fit on the device's screen.

Clarius Scanner PAL HD3: Doppler Sensitivity, Linear Array

Sensitivity	Depth (cm)	Flow (ml/sec)
PW Doppler flow sensitivity at depth	5.0	0.1
CFI Doppler flow sensitivity at depth	5.0	0.1
PDI Doppler flow sensitivity at depth	5.0	0.1
PW Doppler depth sensitivity	6.9	–
CFI Doppler depth sensitivity	6.8	–
PDI Doppler depth sensitivity	6.2	–

Clarius Scanner PAL HD3 (Phased Array)

Clarius Scanner PAL HD3: B-Mode, Phased Array

Measurement	Tolerance	Range
Axial Distance	≤ ± 2%	0 – 30.5 cm
Lateral Distance	≤ ± 5%	0 – 30.5 cm

Clarius Scanner PAL HD3: M-Mode, Phased Array

Measurement	Tolerance	Range
Distance	≤ ± 2%	0 – 30.5 cm
Time	≤ ± 2%	minimum = 0 ms maximum = variable[1]
Heart Rate	≤ ± 2%	minimum = ≤ 1 beat maximum = variable[1]

1. Range depends on the viewing device used and the amount of spectrum that can fit on the device's screen.

Clarius Scanner PAL HD3: PW-Mode, Phased Array

Measurement	Tolerance	Range
Velocity	≤ ± 2%	0 – 653.3 cm/s
Time	≤ ± 2%	minimum = 0 ms maximum = variable[1]
Heart Rate	≤ ± 2%	minimum = ≤ 1 beat maximum = variable[1]

1. Range depends on the viewing device used and the amount of spectrum that can fit on the device's screen.

Clarius Scanner PAL HD3: Doppler Sensitivity, Phased Array

Sensitivity	Depth (cm)	Flow (ml/sec)
PW Doppler flow sensitivity at depth	5.0	0.1
CFI Doppler flow sensitivity at depth	5.0	0.1
PDI Doppler flow sensitivity at depth	5.0	0.1
PW Doppler depth sensitivity	11.5	–
CFI Doppler depth sensitivity	13.1	–
PDI Doppler depth sensitivity	12.7	–

Acoustic Output Tables

Clarius Scanner C3 HD3: B-Mode

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.682	0.190		0.306		(a)
Index Component Value				0.190	0.190	0.306	0.190	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	1.28					
	P	(mW)		21.9		21.9		#
	P_{1x1}	(mW)		11.4		11.4		
	z_s	(cm)			2.70			
	z_b	(cm)					2.70	
	z_{MI}	(cm)	2.70					
	$Z_{pii,a}$	(cm)	2.70					
	f_{awf}	(MHz)	3.51	3.51		3.51		#
Other Information	prr	(Hz)	6144					
	srr	(Hz)	32.0					
	n_{pps}		2					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	82.9					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	5.19					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	9.98					
	p_r at Z_{pii}	(MPa)	1.77					
Operating Control Conditions	Control 1		✔	✔	✔	✔	✔	
	Control 2							
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.

Control 1: Exam Type: Abdomen; Depth: 3.9 cm; Mode: B

Clarius Scanner C3 HD3: Color Doppler Mode

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			1.04	0.409		0.669		(a)
Index Component Value				0.409	0.409	0.669	0.409	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	1.94					
	P	(mW)		47.7		47.7		#
	P_{1x1}	(mW)		24.9		24.9		
	z_s	(cm)			2.70			
	z_b	(cm)					2.70	
	z_{MI}	(cm)	2.70					
	$Z_{pii,a}$	(cm)	2.70					
	f_{awf}	(MHz)	3.46	3.46		3.46		#
Other Information	prr	(Hz)	2560					
	srr	(Hz)	32.0					
	n_{pps}		10					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	167					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	18.2					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	34.6					
	p_r at Z_{pii}	(MPa)	2.68					
Operating Control Conditions	Control 1		✔	✔	✔	✔	✔	
	Control 2							
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.

Control 1: Exam Type: Cardiac; Depth: 5.2 cm; Mode: CD

Clarius Scanner C3 HD3: M-Mode

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.682	0.012		0.027		(a)
Index Component Value				0.012	0.006	0.010	0.027	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	1.28					
	P	(mW)		0.711		0.711		#
	P_{1x1}	(mW)		0.711		0.711		
	z_s	(cm)			2.60			
	z_b	(cm)					2.67	
	z_{MI}	(cm)	2.60					
	$Z_{pii,a}$	(cm)	2.60					
	f_{awf}	(MHz)	3.51	3.51		3.51		#
Other Information	prr	(Hz)	200					
	srr	(Hz)	—					
	n_{pps}		1					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	82.9					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	5.34					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	10.3					
	p_r at Z_{pii}	(MPa)	1.77					
Operating Control Conditions	Control 1		✔	✔	✔	✔	✔	
	Control 2							
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.
— Not applicable for this scanner or mode.

Control 1: Exam Type: Abdomen; Depth: 3.9 cm; Mode: M

Clarius Scanner C3 HD3: PW Doppler Mode

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.734	0.231		0.604		(a)
Index Component Value				0.231	0.096	0.268	0.604	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	1.17					
	P	(mW)		19.1		19.1		#
	P_{1x1}	(mW)		19.1		19.1		
	z_s	(cm)			2.60			
	z_b	(cm)					4.53	
	z_{MI}	(cm)	2.60					
	$Z_{pii,a}$	(cm)	2.60					
	f_{awf}	(MHz)	2.54	2.54		2.54		#
Other Information	prr	(Hz)	1000					
	srr	(Hz)	—					
	n_{pps}		1					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	70.2					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	104					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	252					
	p_r at Z_{pii}	(MPa)	1.82					
Operating Control Conditions	Control 1		✔	✔	✔	✔	✔	
	Control 2							
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.
— Not applicable for this scanner or mode.

Control 1: Exam Type: Cardiac; Gate Depth: 4.5 cm; Mode: PWD

Clarius Scanner C7 HD3: B-Mode

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			1.10	0.137		0.211		(a)
Index Component Value				0.137	0.137	0.211	0.137	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	2.44					
	P	(mW)		7.63		7.63		#
	P_{1x1}	(mW)		5.81		5.81		
	z_s	(cm)			1.90			
	z_b	(cm)					1.90	
	z_{MI}	(cm)	1.90					
	$Z_{pii,a}$	(cm)	1.90					
	f_{awf}	(MHz)	4.94	4.94		4.94		#
Other Information	prr	(Hz)	4800					
	srr	(Hz)	25.0					
	n_{pps}		2					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	271					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	13.9					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	26.5					
	p_r at Z_{pii}	(MPa)	3.37					
Operating Control Conditions	Control 1		✔	✔	✔	✔	✔	
	Control 2							
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.

Control 1: Exam Type: Abdomen; Depth: 4 cm; Mode: B

Clarius Scanner C7 HD3: Color Doppler Mode

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			1.12	0.615		1.16		(a)
Index Component Value				0.615	0.615	1.16	0.615	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	2.27					
	P	(mW)		41.8		41.8		#
	P_{1x1}	(mW)		31.8		31.8		
	z_s	(cm)			1.50			
	z_b	(cm)					1.50	
	z_{MI}	(cm)	1.50					
	$Z_{pii,a}$	(cm)	1.50					
	f_{awf}	(MHz)	4.09	4.06		4.06		#
Other Information	prr	(Hz)	6300					
	srr	(Hz)	300					
	n_{pps}		10					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	251					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	191					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	291					
	p_r at Z_{pii}	(MPa)	2.81					
Operating Control Conditions	Control 1		✔					
	Control 2			✔	✔	✔	✔	
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.

Control 1: Exam Type: Cardiac; Depth: 3 cm; Mode: CD
Control 2: Exam Type: Cardiac; Depth: 7.8 cm; Mode: CD

Clarius Scanner C7 HD3: M-Mode

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			1.10	0.008		0.038		(a)
Index Component Value				0.008	0.004	0.009	0.038	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	2.44					
	P	(mW)		0.319		0.319		#
	P_{1x1}	(mW)		0.319		0.319		
	z_s	(cm)			1.90			
	z_b	(cm)					1.90	
	z_{MI}	(cm)	1.90					
	$Z_{pii,a}$	(cm)	1.90					
	f_{awf}	(MHz)	4.94	4.94		4.94		#
Other Information	prr	(Hz)	200					
	srr	(Hz)	—					
	n_{pps}		1					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	271					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	25.3					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	48.3					
	p_r at Z_{pii}	(MPa)	3.37					
Operating Control Conditions	Control 1		✔	✔	✔	✔	✔	
	Control 2							
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.
— Not applicable for this scanner or mode.

Control 1: Exam Type: Abdomen; Depth: 4 cm; Mode: M

Clarius Scanner C7 HD3: PW Doppler Mode

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.814	0.284		1.20		(a)
Index Component Value				0.284	0.153	0.391	1.20	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	1.82					
	P	(mW)		12.0		12.0		#
	P_{1x1}	(mW)		12.0		12.0		
	z_s	(cm)			1.80			
	z_b	(cm)					1.60	
	z_{MI}	(cm)	1.80					
	$Z_{pii,a}$	(cm)	1.80					
	f_{awf}	(MHz)	4.98	4.98		4.98		#
Other Information	prr	(Hz)	3000					
	srr	(Hz)	—					
	n_{pps}		1					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	232					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	486					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	902					
	p_r at Z_{pii}	(MPa)	2.48					
Operating Control Conditions	Control 1		✔	✔	✔	✔	✔	
	Control 2							
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.
— Not applicable for this scanner or mode.

Control 1: Exam Type: Cardiac; Gate Depth: 1.8 cm; Mode: PWD

Clarius Scanner EC7 HD3: B-Mode

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.729	0.069		0.076		(a)
Index Component Value				0.069	0.069	0.076	0.069	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	1.79					
	P	(mW)		2.39		2.39		#
	P_{1x1}	(mW)		2.39		2.39		
	z_s	(cm)			1.07			
	z_b	(cm)					1.07	
	z_{MI}	(cm)	1.07					
	$Z_{pii,a}$	(cm)	1.07					
	f_{awf}	(MHz)	6.05	6.05		6.05		#
Other Information	prr	(Hz)	4800					
	srr	(Hz)	25.0					
	n_{pps}		2					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	107					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	2.58					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	4.03					
	p_r at Z_{pii}	(MPa)	2.24					
Operating Control Conditions	Control 1		✔	✔	✔	✔	✔	
	Control 2							
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.

Control 1: Exam Type: Pelvic; Depth: 5 cm; Mode: B

Clarius Scanner EC7 HD3: Color Doppler Mode

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.920	0.492		0.647		(a)
Index Component Value				0.492	0.492	0.647	0.492	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	2.07					
	P	(mW)		20.2		20.2		#
	P_{1x1}	(mW)		20.2		20.2		
	z_s	(cm)			1.10			
	z_b	(cm)					1.10	
	z_{MI}	(cm)	0.900					
	$Z_{pii,a}$	(cm)	0.900					
	f_{awf}	(MHz)	5.04	5.11		5.11		#
Other Information	prr	(Hz)	5400					
	srr	(Hz)	300					
	n_{pps}		10					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	163					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	67.2					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	92.4					
	p_r at Z_{pii}	(MPa)	2.42					
Operating Control Conditions	Control 1		✔					
	Control 2			✔	✔	✔	✔	
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.

Control 1: Exam Type: Pelvic; Depth: 3 cm; Mode: CD

Control 2: Exam Type: Pelvic; Depth: 3 cm; Mode: CD

Clarius Scanner EC7 HD3: M-Mode

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.729	0.003		0.011		(a)
Index Component Value				0.003	0.002	0.003	0.011	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	1.79					
	P	(mW)		0.099		0.099		#
	P_{1x1}	(mW)		0.099		0.099		
	z_s	(cm)			1.07			
	z_b	(cm)					1.07	
	z_{MI}	(cm)	1.07					
	$Z_{pii,a}$	(cm)	1.07					
	f_{awf}	(MHz)	6.05	6.05		6.05		#
Other Information	prr	(Hz)	200					
	srr	(Hz)	—					
	n_{pps}		1					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	107					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	4.66					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	7.30					
	p_r at Z_{pii}	(MPa)	2.24					
Operating Control Conditions	Control 1		✔	✔	✔	✔	✔	
	Control 2							
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.
— Not applicable for this scanner or mode.

Control 1: Exam Type: Pelvic; Depth: 5 cm; Mode: M

Clarius Scanner EC7 HD3: PW Doppler Mode

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.768	0.115		0.376		(a)
Index Component Value				0.115	0.059	0.189	0.376	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	1.73					
	P	(mW)		4.78		4.78		#
	P_{1x1}	(mW)		4.78		4.78		
	z_s	(cm)			1.90			
	z_b	(cm)					1.90	
	z_{MI}	(cm)	1.90					
	$Z_{pii,a}$	(cm)	1.90					
	f_{awf}	(MHz)	5.05	5.05		5.05		#
Other Information	prr	(Hz)	1000					
	srr	(Hz)	—					
	n_{pps}		1					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	196					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	144					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	279					
	p_r at Z_{pii}	(MPa)	2.41					
Operating Control Conditions	Control 1		✔	✔	✔	✔	✔	
	Control 2							
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.
— Not applicable for this scanner or mode.

Control 1: Exam Type: Pelvic; Depth: 1.9 cm; Mode: PWD

Clarius Scanner L7 HD3: B-Mode

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.432	0.044		0.047		(a)
Index Component Value				0.044	0.044	0.047	0.044	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	1.17					
	P	(mW)		1.66		1.66		#
	P_{1x1}	(mW)		1.25		1.25		
	z_s	(cm)			1.90			
	z_b	(cm)					1.90	
	z_{MI}	(cm)	1.90					
	$Z_{pii,a}$	(cm)	1.90					
	f_{awf}	(MHz)	7.34	7.34		7.34		#
Other Information	prr	(Hz)	9600					
	srr	(Hz)	25.0					
	n_{pps}		2					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	50.8					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	1.13					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	2.97					
	p_r at Z_{pii}	(MPa)	1.89					
Operating Control Conditions	Control 1		✔	✔	✔	✔	✔	
	Control 2							
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.

Control 1: Exam Type: Vascular; Depth: 4 cm; Mode: B

Clarius Scanner L7 HD3: Color Doppler Mode

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.674	0.106		0.166		(a)
Index Component Value				0.106	0.106	0.166	0.106	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	1.51					
	P	(mW)		5.84		5.84		#
	P_{1x1}	(mW)		4.38		4.38		
	z_s	(cm)			1.43			
	z_b	(cm)					1.43	
	z_{MI}	(cm)	1.43					
	$Z_{pii,a}$	(cm)	1.43					
	f_{awf}	(MHz)	5.06	5.06		5.06		#
Other Information	prr	(Hz)	5400					
	srr	(Hz)	300					
	n_{pps}		12					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	96.8					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	30.9					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	50.8					
	p_r at Z_{pii}	(MPa)	1.94					
Operating Control Conditions	Control 1		✔	✔	✔	✔	✔	
	Control 2							
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.

Control 1: Exam Type: Vascular; Depth: 3 cm; Mode: CD

Clarius Scanner L7 HD3: M-Mode

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.432	0.001		0.003		(a)
Index Component Value				0.001	0.000	0.001	0.003	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	1.17					
	P	(mW)		0.035		0.035		#
	P_{1x1}	(mW)		0.035		0.035		
	z_s	(cm)			1.90			
	z_b	(cm)					1.90	
	z_{MI}	(cm)	1.90					
	$Z_{pii,a}$	(cm)	1.90					
	f_{awf}	(MHz)	7.34	7.34		7.34		#
Other Information	prr	(Hz)	200					
	srr	(Hz)	—					
	n_{pps}		1					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	50.8					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	1.75					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	4.59					
	p_r at Z_{pii}	(MPa)	1.89					
Operating Control Conditions	Control 1		✔	✔	✔	✔	✔	
	Control 2							
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.
— Not applicable for this scanner or mode.

Control 1: Exam Type: Vascular; Depth: 4 cm; Mode: M

Clarius Scanner L7 HD3: Needle Enhance B-Mode

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.987	0.329		0.501		(a)
Index Component Value				0.329	0.329	0.501	0.329	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	2.26					
	P	(mW)		17.6		17.6		#
	P_{1x1}	(mW)		13.2		13.2		
	z_s	(cm)			2.00			
	z_b	(cm)					2.00	
	z_{MI}	(cm)	2.00					
	$Z_{pii,a}$	(cm)	2.00					
	f_{awf}	(MHz)	5.24	5.24		5.24		#
Other Information	prr	(Hz)	4800					
	srr	(Hz)	25.0					
	n_{pps}		2					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	258					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	11.5					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	23.6					
	p_r at Z_{pii}	(MPa)	3.24					
Operating Control Conditions	Control 1		✔	✔	✔	✔	✔	
	Control 2							
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.

Control 1: Exam Type: MSK; Depth: 4 cm; Mode: B

Clarius Scanner L7 HD3: Ocular (Ophthalmic) B-Mode

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.157	0.006		0.007		(a)
Index Component Value				0.006	0.006	0.007	0.006	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	0.404					
	P	(mW)		0.245		0.245		#
	P_{1x1}	(mW)		0.184		0.184		
	z_s	(cm)			1.57			
	z_b	(cm)					1.57	
	z_{MI}	(cm)	1.57					
	$Z_{pii,a}$	(cm)	1.57					
	f_{awf}	(MHz)	6.58	6.58		6.58		#
Other Information	prr	(Hz)	9600					
	srr	(Hz)	25.0					
	n_{pps}		2					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	4.16					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	0.237					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	0.484					
	p_r at Z_{pii}	(MPa)	0.577					
Operating Control Conditions	Control 1		✔	✔	✔	✔	✔	
	Control 2							
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.

Control 1: Exam Type: Ocular; Depth: 4 cm; Mode: B

Clarius Scanner L7 HD3: PW Doppler Mode

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.728	0.293		0.729		(a)
Index Component Value				0.293	0.147	0.256	0.729	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	1.64					
	P	(mW)		12.3		7.57		#
	P_{1x1}	(mW)		12.3		7.57		
	z_s	(cm)			2.00			
	z_b	(cm)					1.70	
	z_{MI}	(cm)	1.70					
	$Z_{pii,a}$	(cm)	1.70					
	f_{awf}	(MHz)	5.04	5.02		5.04		#
Other Information	prr	(Hz)	3500					
	srr	(Hz)	—					
	n_{pps}		1					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	124					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	317					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	574					
	p_r at Z_{pii}	(MPa)	2.20					
Operating Control Conditions	Control 1		✔			✔	✔	
	Control 2			✔	✔			
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.
— Not applicable for this scanner or mode.

Control 1: Exam Type: Vascular; Gate Depth: 2.3 cm; Mode: PWD
Control 2: Exam Type: Vascular; Gate Depth: 4 cm; Mode: PWD

Clarius Scanner L15 HD3: B-Mode

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.533	0.060		0.123		(a)
Index Component Value				0.060	0.060	0.123	0.060	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	1.54					
	P	(mW)		2.43		2.43		#
	P_{1x1}	(mW)		1.46		1.46		
	z_s	(cm)			1.80			
	z_b	(cm)					1.80	
	z_{MI}	(cm)	1.40					
	$Z_{pii,a}$	(cm)	1.40					
	f_{awf}	(MHz)	8.33	8.69		8.69		#
Other Information	prr	(Hz)	4800					
	srr	(Hz)	25.0					
	n_{pps}		2					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	84.5					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	1.35					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	3.03					
	p_r at Z_{pii}	(MPa)	2.30					
Operating Control Conditions	Control 1		✔					
	Control 2			✔	✔	✔	✔	
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.

Control 1: Exam Type: Vascular; Depth: 1 cm; Mode: B

Control 2: Exam Type: Vascular; Depth: 2 cm; Mode: B

Clarius Scanner L15 HD3: Color Doppler Mode

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.945	0.190		1.01		(a)
Index Component Value				0.190	0.190	1.01	0.190	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	2.58					
	P	(mW)		8.89		8.89		#
	P_{1x1}	(mW)		5.33		5.33		
	z_s	(cm)			2.07			
	z_b	(cm)					2.07	
	z_{MI}	(cm)	1.47					
	$Z_{pii,a}$	(cm)	1.47					
	f_{awf}	(MHz)	7.45	7.47		7.47		#
Other Information	prr	(Hz)	4160					
	srr	(Hz)	130					
	n_{pps}		12					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	348					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	28.8					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	61.3					
	p_r at Z_{pii}	(MPa)	3.76					
Operating Control Conditions	Control 1		✔					
	Control 2			✔	✔	✔	✔	
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.

Control 1: Exam Type: Vascular; Depth: 2.8 cm; Mode: CD

Control 2: Exam Type: Vascular; Depth: 7 cm; Mode: CD

Clarius Scanner L15 HD3: M-Mode

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.533	0.004		0.005		(a)
Index Component Value				0.004	0.001	0.005	0.004	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	1.54					
	P	(mW)		0.101		0.101		#
	P_{1x1}	(mW)		0.101		0.101		
	z_s	(cm)			1.80			
	z_b	(cm)					1.80	
	z_{MI}	(cm)	1.40					
	$Z_{pii,a}$	(cm)	1.40					
	f_{awf}	(MHz)	8.33	8.69		8.69		#
Other Information	prr	(Hz)	200					
	srr	(Hz)	—					
	n_{pps}		1					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	84.5					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	2.53					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	5.69					
	p_r at Z_{pii}	(MPa)	2.30					
Operating Control Conditions	Control 1		✔					
	Control 2			✔	✔	✔	✔	
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.
— Not applicable for this scanner or mode.

Control 1: Exam Type: Vascular; Depth: 1 cm; Mode: M
Control 2: Exam Type: Vascular; Depth: 2 cm; Mode: M

Clarius Scanner L15 HD3: Needle Enhance B-Mode

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.620	0.090		0.657		(a)
Index Component Value				0.090	0.090	0.657	0.090	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	1.69					
	P	(mW)		4.33		4.33		#
	P_{1x1}	(mW)		2.60		2.60		
	z_s	(cm)			1.67			
	z_b	(cm)					1.67	
	z_{MI}	(cm)	1.43					
	$Z_{pii,a}$	(cm)	1.43					
	f_{awf}	(MHz)	7.40	7.31		7.31		#
Other Information	prr	(Hz)	3456					
	srr	(Hz)	18.0					
	n_{pps}		2					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	116					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	3.00					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	6.25					
	p_r at Z_{pii}	(MPa)	2.43					
Operating Control Conditions	Control 1		✔					
	Control 2			✔	✔	✔	✔	
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.

Control 1: Exam Type: Vascular; Depth: 2.8 cm; Mode: B

Control 2: Exam Type: Vascular; Depth: 7 cm; Mode: B

Clarius Scanner L15 HD3: Ocular (Ophthalmic) B-Mode

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.087	0.004		0.004		(a)
Index Component Value				0.004	0.004	0.004	0.004	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	0.280					
	P	(mW)		0.085		0.085		#
	P_{1x1}	(mW)		0.085		0.085		
	z_s	(cm)			2.00			
	z_b	(cm)					2.00	
	z_{MI}	(cm)	2.00					
	$Z_{pii,a}$	(cm)	2.00					
	f_{awf}	(MHz)	10.3	10.3		10.3		#
Other Information	prr	(Hz)	3648					
	srr	(Hz)	19.0					
	n_{pps}		2					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	2.35					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	0.025					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	0.103					
	p_r at Z_{pii}	(MPa)	0.573					
Operating Control Conditions	Control 1		✔	✔	✔	✔	✔	
	Control 2							
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.

Control 1:Exam Type: Ocular; Depth: 4 cm; Mode: B

Clarius Scanner L15 HD3: PW Doppler Mode

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.819	0.615		1.60		(a)
Index Component Value				0.615	0.269	1.60	0.552	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	2.23					
	P	(mW)		15.7		15.7		#
	P_{1x1}	(mW)		15.7		15.7		
	z_s	(cm)			1.57			
	z_b	(cm)					1.40	
	z_{MI}	(cm)	1.37					
	$Z_{pii,a}$	(cm)	1.37					
	f_{awf}	(MHz)	7.44	8.21		8.21		#
Other Information	prr	(Hz)	3500					
	srr	(Hz)	—					
	n_{pps}		1					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	278					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	469					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	948					
	p_r at Z_{pii}	(MPa)	3.17					
Operating Control Conditions	Control 1		✔					
	Control 2			✔	✔	✔	✔	
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.
— Not applicable for this scanner or mode.

Control 1: Exam Type: Vascular; Gate Depth: 1.4 cm; Mode: PWD
Control 2: Exam Type: Vascular; Gate Depth: 5 cm; Mode: PWD

Clarius Scanner L20 HD3: B-Mode

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.564	0.045		0.063		(a)
Index Component Value				0.045	0.045	0.063	0.045	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	1.91					
	P	(mW)		0.822		0.822		#
	P_{1x1}	(mW)		0.822		0.822		
	z_s	(cm)			1.00			
	z_b	(cm)					1.00	
	z_{MI}	(cm)	1.00					
	$Z_{pii,a}$	(cm)	1.00					
	f_{awf}	(MHz)	11.4	11.4		11.4		#
Other Information	prr	(Hz)	7296					
	srr	(Hz)	19.0					
	n_{pps}		2					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	120					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	3.74					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	8.24					
	p_r at Z_{pii}	(MPa)	2.83					
Operating Control Conditions	Control 1		✔	✔	✔	✔	✔	
	Control 2							
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.

Control 1: Exam Type: Vascular; Depth: 4 cm; Mode: B

Clarius Scanner L20 HD3: Color Doppler Mode

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.243	0.021		0.022		(a)
Index Component Value				0.021	0.021	0.022	0.021	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	0.927					
	P	(mW)		0.298		0.298		#
	P_{1x1}	(mW)		0.298		0.298		
	z_s	(cm)			1.00			
	z_b	(cm)					1.00	
	z_{MI}	(cm)	1.00					
	$Z_{pii,a}$	(cm)	1.00					
	f_{awf}	(MHz)	14.6	14.6		14.6		#
Other Information	prr	(Hz)	2080					
	srr	(Hz)	13.0					
	n_{pps}		12					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	32.4					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	0.492					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	1.34					
	p_r at Z_{pii}	(MPa)	1.53					
Operating Control Conditions	Control 1		✔	✔	✔	✔	✔	
	Control 2							
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.

Control 1: Exam Type: Vascular; Depth: 4 cm; Mode: CD

Clarius Scanner L20 HD3: M-Mode

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.437	0.002		0.003		(a)
Index Component Value				0.002	0.001	0.002	0.003	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	1.52					
	P	(mW)		0.028		0.028		#
	P_{1x1}	(mW)		0.028		0.028		
	z_s	(cm)			1.00			
	z_b	(cm)					1.07	
	z_{MI}	(cm)	1.00					
	$Z_{pii,a}$	(cm)	1.00					
	f_{awf}	(MHz)	12.1	12.1		12.1		#
Other Information	prr	(Hz)	250					
	srr	(Hz)	—					
	n_{pps}		1					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	78.8					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	1.97					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	4.53					
	p_r at Z_{pii}	(MPa)	2.31					
Operating Control Conditions	Control 1		✔	✔	✔	✔	✔	
	Control 2							
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.
— Not applicable for this scanner or mode.

Control 1: Exam Type: Vascular; Depth: 1.5 cm; Mode: M

Clarius Scanner L20 HD3: Needle Enhance B-Mode

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.441	0.018		0.018		(a)
Index Component Value				0.018	0.018	0.017	0.018	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	1.52					
	P	(mW)		0.319		0.319		#
	P_{1x1}	(mW)		0.319		0.319		
	z_s	(cm)			0.900			
	z_b	(cm)					0.900	
	z_{MI}	(cm)	0.900					
	$Z_{pii,a}$	(cm)	0.900					
	f_{awf}	(MHz)	11.9	11.9		11.9		#
Other Information	prr	(Hz)	2304					
	srr	(Hz)	12.0					
	n_{pps}		1					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	84.6					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	0.570					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	1.20					
	p_r at Z_{pii}	(MPa)	2.20					
Operating Control Conditions	Control 1		✔	✔	✔	✔	✔	
	Control 2							
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.

Control 1: Exam Type: Vascular; Depth: 2 cm; Mode: B

Clarius Scanner L20 HD3: Ocular (Ophthalmic) B-Mode

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.116	0.001		0.001		(a)
Index Component Value				0.001	0.001	0.001	0.001	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	0.407					
	P	(mW)		0.017		0.017		#
	P_{1x1}	(mW)		0.017		0.017		
	z_s	(cm)			1.00			
	z_b	(cm)					1.00	
	z_{MI}	(cm)	1.00					
	$Z_{pii,a}$	(cm)	1.00					
	f_{awf}	(MHz)	12.3	12.3		12.3		#
Other Information	prr	(Hz)	2080					
	srr	(Hz)	13.0					
	n_{pps}		2					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	4.82					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	0.020					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	0.048					
	p_r at Z_{pii}	(MPa)	0.624					
Operating Control Conditions	Control 1		✔	✔	✔	✔	✔	
	Control 2							
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.

Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.

Control 1: Exam Type: Ocular; Depth: 4 cm; Mode: B

Clarius Scanner L20 HD3: PW Doppler Mode

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.578	0.222		0.378		(a)
Index Component Value				0.222	0.120	0.378	0.262	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	1.82					
	P	(mW)		4.71		4.71		#
	P_{1x1}	(mW)		4.71		4.71		
	z_s	(cm)			0.900			
	z_b	(cm)					1.07	
	z_{MI}	(cm)	0.900					
	$Z_{pii,a}$	(cm)	0.900					
	f_{awf}	(MHz)	9.93	9.93		9.93		#
Other Information	prr	(Hz)	5000					
	srr	(Hz)	—					
	n_{pps}		1					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	143					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	263					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	488					
	p_r at Z_{pii}	(MPa)	2.48					
Operating Control Conditions	Control 1		✔	✔	✔	✔	✔	
	Control 2							
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.
— Not applicable for this scanner or mode.

Control 1: Exam Type: Vascular; Depth: 0.9 cm; Mode: PWD

Clarius Scanner PA HD3: B-Mode

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.972	0.150		0.276		(a)
Index Component Value				0.150	0.150	0.276	0.150	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	1.64					
	P	(mW)		18.0		18.0		#
	P_{1x1}	(mW)		11.2		11.2		
	z_s	(cm)			2.43			
	z_b	(cm)					2.43	
	z_{MI}	(cm)	1.77					
	$Z_{pii,a}$	(cm)	1.77					
	f_{awf}	(MHz)	2.83	2.81		2.81		#
Other Information	prr	(Hz)	4800					
	srr	(Hz)	30.0					
	n_{pps}		4					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	73.9					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	8.25					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	11.7					
	p_r at Z_{pii}	(MPa)	1.94					
Operating Control Conditions	Control 1		✔					
	Control 2			✔	✔	✔	✔	
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.

Control 1: Exam Type: Cardiac; Depth: 3.2 cm; Mode: B

Control 2: Exam Type: Cardiac; Depth: 4.5 cm; Mode: B

Clarius Scanner PA HD3: Color Doppler Mode

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.891	0.514		0.790		(a)
Index Component Value				0.514	0.514	0.790	0.514	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	1.62					
	P	(mW)		51.5		51.5		#
	P_{1x1}	(mW)		32.2		32.2		
	z_s	(cm)			2.40			
	z_b	(cm)					2.40	
	z_{MI}	(cm)	1.77					
	$Z_{pii,a}$	(cm)	1.77					
	f_{awf}	(MHz)	3.30	3.35		3.35		#
Other Information	prr	(Hz)	7800					
	srr	(Hz)	300					
	n_{pps}		10					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	61.6					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	49.1					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	73.6					
	p_r at Z_{pii}	(MPa)	1.98					
Operating Control Conditions	Control 1		✔					
	Control 2			✔	✔	✔	✔	
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.

Control 1: Exam Type: Cardiac; Depth: 3.2 cm; Mode: CD

Control 2: Exam Type: Cardiac; Depth: 4.5 cm; Mode: CD

Clarius Scanner PA HD3: M-Mode

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.972	0.010		0.041		(a)
Index Component Value				0.010	0.006	0.011	0.041	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	1.64					
	P	(mW)		0.748		0.748		#
	P_{1x1}	(mW)		0.748		0.748		
	z_s	(cm)			2.40			
	z_b	(cm)					2.43	
	z_{MI}	(cm)	1.40					
	$Z_{pii,a}$	(cm)	1.40					
	f_{awf}	(MHz)	2.83	2.81		2.81		#
Other Information	prr	(Hz)	200					
	srr	(Hz)	—					
	n_{pps}		1					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	73.9					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	10.2					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	14.4					
	p_r at Z_{pii}	(MPa)	1.94					
Operating Control Conditions	Control 1		✔					
	Control 2			✔	✔	✔	✔	
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.
— Not applicable for this scanner or mode.

Control 1: Exam Type: Cardiac; Depth: 3.2 cm; Mode: M
Control 2: Exam Type: Cardiac; Depth: 4.5 cm; Mode: M

Clarius Scanner PA HD3: PW Doppler Mode

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.725	0.092		0.262		(a)
Index Component Value				0.092	0.048	0.158	0.262	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	1.14					
	P	(mW)		7.92		7.92		#
	P_{1x1}	(mW)		7.92		7.92		
	z_s	(cm)			3.00			
	z_b	(cm)					3.90	
	z_{MI}	(cm)	3.00					
	$Z_{pii,a}$	(cm)	3.00					
	f_{awf}	(MHz)	2.45	2.45		2.45		#
Other Information	prr	(Hz)	500					
	srr	(Hz)	—					
	n_{pps}		1					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	60.4					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	45.2					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	87.5					
	p_r at Z_{pii}	(MPa)	1.58					
Operating Control Conditions	Control 1		✔	✔	✔	✔	✔	
	Control 2							
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.
— Not applicable for this scanner or mode.

Control 1: Exam Type: Cardiac; Gate Depth: 4 cm; Mode: PWD

Clarius Scanner PA HD3: Transcranial B-Mode

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.972	0.150		0.276		0.276
Index Component Value				0.150	0.150	0.276	0.150	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	1.64					
	P	(mW)		18.0		18.0		18.0
	P_{1x1}	(mW)		11.2		11.2		
	z_s	(cm)			2.43			
	z_b	(cm)					2.43	
	z_{MI}	(cm)	1.77					
	$Z_{pii,a}$	(cm)	1.77					
	f_{awf}	(MHz)	2.83	2.81		2.81		2.81
Other Information	prr	(Hz)	4800					
	srr	(Hz)	30.0					
	n_{pps}		4					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	73.9					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	8.25					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	11.7					
	p_r at Z_{pii}	(MPa)	1.94					
Operating Control Conditions	Control 1		✔					
	Control 2			✔	✔	✔	✔	✔
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

Control 1: Exam Type: Cardiac; Depth: 3.2 cm; Mode: B

Control 2: Exam Type: Cardiac; Depth: 4.5 cm; Mode: B

Clarius Scanner PA HD3: Transcranial Color Doppler Mode

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.666	0.963		1.55		1.55
Index Component Value				0.963	0.963	1.55	0.963	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	1.04					
	P	(mW)		82.4		82.4		82.4
	P_{1x1}	(mW)		82.4		82.4		
	z_s	(cm)			4.27			
	z_b	(cm)					4.27	
	z_{MI}	(cm)	4.27					
	$Z_{pii,a}$	(cm)	4.27					
	f_{awf}	(MHz)	2.46	2.46		2.46		2.46
Other Information	prr	(Hz)	4800					
	srr	(Hz)	30.0					
	n_{pps}		10					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	53.7					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	38.9					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	80.6					
	p_r at Z_{pii}	(MPa)	1.50					
Operating Control Conditions	Control 1		✔	✔	✔	✔	✔	✔
	Control 2							
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

Control 1: Exam Type: Transcranial; Depth: 4 cm; Mode: CD

Clarius Scanner PA HD3: Transcranial M-Mode

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.972	0.010		0.041		0.011
Index Component Value				0.010	0.006	0.011	0.041	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	1.64					
	P	(mW)		0.748		0.748		0.748
	P_{1x1}	(mW)		0.748		0.748		
	z_s	(cm)			2.40			
	z_b	(cm)					2.43	
	z_{MI}	(cm)	1.40					
	$Z_{pii,a}$	(cm)	1.40					
	f_{awf}	(MHz)	2.83	2.81		2.81		2.81
Other Information	prr	(Hz)	200					
	srr	(Hz)	—					
	n_{pps}		1					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	73.9					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	10.2					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	14.4					
	p_r at Z_{pii}	(MPa)	1.94					
Operating Control Conditions	Control 1		✔					
	Control 2			✔	✔	✔	✔	✔
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

— Not applicable for this scanner or mode.

Control 1: Exam Type: Cardiac; Depth: 3.2 cm; Mode: M

Control 2: Exam Type: Cardiac; Depth: 4.5 cm; Mode: M

Clarius Scanner PA HD3: Transcranial PW Doppler Mode

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.696	0.571		1.99		1.16
Index Component Value				0.571	0.327	1.16	1.99	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	0.983					
	P	(mW)		60.0		60.0		60.0
	P_{1x1}	(mW)		60.0		60.0		
	z_s	(cm)			3.53			
	z_b	(cm)					4.20	
	z_{MI}	(cm)	3.53					
	$Z_{pii,a}$	(cm)	3.53					
	f_{awf}	(MHz)	2.00	2.00		2.00		2.00
Other Information	prr	(Hz)	4000					
	srr	(Hz)	—					
	n_{pps}		1					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	42.2					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	312					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	544					
	p_r at Z_{pii}	(MPa)	1.30					
Operating Control Conditions	Control 1		✔	✔	✔	✔	✔	✔
	Control 2							
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

— Not applicable for this scanner or mode.

Control 1: Exam Type: Transcranial; Gate Depth: 4 cm; Mode: PWD

Clarius Scanner PAL HD3: B-Mode, Linear Array

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.349	0.046		0.067		(a)
Index Component Value				0.046	0.046	0.067	0.046	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	0.989					
	P	(mW)		1.192		1.192		#
	P_{1x1}	(mW)		1.192		1.192		
	z_s	(cm)			1.953			
	z_b	(cm)					1.953	
	z_{MI}	(cm)	1.953					
	$Z_{pii,a}$	(cm)	1.953					
	f_{awf}	(MHz)	8.045	8.045		8.045		#
Other Information	prr	(Hz)	5376					
	srr	(Hz)	24.0					
	n_{pps}		2					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	47.092					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	1.533					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	4.527					
	p_r at Z_{pii}	(MPa)	1.699					
Operating Control Conditions	Control 1		✔	✔	✔	✔	✔	
	Control 2							
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.

Control 1: Exam Type: Vascular; Depth: 4 cm; Focal Depth: 2.4 cm; Mode: B

Clarius Scanner PAL HD3: Color Doppler Mode, Linear Array

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.395	0.072		0.117		(a)
Index Component Value				0.072	0.072	0.117	0.072	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	1.013					
	P	(mW)		2.294		2.294		#
	P_{1x1}	(mW)		2.294		2.294		
	z_s	(cm)			1.770			
	z_b	(cm)					1.770	
	z_{MI}	(cm)	1.770					
	$Z_{pii,a}$	(cm)	1.770					
	f_{awf}	(MHz)	6.595	6.595		6.595		#
Other Information	prr	(Hz)	4032					
	srr	(Hz)	18					
	n_{pps}		12					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	33.737					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	3.070					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	6.923					
	p_r at Z_{pii}	(MPa)	1.517					
Operating Control Conditions	Control 1		✔	✔	✔	✔	✔	
	Control 2							
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.

Control 1: Exam Type: Vascular; Depth: 4 cm; Focal Depth: 1.8 cm; Mode: CD

Clarius Scanner PAL HD3: M-Mode, Linear Array

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.343	0.002		0.004		(a)
Index Component Value				0.002	0.001	0.004	0.004	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	0.981					
	P	(mW)		0.061		0.061		#
	P_{1x1}	(mW)		0.061		0.061		
	z_s	(cm)			1.907			
	z_b	(cm)					1.907	
	z_{MI}	(cm)	1.907					
	$Z_{pii,a}$	(cm)	1.907					
	f_{awf}	(MHz)	8.217	8.217		8.217		#
Other Information	prr	(Hz)	350					
	srr	(Hz)	—					
	n_{pps}		1					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	48.160					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	1.623					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	4.816					
	p_r at Z_{pii}	(MPa)	1.687					
Operating Control Conditions	Control 1		✔	✔	✔	✔	✔	
	Control 2							
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.
— Not applicable for this scanner or mode.

Control 1: Exam Type: Vascular; Depth: 4.5 cm; Focal Depth: 1.9 cm; Mode: M

Clarius Scanner PAL HD3: Needle Enhance B-Mode, Linear Array

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.317	0.056		0.056		(a)
Index Component Value				0.056	0.056	0.056	0.056	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	0.901					
	P	(mW)		1.464		1.464		#
	P_{1x1}	(mW)		1.464		1.464		
	z_s	(cm)			2.456			
	z_b	(cm)					2.456	
	z_{MI}	(cm)	2.456					
	$Z_{pii,a}$	(cm)	2.456					
	f_{awf}	(MHz)	8.103	8.103		8.103		#
Other Information	prr	(Hz)	5376					
	srr	(Hz)	24.0					
	n_{pps}		2					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	40.987					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	1.053					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	4.079					
	p_r at Z_{pii}	(MPa)	1.789					
Operating Control Conditions	Control 1		✔	✔	✔	✔	✔	
	Control 2							
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.

Control 1: Exam Type: Vascular; Depth: 5.7 cm; Focal Depth: 2.5 cm; Mode: B

Clarius Scanner PAL HD3: Ocular (Ophthalmic) B-Mode, Linear Array

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.066	0.002		0.002		(a)
Index Component Value				0.002	0.002	0.002	0.002	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	0.211					
	P	(mW)		0.043		0.043		#
	P_{1x1}	(mW)		0.043		0.043		
	z_s	(cm)			2.00			
	z_b	(cm)					2.00	
	z_{MI}	(cm)	2.00					
	$Z_{pii,a}$	(cm)	2.00					
	f_{awf}	(MHz)	10.265	10.265		10.265		#
Other Information	prr	(Hz)	4256					
	srr	(Hz)	19.0					
	n_{pps}		2					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	1.788					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	0.030					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	0.124					
	p_r at Z_{pii}	(MPa)	0.429					
Operating Control Conditions	Control 1		✔	✔	✔	✔	✔	
	Control 2							
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.

Control 1: Exam Type: Ocular; Depth: 4 cm; Focal Depth: 2 cm; Mode: B

Clarius Scanner PAL HD3: PW Doppler Mode, Linear Array

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.414	0.292		0.616		(a)
Index Component Value				0.292	0.135	0.616	0.616	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	1.067					
	P	(mW)		9.236		9.236		#
	P_{1x1}	(mW)		9.236		9.236		
	z_s	(cm)			1.681			
	z_b	(cm)					1.681	
	z_{MI}	(cm)	1.681					
	$Z_{pii,a}$	(cm)	1.681					
	f_{awf}	(MHz)	6.630	6.630		6.630		#
Other Information	prr	(Hz)	8000					
	srr	(Hz)	—					
	n_{pps}		1					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	53.488					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	222.443					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	479.649					
	p_r at Z_{pii}	(MPa)	1.567					
Operating Control Conditions	Control 1		✔	✔	✔	✔	✔	
	Control 2							
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.
— Not applicable for this scanner or mode.

Control 1: Exam Type: Vascular; Gate Depth: 4 cm; Focal Depth: 1.7 cm; Mode: PWD

Clarius Scanner PAL HD3: B-Mode, Phased Array

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.556	0.222		0.952		(a)
Index Component Value				0.222	0.222	0.952	0.222	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	0.764					
	P	(mW)		24.744		24.744		#
	P_{1x1}	(mW)		24.744		24.744		
	z_s	(cm)			3.133			
	z_b	(cm)					3.133	
	z_{MI}	(cm)	3.133					
	$Z_{pii,a}$	(cm)	3.133					
	f_{awf}	(MHz)	1.886	1.886		1.886		#
Other Information	prr	(Hz)	4640					
	srr	(Hz)	29.0					
	n_{pps}		2					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	18.566					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	12.697					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	19.086					
	p_r at Z_{pii}	(MPa)	0.937					
Operating Control Conditions	Control 1		✔	✔	✔	✔	✔	
	Control 2							
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.

Control 1: Exam Type: Cardiac; Depth: 12.3 cm; Focal Depth: 3.2 cm; Mode: B

Clarius Scanner PAL HD3: Color Doppler Mode, Phased Array

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.639	0.218		0.866		(a)
Index Component Value				0.218	0.218	0.866	0.218	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	0.804					
	P	(mW)		28.893		28.893		#
	P_{1x1}	(mW)		28.893		28.893		
	z_s	(cm)			3.900			
	z_b	(cm)					3.900	
	z_{MI}	(cm)	3.900					
	$Z_{pii,a}$	(cm)	3.900					
	f_{awf}	(MHz)	1.584	1.584		1.584		#
Other Information	prr	(Hz)	2720					
	srr	(Hz)	17					
	n_{pps}		8					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	15.203					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	11.543					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	17.676					
	p_r at Z_{pii}	(MPa)	0.995					
Operating Control Conditions	Control 1		✔	✔	✔	✔	✔	
	Control 2							
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.

Control 1: Exam Type: Cardiac; Depth: 8 cm; Focal Depth: 4.9 cm; Mode: CD

Clarius Scanner PAL HD3: M-Mode, Phased Array

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.559	0.017		0.071		(a)
Index Component Value				0.017	0.011	0.071	0.057	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	0.771					
	P	(mW)		1.829		1.829		#
	P_{1x1}	(mW)		1.829		1.829		
	z_s	(cm)			3.353			
	z_b	(cm)					3.353	
	z_{MI}	(cm)	3.353					
	$Z_{pii,a}$	(cm)	3.353					
	f_{awf}	(MHz)	1.906	1.906		1.906		#
Other Information	prr	(Hz)	350					
	srr	(Hz)	—					
	n_{pps}		1					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	19.938					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	6.892					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	10.718					
	p_r at Z_{pii}	(MPa)	0.962					
Operating Control Conditions	Control 1		✔	✔	✔	✔	✔	
	Control 2							
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.
— Not applicable for this scanner or mode.

Control 1: Exam Type: Cardiac; Depth: 12.5 cm; Focal Depth: 3.4 cm; Mode: M

Clarius Scanner PAL HD3: PW Doppler Mode, Phased Array

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.679	0.779		3.223		(a)
Index Component Value				0.779	0.497	2.570	3.223	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	0.893					
	P	(mW)		94.638		94.638		#
	P_{1x1}	(mW)		94.638		94.638		
	z_s	(cm)			3.785			
	z_b	(cm)					3.785	
	z_{MI}	(cm)	3.785					
	$Z_{pii,a}$	(cm)	3.785					
	f_{awf}	(MHz)	1.728	1.728		1.728		#
Other Information	prr	(Hz)	7000					
	srr	(Hz)	—					
	n_{pps}		1					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm^2)	25.554					
	$I_{spta,a}$ at $Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm^2)	429.727					
	$I_{spta,a}$ at Z_{pii} or Z_{sii}	(mW/cm^2)	673.272					
	p_r at Z_{pii}	(MPa)	1.118					
Operating Control Conditions	Control 1		✔	✔	✔	✔	✔	
	Control 2							
	Control 3							
	Control 4							
	Control 5							
	Control 6							
	Control 7							

(a) This scanner is not intended for transcranial or neonatal cephalic use.
Not reported for this operating condition; the maximum index value is not reported for the reasons shown in the Maximum Index Value fields.
— Not applicable for this scanner or mode.

Control 1: Exam Type: Cardiac; Gate Depth: 8 cm; Focal Depth: 3.8 cm; Mode: PWD

Clarius AI User Guide

The Clarius AI User Guide is part of the Clarius Ultrasound Scanner User Manual and is intended for use only in approved jurisdictions. For a list of authorized jurisdictions of Clarius AI products, refer to https://clarius.com/clearances. Clarius MSK AI, Clarius Bladder AI, and Clarius OB AI are not for interventional purposes. You must verify all measurements for accuracy, and where necessary, manually adjust the calipers placed by these AI tools.

About Clarius MSK AI

1

Indications for Use

Clarius MSK AI is intended to semi-automatically place calipers for non-invasive measurements of musculoskeletal structures (e.g., Achilles' tendon, plantar fascia, patellar tendon) on ultrasound data acquired by the Clarius Ultrasound Scanner (i.e., L7 HD3 and L15 HD3). The user shall be a healthcare professional trained and qualified in MSK (musculoskeletal) ultrasound. The user shall retain the ultimate responsibility of ascertaining the measurements based on standard practices and clinical judgment.

Note to User — Scanners & Presets for MSK

Clarius AI for MSK (musculoskeletal) applies only to the Clarius L7 HD3 and L15 HD3 scanners in the following presets: Foot/Ankle, Knee, and Plantar. Purchasing the Clarius Membership gives user access to these presets and ability to see the AI button.

Note to User – Auto Hiding Controls

To minimize distractions and improve usability, the Clarius App automatically hides the on-screen controls. This feature can be turned off.

▼If you want the controls to remain visible:

1. Go to the side panel and select **Settings**.
2. Select **Advanced Settings**.
3. Locate **Auto Hiding Controls** and toggle it off.

Note to User – Imaging Artifacts, Performance, & Limitations

The performance of the MSK AI model may be impacted by the presence of artifacts common in MSK ultrasound such as acoustic shadow, lateral shadow, anisotropic effect, reverberation, and refraction. To reduce these artifacts during use, adopt the following techniques:

- Scan from different angles and planes.
- Use a linear scanner with high center frequency.
- Ensure the anatomy is in focus.

The MSK AI model is sensitive to fluid collection within the tendon, which reduces the pixel brightness and echogenicity of tendons. The MSK AI model has been found to have suboptimal performance under this condition. Be aware that the MSK AI model is not indicated for diagnostic purposes for conditions like tendon tears and effusion. It is a workflow tool intended to inform clinical management; it is not intended to replace clinical decision-making. When the MSK AI performance is suboptimal, you can override its output with manual measurements.

Be aware of potential imaging artifacts (e.g., fluid-filled tendons and shadows) and the techniques to reduce such artifacts.

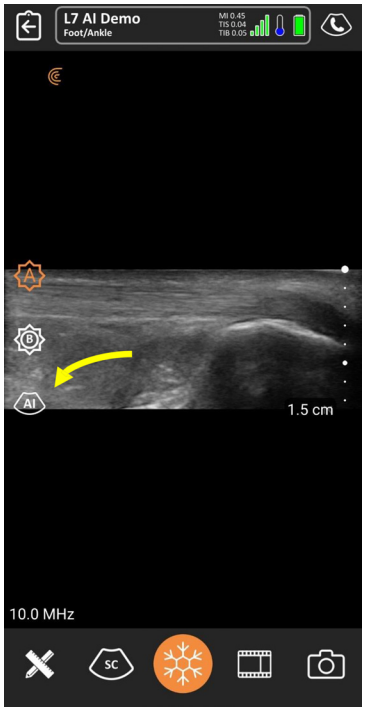
Operating System

See ***System Requirements*** on page 23.

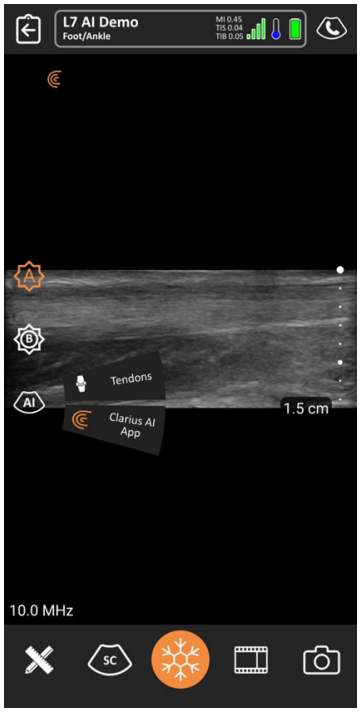
How to Use Clarius MSK AI

▼To use Clarius AI for MSK applications:

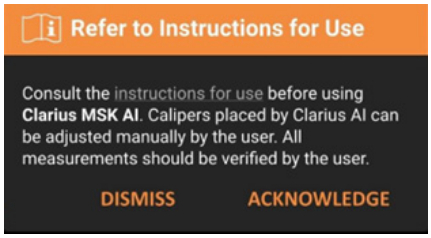
1. Tap the **AI** button to activate tendon detection and highlighting. The AI button is highlighted by the yellow arrow in the image below. If the AI button is not visible, tap on the screen to make it appear.



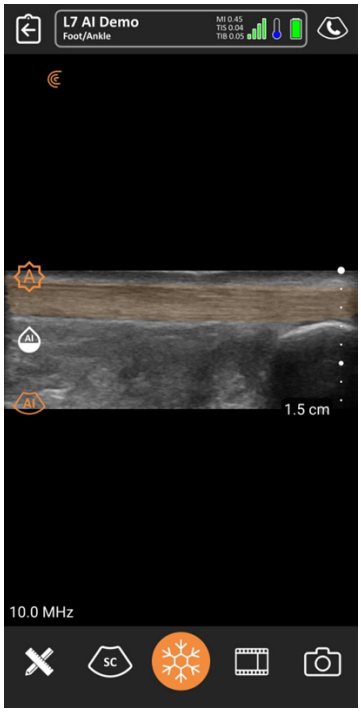
2. A circular carousel will appear with all available AI models. Select **Tendons**.



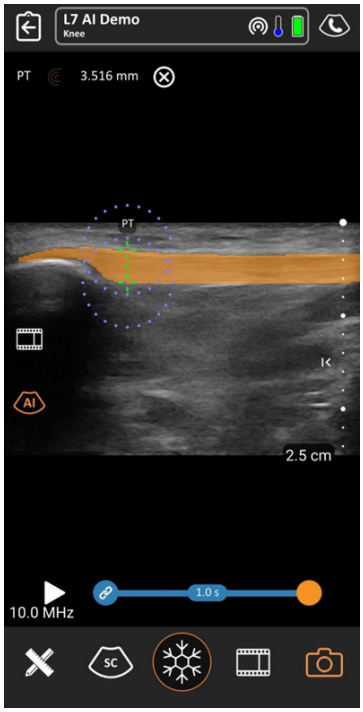
3. If activating for the first time, a pop-up will appear referring to the “Instructions for Use”. Selecting **Dismiss** will dismiss the pop-up but it will re-appear on subsequent uses of MSK AI. Selecting **Acknowledge** will dismiss the pop-up and it will not be shown again.



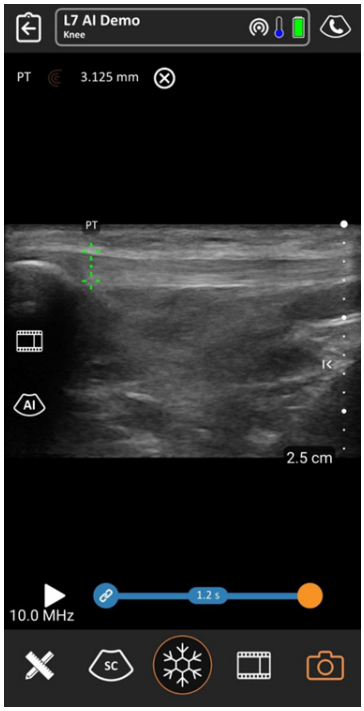
4. Once the AI is activated the AI button will turn orange as shown in the image below. If the tendon is in view, it will also be automatically highlighted by an orange mask on top as shown in the image below.



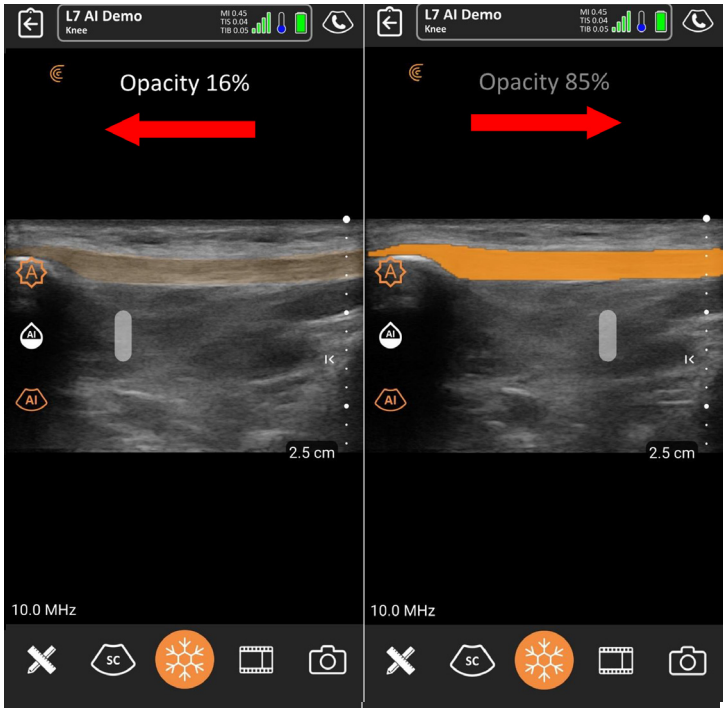
5. Once a tendon is detected and highlighted by an orange mask, the tendon thickness can be calculated. To display the tendon thickness, pause the acquisition by pressing on the **Freeze** button. The calipers will be placed automatically, and the tendon thickness will be displayed in the top left corner of the screen.



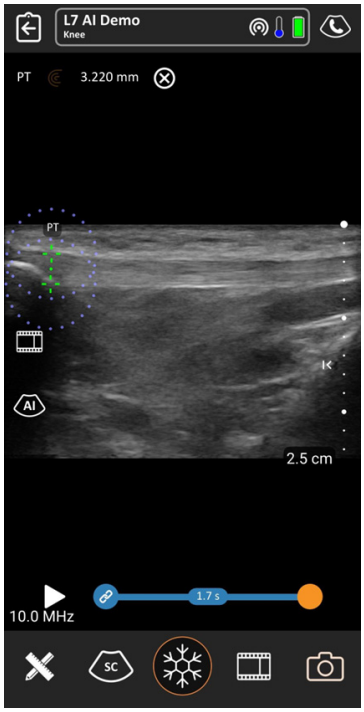
To remove the segmentation mask and disable the AI, tap the **AI** button until it turns white. As a reminder, AI button color orange signifies-> ON, whereas white signifies-> OFF. The tendon mask can also be disabled in Freeze mode. Once the acquisition is Frozen, disable the AI by tapping the button (color should change from orange -> white). This is particularly useful for users who want to see the tendon thickness without the tendon mask overlay. Refer to the image below.



6. The opacity of the mask can also be adjusted by making sure the Slider Control carousel wheel is selected to be on **AI Opacity**. Scroll directions are highlighted by the red arrow in the images below. Opacity is displayed upon change.



Manually adjust measurements: To adjust the measurements manually, freeze the image by pressing the **Freeze** button. Then remove the AI predicted overlay mask from the image by pressing the **AI** button. After disabling the AI feature, only the measurement calipers will remain on the image as shown in the figure below. Adjust the measurement by moving the caliper crosshairs.



For instructions on manually adjusting the calipers placed by MSK AI, go to https://clarius.com/msk-ai-vid.

About Clarius Bladder AI

2

Indications for Use

Clarius Bladder AI is intended for semi-automatic non-invasive measurements of bladder volume on ultrasound data acquired by the Clarius Ultrasound Scanner (i.e., curvilinear and phased array scanners). The user shall be a healthcare professional trained and qualified in ultrasound. The user shall retain the ultimate responsibility of ascertaining the measurements based on standard practices and clinical judgment. Clarius Bladder AI is indicated for use in adult patients only.

Note to User – Scanners & Presets for Bladder

Clarius AI for Bladder Volume applies only to the Clarius C3 HD3, PA HD3, and PAL HD3 scanners using the Bladder preset. Purchasing the Clarius Membership gives you access to the Bladder preset and see the AI button.

Note to User – Auto Hiding Controls

To minimize distractions and improve usability, the Clarius App automatically hides the on-screen controls. You can turn this feature off.

▼If you want the controls to remain visible:

1. Go to the side panel and select **Settings**.
2. Select **Advanced Settings**.
3. Locate **Auto Hiding Controls** and toggle it off.

Note to User – Imaging Artifacts, Performance, & Limitations

The performance of the Bladder AI model may be impacted by the presence of artifacts common in bladder ultrasound such as acoustic shadow, lateral shadow, anisotropic effect, reverberation, and refraction. To reduce these artifacts during use, adopt the following techniques:

- Scan from different angles and planes
- Ensure the anatomy is centered and in focus

The Clarius Bladder AI model is sensitive to free-fluid collection within the pelvis and has been found to have suboptimal performance under this condition. Ensure that there is no abdominal fluid or pathological features overlying or distorting the bladder when using Clarius Bladder AI.

The Clarius Bladder AI performance is unreliable for bladder volumes exceeding 400 ml. Refer to ***Performance Data & Uncertainty*** on page 146.

Operating System

See ***System Requirements*** on page 23.

Note to User — Performance Specifications of Clarius Bladder AI & Measurement Output Information

Clarius Bladder AI is only indicated as a workflow tool intended to inform clinical management and is not intended to replace clinical decision-making. Users can override the Clarius Bladder AI model output when performance is suboptimal and can perform manual measurements instead as needed.

The following information describes the performance test results of Clarius Bladder AI based on data collected from a study showing agreement between the output of Clarius Bladder AI and the expert clinicians' measurements.

Performance Data & Uncertainty

The Clarius Bladder AI application has been verified by representative users who confirmed that Clarius Bladder AI measurements were non-inferior to those of human experts / qualified ultrasound users.

The difference between Clarius Bladder AI and manual measurements by human experts was found to be no greater than the difference between manual measurements within the clinically significant difference margin with a statistical significance level of 0.05.

The performance agreement of Bladder AI compared to human experts obtained from retrospective and prospective study is shown in the table below:

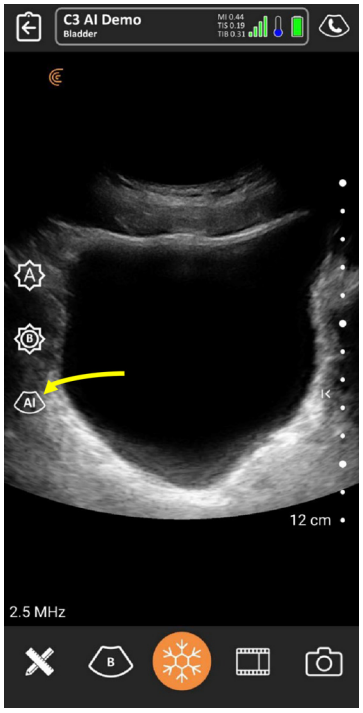
	Mean difference between human experts & Clarius Bladder AI	Upper limit of agreement	Lower limit of agreement
0 – 100 ml	-2.31 ml	20.83 ml	-25.45 ml
100 – 200 ml	-6.82 ml	51.14 ml	-64.78 ml
200 – 400 ml	-15.60 ml	60.50 ml	-91.70 ml

* The measurement performance assumes that Clarius Bladder AI is being compared to manual measurements by human experts.
* The volume range for optimal performance of Clarius Bladder AI is 0 – 400 ml. Although higher bladder volumes (>400 ml) can be estimated, Clarius Bladder AI cannot guarantee the accuracy of measurements beyond this volume.

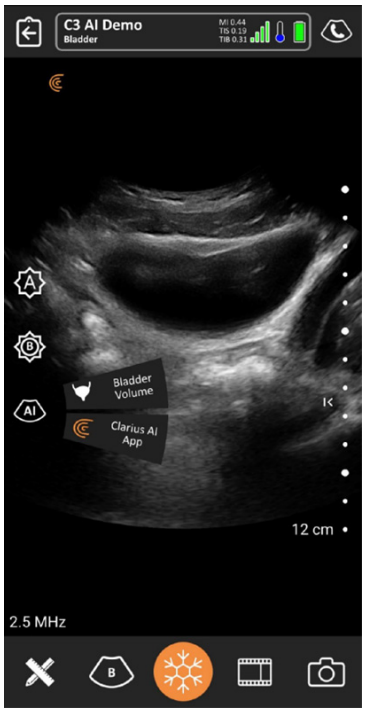
How to Use Clarius Bladder AI

▼To use Clarius Bladder AI for Bladder applications:

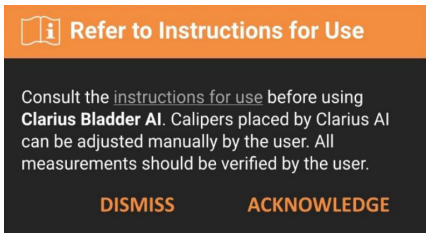
1. Tap the AI button to activate bladder detection and highlighting. The AI button is highlighted by the yellow arrow in the image below. If the AI button is not visible, tap on the screen to make it appear.



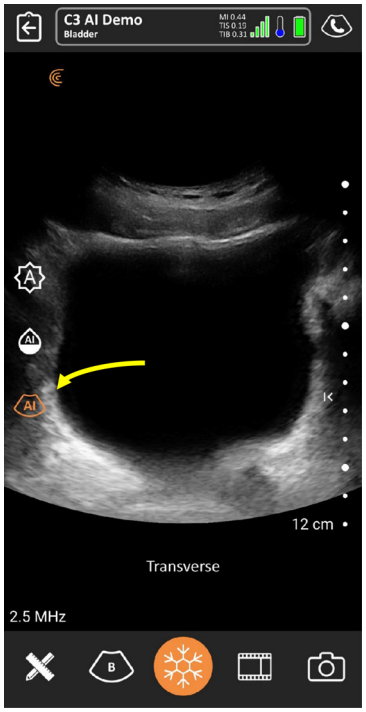
2. A circular carousel will appear with all available AI models. Select “Bladder Volume”.



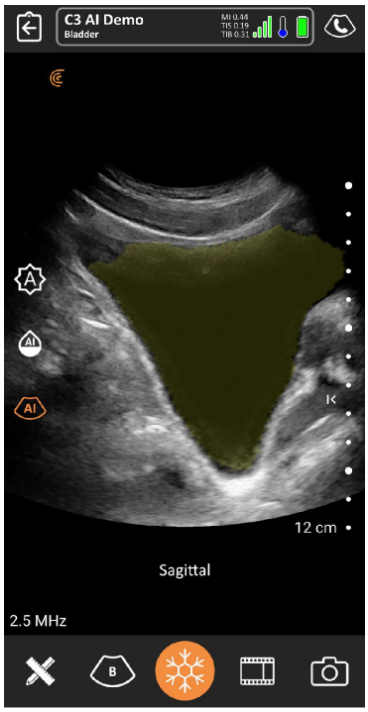
3. If activating for the first time, a pop-up will appear referring to the “Instructions for Use”. Selecting **Dismiss** will dismiss the pop-up but it will re-appear on subsequent uses of Bladder AI. Selecting **Acknowledge** will dismiss the pop-up and it will not be shown again.



4. Once the AI is activated the AI button will turn orange as shown in the image below.

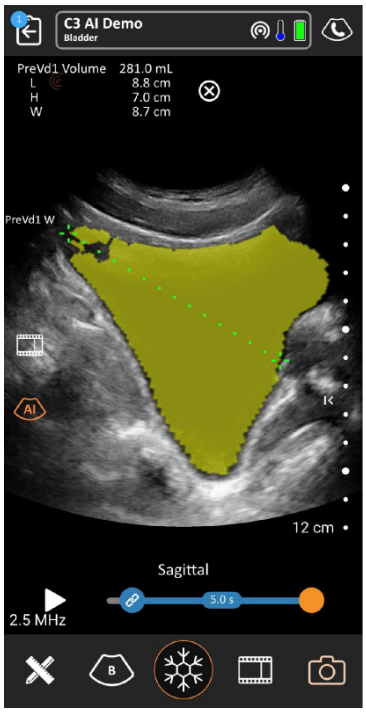


5. Once activated, and the bladder is in view, the bladder is automatically highlighted by a yellow mask on top. The highlighted bladder is shown in the picture below.

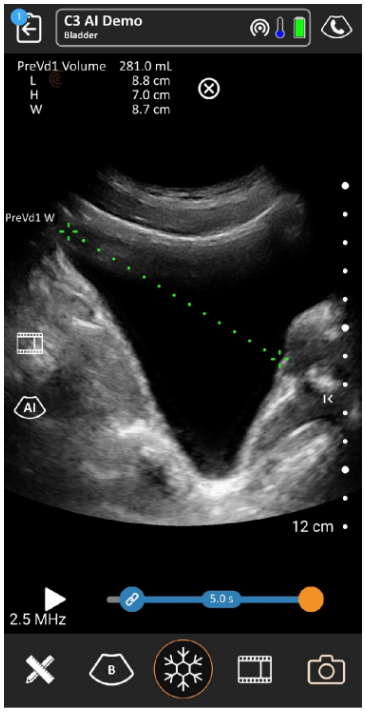


It is necessary to capture both sagittal and transverse images. To display the length, width, and height of the bladder, pause the acquisition by pressing the **Freeze** button. The calipers will be placed automatically depending on the view, with measurements

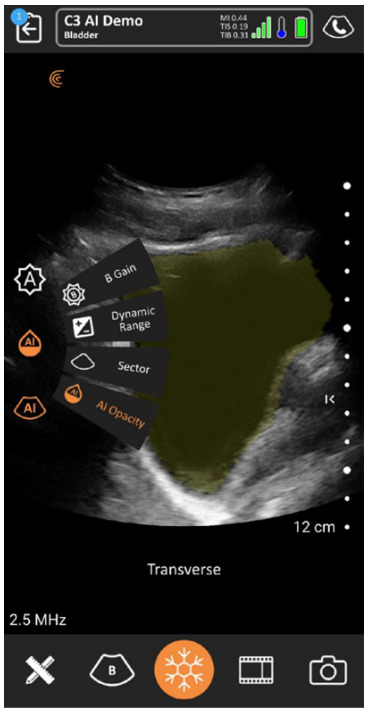
calculated automatically and shown in the top left corner of the screen. Once all three measurements have been captured, the bladder volume will be displayed in the top left corner of the screen.



6. To remove the segmentation mask and disable the AI, tap the AI button and select “Bladder Volume” from the AI carousel wheel. The AI button will then turn white. As a reminder, an orange-colored AI button signifies ON, whereas a white colored AI button signifies OFF. The segmentation mask can also be disabled in Freeze mode. Once the acquisition is Frozen, disable the AI by tapping the button (color should change from orange -> white). This is particularly useful for users who want to see the bladder without the segmentation mask overlay. Refer to the image below.

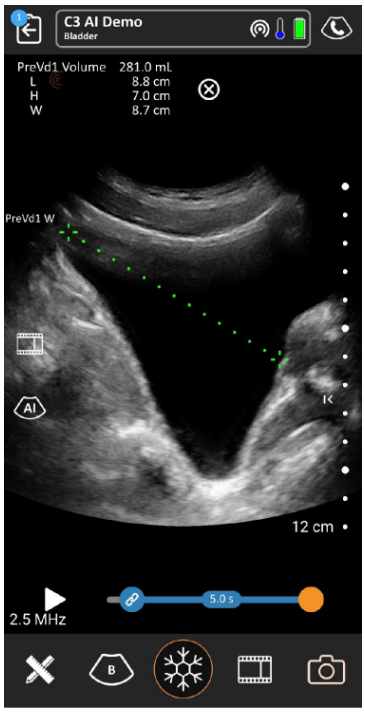


7. The opacity of the mask can also be adjusted by making sure the Slider Control carousel wheel is selected to be on **AI Opacity**. Scroll directions are highlighted by the red arrow in the images below. Opacity is displayed upon change.



Manually adjust measurements: To adjust the measurements manually, freeze the image by pressing the **Freeze** button. Then remove the AI predicted overlay mask from

the image by pressing the AI button. After disabling the AI feature, only the measurement calipers will remain on the image as shown in the figure below. Adjust the measurement by moving the caliper crosshairs.



For instructions on manually adjusting the calipers placed by Bladder AI and video instructions, go to https://clarius.com/user-guide/bladder-ai.

About Clarius OB AI

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Clarius OB AI is a deep learning model developed by Clarius Mobile Health as a workflow tool to assist users in obtaining fetal biometric measurements on Clarius Ultrasound Scanners.

Indications for Use

Clarius OB AI is intended to assist in measurements of fetal biometric parameters (i.e., head circumference, abdominal circumference, femur length, bi-parietal diameter, crown rump length) on ultrasound data acquired by the Clarius Ultrasound Scanner (i.e., curvilinear scanner). The user shall be a healthcare professional trained and qualified in ultrasound. The user retains the responsibility of confirming the validity of the measurements based on standard practices and clinical judgment. Clarius OB AI is indicated for use in adult patients only.

Note to User — Scanners & Presets for Obstetrics

Clarius OB AI applies only to the Clarius Scanner C3 HD3, using the Obstetrics application. Select the correct preset before scanning:

- Early OB: CRL measurement when gestational age ≤ 13 weeks.
- OB: BPD, HC, AC, or FL measurements when gestational age is > 13 weeks.

Purchasing the Clarius Membership gives you access to the OB presets and see the AI button.

Note to User — Auto Hiding Controls

To minimize distractions and improve usability, the Clarius App automatically hides the on-screen controls. This feature can be turned off.

▼If you want the controls to remain visible:

1. Go to the side panel and select **Settings**.
2. Select **Advanced Settings**.
3. Locate **Auto Hiding Controls** and toggle it off.

Note to User — Imaging Artifacts, Performance, & Limitations

The performance of the Clarius OB AI model may be impacted by the presence of artifacts common in ultrasound such as acoustic shadow, lateral shadow, anisotropic effect, reverberation, and refraction. To reduce these artifacts during use, adopt the following techniques:

- Scanning from different angles and planes.
- Ensuring the anatomy of interest is centered and at focus.

The Clarius OB AI model is sensitive to multiple gestations, gestational age less than eight weeks, and when there is little amount of amniotic fluid (e.g., oligohydramnios). The Clarius OB AI model may have suboptimal performance under these conditions. It is only indicated as a workflow tool intended to inform clinical management; it is not intended to replace clinical decision-making. When the Clarius OB AI performance is suboptimal, you can override its output with manual measurements.

Note to User — Management of Cybersecurity Risks

Information Security

See *Information Security* on page 20.

Network Security

See *Network Security* on page 21.

Confidentiality

See ***Confidentiality*** on page 21.

Integrity

See ***Integrity*** on page 22.

Availability

See ***Availability*** on page 22.

Authorization

To use the Clarius Ultrasound Scanners, each individual user must have their own unique Clarius account. This ensures accountability, and limits the use of the system to authorized users. Clarius monitors logins for anomalous activity (i.e., "too many failed login attempts" and "logging in from an unknown location"). If anomalous activity is detected, the user and their Clarius institution admins will be notified via e-mail.

Configuration changes made within the Clarius App are saved to the Clarius Cloud. If the Clarius App is reinstalled or is used on another device, the configuration will be restored upon logging in with the Clarius account.

End-of-Support Transfer of Risk

Clarius provides security-related fixes via software updates. Clarius devices are supported for at least five years after the device model is no longer sold. After five years, Clarius makes a best effort to continue supporting devices via software updates. In the event Clarius can no longer offer software updates for a discontinued device, Clarius will notify users, at least 6 months in advance, via e-mail and on the Clarius Support site (support.clarius.com/hc/en-us) of the planned discontinuation of software update support. After software updates are ceased, the user takes responsibly for all cybersecurity risks if the device continues to be used.

Operating System

See ***System Requirements*** on page 23.

Performance & Uncertainty

The Clarius OB AI application has been adequately verified by representative users who confirmed that Clarius OB AI measurements were non-inferior to those of human experts / qualified ultrasound users.

The difference between Clarius OB AI and manual measurements by human experts was found to be no greater than the difference between manual measurements within the clinically significant difference margin with a statistical significance level of 0.025.

The table shows the Mean of differences and the Variance of the differences in measurements for the biometric measurements, where:

A = Absolute percent (%) change between the automatic measurement and mean reviewer measurement.

M = Mean of the absolute percent (%) change between reviewer pairs.

Biometric Measurement	Mean of differences (A–M)	Variance
HC	-0.009	0.00027
BPD	-0.017	0.00047
AC	-0.013	0.00064
FL	-0.017	0.00066
CRL	-0.036	0.00292

*The measurement performance assumes that Clarius OB AI is being compared to manual measurements by human experts.
*The corresponding gestational age range for optimal performance of Clarius OB AI is between 8 to 39 weeks. Although lower and higher gestational ages can be estimated, Clarius OB AI cannot guarantee the accuracy of measurements beyond this range.

Note to User — Predetermined Changes to Clarius OB AI / PCCP

Clarius OB AI contains an authorized Predetermined Change Control Plan (PCCP) which details the plan for implementing predetermined modifications to Clarius OB AI following the initial release of the Clarius OB AI model.

Description of Planned Modifications

See ***Version History of Clarius OB AI & Notification to Users*** on page 157 for a summary description of the implemented modifications to Clarius OB AI.

According to the PCCP, the planned modifications to Clarius OB AI will be implemented as:

- Modification of model architecture. This modification will involve re-training the Clarius OB AI model using new DNN architectures within the intended use population
- Modification of model training methods and parameters. This modification will involve changes to components and elements of the Clarius OB AI algorithm, namely the

activation functions, loss functions, optimization methods, learning rate decay schedules, input and output resolution, and input pre-processing.

- Modification of post-processing algorithms. This modification will involve changes to the post-processing steps used in the Clarius OB AI algorithm.
- Modification of data input sources. This modification expands the scope of the input data that the Clarius OB AI algorithm operates on to incorporate different models of Clarius Ultrasound Scanner that have been 510(k)-cleared by the FDA and that align with the current standard of care for use in obstetric ultrasound imaging and measurement of fetal biometry. This includes Clarius Ultrasound Scanner models that have already attained FDA clearance (e.g., K213436, K232704) and future scanner models which will undergo 510(k) premarket notification submission and clearance.

See ***Performance & Uncertainty*** on page 155, which shows the current performance of Clarius OB AI compared to human experts for each biometric parameter.

Version History of Clarius OB AI & Notification to Users

Clarius OB AI model version	Modification(s) Implemented	Date of Release (DD/MM/YYYY)	Jurisdiction
Clarius OB AI v 1.6.0	Not applicable. First release.	11/06/2024	Canada
Clarius OB AI v 1.6.0	Not applicable. First release.	25/06/2024	United States of America

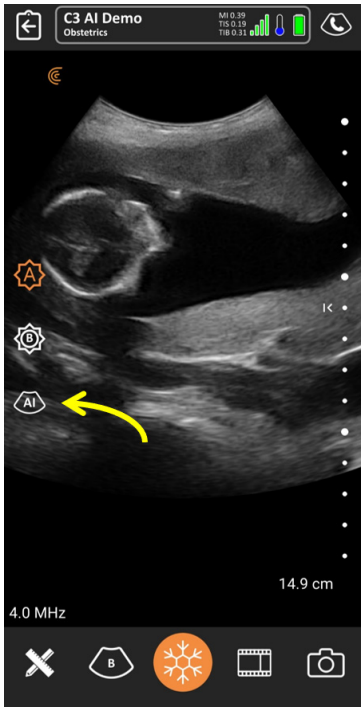
The planned modifications to Clarius OB AI will be implemented, verified, validated, and deployed through updates to the Clarius App software.

The Clarius App update procedures include appropriate transparency to users about the modifications made to Clarius OB AI. Communication to users is provided through software release notes within the Clarius App. Users will be provided with clear and concise information regarding the updated version of the Clarius OB AI model, including any site-specific modifications that were implemented.

How to use Clarius OB AI

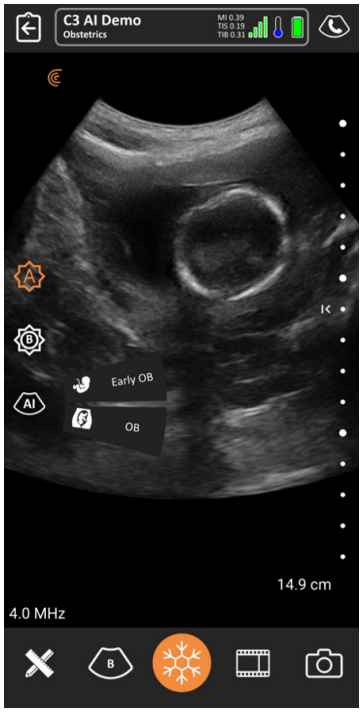
▼To use Clarius OB AI for Obstetrics applications:

1. Tap the AI button to activate Clarius OB AI. The AI button is highlighted by the yellow arrow in the image below. If the AI button is not visible, tap on the screen to make it appear.

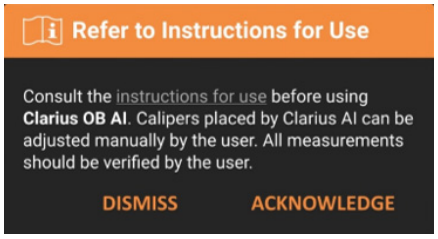


2. A circular carousel will appear. Select one of the following:

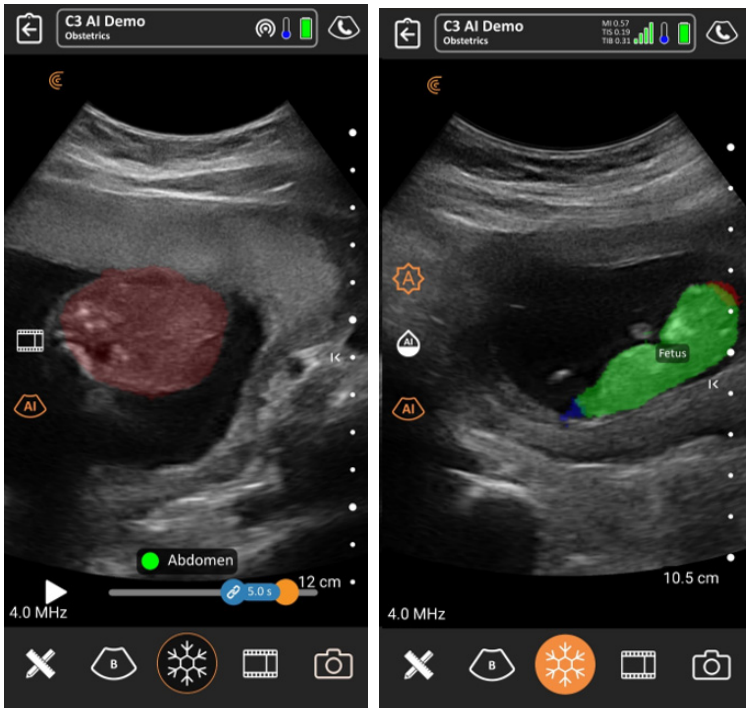
   - Early OB: CRL measurement when gestational age ≤ 13 weeks.
   - OB: BPD, HC, AC, or FL measurements when gestational age is > 13 weeks.



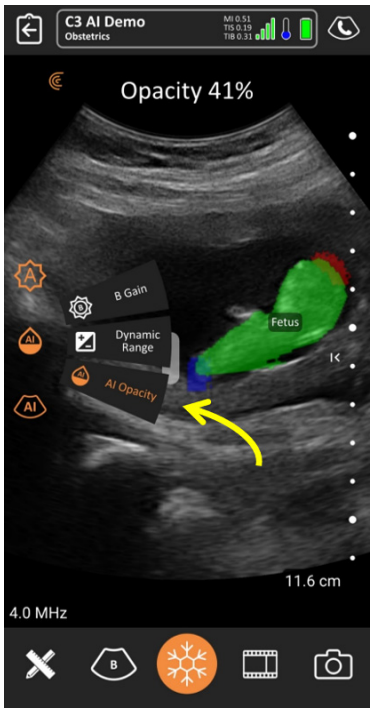
3. If activating for the first time, a pop-up will appear referring to the "Instruction for Use". Selecting **Dismiss** will dismiss the pop-up but it will re-appear on subsequent uses of Clarius OB AI. Selecting **Acknowledge** will dismiss the pop-up and it will not be shown again.



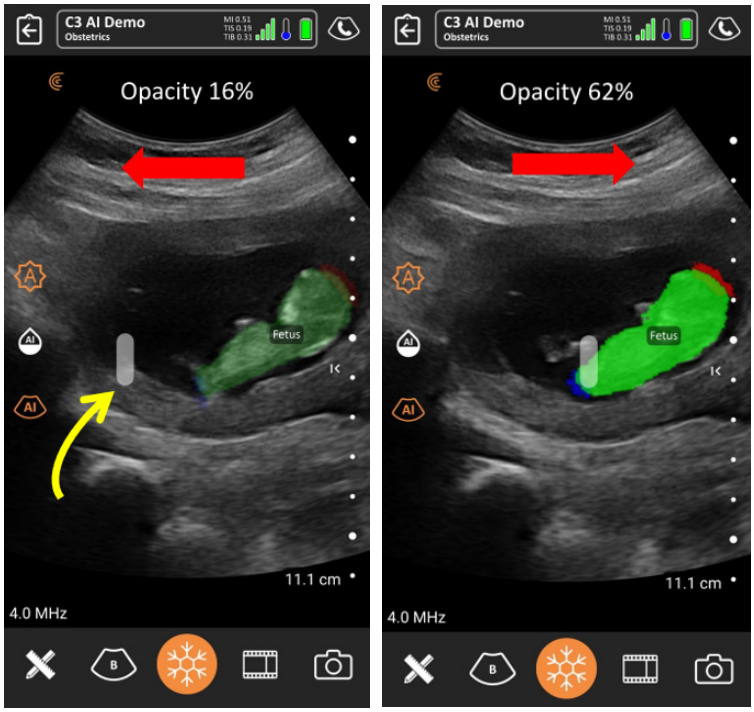
4. Once the AI is activated the AI button will turn orange and the desired fetal anatomy, when in view, is automatically highlighted by a green (head), red (abdomen), or blue (femur) mask as shown in the images below. Note that other mask colors may briefly appear and indicate sub-optimal views. The fetus is highlighted in a case of ≤ 13 weeks and the abdomen highlighted in a case of > 13 weeks.



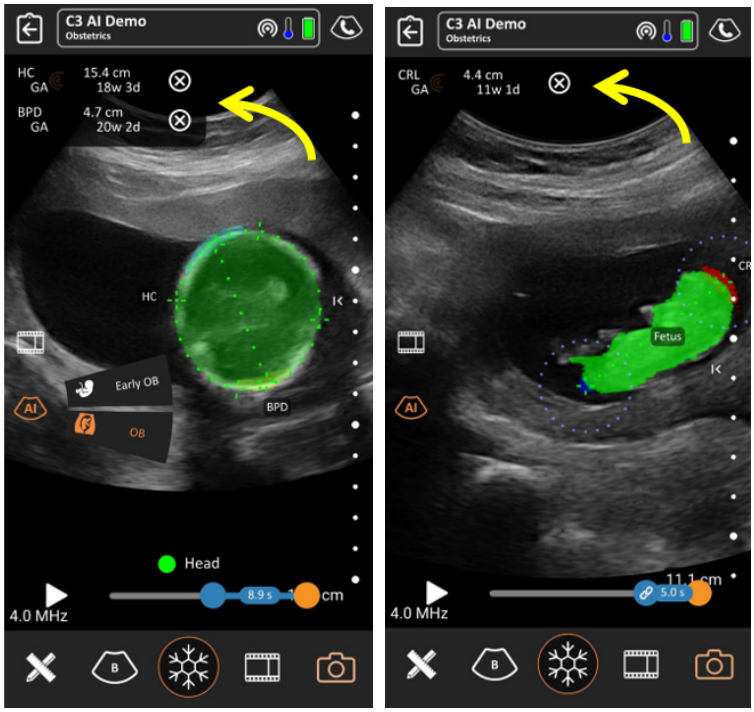
5. The opacity of the mask can also be adjusted by making sure the Slider Control carousel wheel (the teardrop-shaped icon) is selected and then pressing **AI Opacity.** Note that this teardrop-shaped icon may not initially be visible if the user has frozen the image and a film strip may appear in its place (depending on the last function selected by the user). If this is the case, click on the film strip, then select the teardrop-shaped icon to adjust the opacity of the mask.

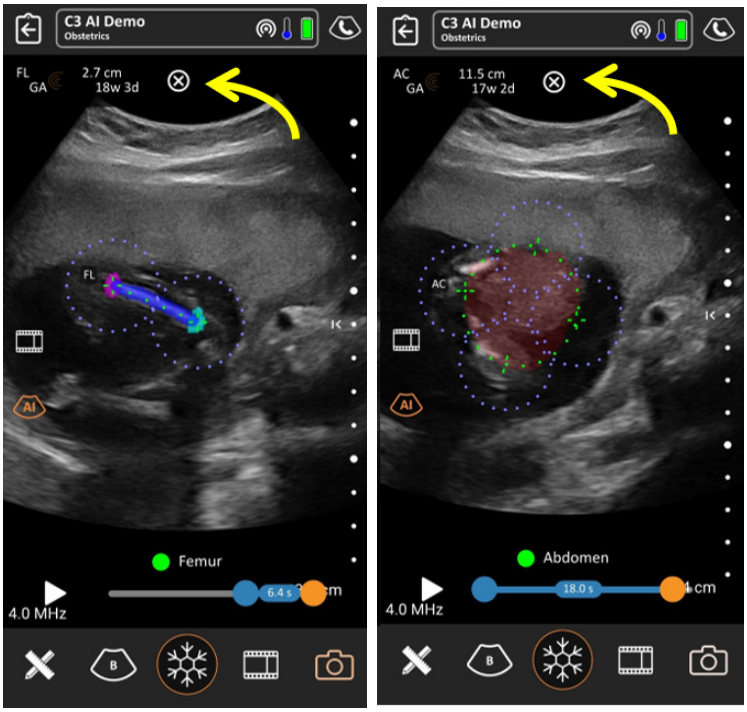


6. The opacity of the mask can be varied by dragging the slider control horizontally. Dragging it to the left will reduce the opacity of the segmentation mask while dragging it to the right will increase the opacity of the mask.



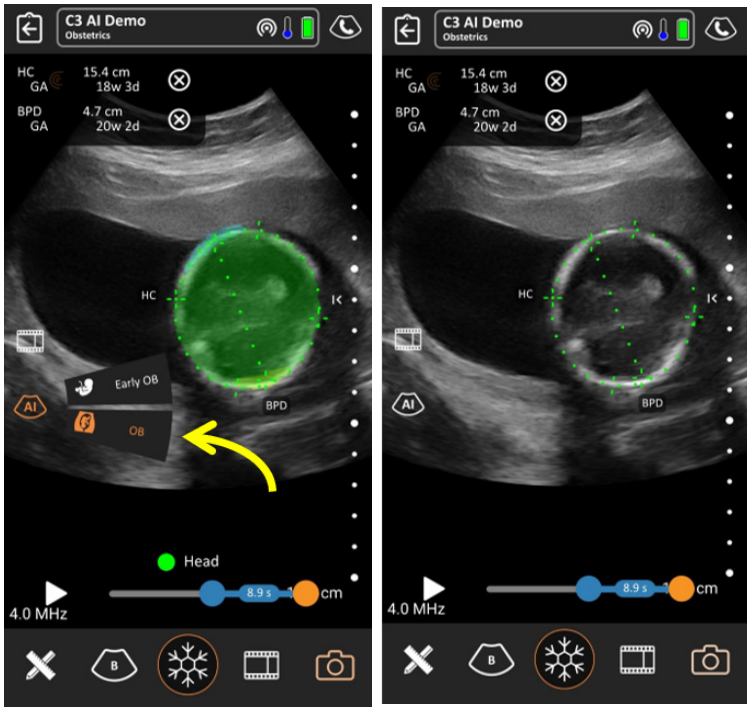
7. To display the measurements and corresponding gestational age, pause the acquisition by pressing the **Freeze** button. The calipers will be placed automatically, with measurements calculated automatically and shown in the top left corner of the screen as shown in the images below showing the various biometric measurements.



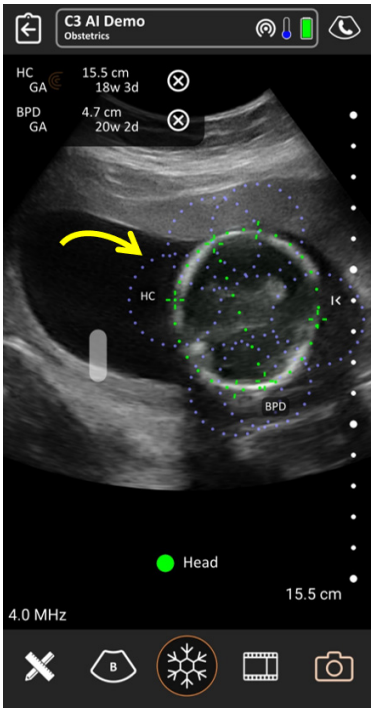


To remove the segmentation mask and disable the AI, tap the AI button and deselect the chosen preset (**OB** or **Early OB**) from the AI carousel wheel. The AI button will then turn white. As a reminder, an orange-colored AI button signifies ON, whereas a white colored AI button signifies OFF. The segmentation mask can also be disabled in Freeze mode. Once the acquisition is frozen, disable the AI by tapping the AI button (the color should change from orange -> white). This is particularly useful for users

who want to see the ultrasound image without the segmentation mask overlay. See the example in the image below. Another option to view the ultrasound image without the segmentation mask overlay is to set the segmentation opacity to 0 by swiping to the left on the screen.



8. Manually adjust measurements: To adjust the measurements manually, freeze the image by pressing the **Freeze** button. Then adjust the measurement by dragging the caliper crosshairs.



For instructions on manually adjusting the calipers placed by Clarius OB AI, and for video instructions, go to https://clarius.com/user-guide/ob-ai.

Revision History

User Manual Revision	Revision Date	Description
1	November 19, 2021	First official release.
2	January 12, 2022	Added: Intended Patient Population. Changed: Symbols Glossary, About the Clarius Ultrasound Scanner, About the Charger, Accessories, Cleaning & Disinfecting, Battery Safety. Removed: Clarius Foot Pedal.
3	April 6, 2022	Added: Chemical Changed: copyright, Symbols Glossary, Precautions, Accessories, Product Safety, “Risk, Product Specification, Design Review, & Verification/ Validation” table, Measurement Accuracy Tables, Acoustic Output Tables, “Fan” to “Clarius Fan HD3”, “Charger” to “Clarius Charger HD3”. Removed: Biocompatibility Moved: “Using the Clarius Charger HD3” from Chapter 2 to 3.
4	May 2, 2022	Changed: Product Classification.
5	November 1, 2022	Added: About the Clarius Power Fan HD3, Cleaning the Micro USB Cable, Disinfecting the Micro USB Cable. Changed: “Clarius Fan HD3” to “Clarius Power Fan HD3”, Charging the Clarius Scanner HD3, Cleaner & Disinfectant Usage, back page.
6	January 12, 2023	Changed: copyright, Clarius Power Fan HD3, back page
7	February 27, 2023	Added: Voice Control. Changed: back page.
8	May 19, 2023	Changed: About this Manual, About the Clarius Ultrasound Scanner, Start Scanning, System Specifications.
9	September 28, 2023	Added: PAL HD3 scanners. Changed: Indications for Use Tables, High-Level Disinfection, Measurement Accuracy Tables, Environmental Specifications, Scanner Specifications, Acoustic Output Tables. Removed: ANATEL.
10	February 14, 2024	Added: About This AI User Guide, About Clarius MSK AI, About Clarius Bladder AI. Changed: copyright, About this Manual, About the Clarius Ultrasound Scanner, Using the Clarius Ultrasound Scanner, Setting Up the Clarius Charger HD3, Cleaning & Disinfecting, Measurement Accuracy Tables.
11	March 6, 2024	Changed: Clarius AI User Guide.
12	March 27, 2024	Changed: “Micro USB cable” to “Clarius Micro USB Cable”, Clarius AI User Guide.
13	April 13, 2024	Changed: Clarius AI User Guide.
14	June 4, 2024	Added: Clarius OB AI. Changed: Network Security, Clarius AI User Guide.
15	June 18, 2024	Changed: Clarius AI User Guide, About Clarius OB AI.
16	June 25,2024	Changed: Clarius AI User Guide.
17	October 10, 2024	Changed: Environmental Specifications, Clarius AI User Guide.
17.1	October 17, 2024	Changed: Status Lights, Charging the Clarius Scanner HD3.
17.2	December 3, 2024	Changed: Syringe Safety.

User Manual Revision	Revision Date	Description
18	December 4, 2024	Changed: Status Lights, Charging the Clarius Scanner HD3,Syringe Safety.
19	January 13, 2025	Changed: copyright, Clarius AI User Guide.
20	March 10, 2025	Changed: Symbols Glossary, Clarius AI User Guide.
21	April 4, 2025	Changed: Clarius AI User Guide, Measurement Accuracy Tables.

Clarius Ultrasound Scanner - HD3 Scanners User Manual

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