User Manual

English

EPIQ Diagnostic Ultrasound Systems

Using VeriSight and VeriSight Pro ICE Catheters with the Ultrasound System

PHILIPS

This Page Left Intentionally Blank

3000 031 06971_I / MAR 2024

Philips

Contents

3000 031 06971_ I / MAR 2024

Philips

3000 031 06971_I / MAR 2024

Philips

1 Read This First

The user information for your Philips product describes the most extensive configuration of the product, with the maximum number of options and accessories. Some functions described may be unavailable on your product's configuration.

This manual is intended to assist you with the safe and effective operation of the VeriSight and VeriSight Pro Intracardiac Echo (ICE) catheters.
This manual contains information specific only to use of the VeriSight and VeriSight Pro ICE catheters on the EPIQ 7C, EPIQ CVx, and EPIQ CVxi ultrasound systems. Before using either ICE catheter, read the instructions for use that accompany the catheter, and strictly observe all warnings and cautions. For information on using the ultrasound system, see the ultrasound system user information.

The VeriSight and VeriSight Pro ICE catheters are sterile, disposable, single-use catheters that enable intracardiac ultrasound imaging of cardiac anatomy and vasculature. The distal end of the catheter contains an ultrasound imaging transducer that produces images on a compatible EPIQ ultrasound system. Both catheters support 2D imaging. The VeriSight Pro ICE Catheter also supports xPlane and 3D imaging. Four-way steering from the catheter handle enables you to flex and lock the catheter tip. For detailed instructions for the catheter, see the instructions for use provided with the catheter.

3000 031 06971_I / MAR 2024

REACH Declaration

The REACH regulation requires Philips to provide chemical content information for "Substances of Very High Concern" (SVHC) if they are present above 0.1% of the product weight. Philips regularly updates its list of products with SVHC above the threshold. For the most-current list, see the Philips REACH website:

www.philips.com/REACH

Indications for Use for the ICE Catheter

The catheter is intended for intracardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart. The catheter is intended for imaging guidance only, not treatment delivery, during cardiac interventional percutaneous procedures.

Indications for Use/Intended Use for the EPIQ Ultrasound System

The intended use of Philips EPIQ series diagnostic ultrasound systems is diagnostic ultrasound imaging and fluid flow analysis of the human body, with the following indications for use: Abdominal, Cardiac Adult, Cardiac other (Fetal), Cardiac Pediatric, Cerebral Vascular, Cephalic (Adult), Cephalic (Neonatal), Fetal/Obstetric, Gynecological, Intra-cardiac Echo, Intra-luminal, Intraoperative (Vascular), Intraoperative (Cardiac), Musculoskeletal (Conventional), Musculoskeletal (Superficial), Other: Urology, Pediatric, Peripheral Vessel, Small Organ (Breast, Thyroid, Testicle), Transesophageal (Cardiac), Transrectal, Transvaginal.

The clinical environments where Philips EPIQ diagnostic ultrasound systems can be used include clinics, hospitals, and clinical point-of-care for diagnosis of patients.

When integrated with Philips EchoNavigator, the systems can assist the interventionalist and surgeon with image guidance during treatment of cardiovascular disease in which the procedure uses both live X-ray and live echo guidance.

The systems are intended to be installed, used, and operated only in accordance with the safety procedures and operating instructions given in the product user information, and only for the purposes for which it was designed. However, nothing stated in the user information reduces your responsibility for sound clinical judgement and best clinical procedure.

Clinical Options

EPIQ ultrasound systems equipped with the VeriSight ICE Catheter or the VeriSight Pro ICE Catheter add the Intracardiac Echo indication for use in Interventional Cardiology options.

3000 031 06971_I / MAR 2024

Philips

2 Safety

Please read this information before using your ICE catheter with an ultrasound system. For complete safety information, see the user information for the ICE catheter and the ultrasound system. This section covers general safety information only. Safety information that applies only to a specific task is included in the procedure for that task.

WARNING
Warnings highlight information vital to the safety of you, the operator, and the patient.

CAUTION
Cautions highlight ways that you could damage the product and consequently void your warranty or service contract or ways that you could lose patient or system data.

NOTE
Notes include additional comment or explanation about installation, operation, or maintenance information that is important but not hazard-related.

3000 031 06971_I / MAR 2024

Philips

Symbols

The International Electrotechnical Commission (IEC) has established a set of symbols for medical electronic equipment that classify a connection or warn of potential hazards. Of those symbols, the following may be used on your product, its accessories, or its packaging.

Symbol	Standard and Reference	Reference Description	Additional Information
	ISO 15223-1, Symbol 5.2.8	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
	IEC 60878, Symbol 2794	Packaging unit	To indicate the number of pieces in the package.
	21 CFR 801.15(c)(1)(i)F	Prescription only	Caution: Federal law restricts this device to sale by or on the order of a physician.
	EN 50419:2006 WEEE Directive 2002/96/EC, Symbol 4.2	WEEE symbol	Indicates the need for separate collection for electrical and electronic equipment in compliance with the Waste Electrical and Electronic Equipment (WEEE) Directive.
	None	Part number	Indicates part number.
	ISO 15223-1, Symbol 5.3.4	Keep dry	Indicates a medical device that needs to be protected from moisture.
	ISO 15223-1, Symbol 5.3.2	Keep away from sunlight	Indicates a medical device that needs protection from light sources.
	IEC 60601-1, Table D.2, Symbol 10	Follow instructions for use	Refer to instruction manual/ booklet.

3000 031 06971_I / MAR 2024

Philips

Symbol	Standard and Reference	Reference Description	Additional Information
IPXØ	IEC 60529	Not protected: no protection from fluid ingress	Indicates that the device is not protected from fluid ingress.
	ISO 15223-1, Symbol 5.4.4	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	ISO 15223-1, Symbol 5.1.7	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	ISO 15223-1, Symbol 5. 1.6	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 15223-1, Symbol 5.1.5	Batch code	Indicates the manufacturer’s batch code so that the batch or lot can be identified.
	ISO 15223-1, Symbol 5.1.3	Date of manufacture	Symbol for date of manufacture. This symbol is accompanied by a date.
	ISO 15223-1, Symbol 5.1.1	Manufacturer/manufactured for	Indicates the medical device manufacturer.
	IEC 62570 and ASTM F2503-13, Fig. 9	MR unsafe	Indicates that the system is MR unsafe and presents a projectile hazard. Keep outside of the MRI scanner room.

3000 031 06971_I / MAR 2024

3 Patient Interface Module

The Patient Interface Module (PIM) is a 2.5-m (8.2-ft) cable that connects the catheter to the ultrasound system.

WARNING
Use the VeriSight and VeriSight Pro ICE catheters with only the Patient Interface Module (PIM) and compatible EPIQ series ultrasound systems. Any other use or inappropriate electrical connection may pose a delay in the availability of the imaging capabilities of the device. For more information on imaging transducer compatibility, see the ultrasound system user information.

WARNING
Using a damaged Patient Interface Module (PIM) can cause prolonged procedure times and complications associated with extended procedure times. Always inspect the entire PIM before use. If the connectors are cracked or chipped, the cable is abraded, or other damage is present, do not use the PIM.

WARNING
Do not use the Patient Interface Module (PIM) in a magnetic resonance environment. The device may not perform as intended and may present additional risks to the patient.

3000 031 06971_I / MAR 2024

Philips

Patient Interface Module (PIM)

Connecting the PIM to the Ultrasound System

1. On the front of the ultrasound system, insert the system-side connector into an open transducer receptacle.
2. Move the locking lever to the left.

Connecting the PIM to the Ultrasound System

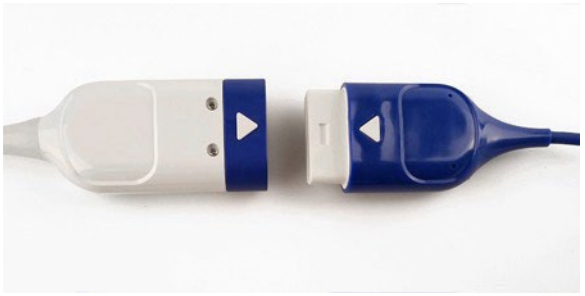
3000 031 06971_I / MAR 2024

Philips

Connecting an ICE Catheter to the PIM

CAUTION
Excessively moving the PIM or ICE catheter connectors side-to-side or up and down while connecting or disconnecting the devices may damage the connectors and cause power and thermal monitoring faults.

1. Align the white arrows on the PIM connector and the ICE catheter connector.
2. Firmly push the connectors together, while keeping them level with each other.
3. If an error message appears, or if the reverberation that indicates proper catheter imaging is absent, disconnect and reconnect the ICE catheter.
4. If the errors persist, contact your Philips representative.



PIM Connector and ICE Catheter Connector

Disconnecting the ICE Catheter from the PIM

CAUTION
Excessively moving the PIM or ICE catheter connectors side-to-side or up and down while connecting or disconnecting the devices may damage the connectors and cause power and thermal monitoring faults.

Firmly pull the PIM and ICE catheter connectors away from each other in a straight line, keeping your hands level.

3000 031 06971_I / MAR 2024

Philips

4 Imaging with the ICE Catheter

WARNING

To avoid the risk of electrical shock hazards, always inspect the entire ICE catheter before use. Check the distal end, catheter housing, cable, and connector before use. Do not use the catheter if the transducer face is cracked, chipped, or torn; the housing or connector is damaged; or the cable has abrasions or other damage.

CAUTION

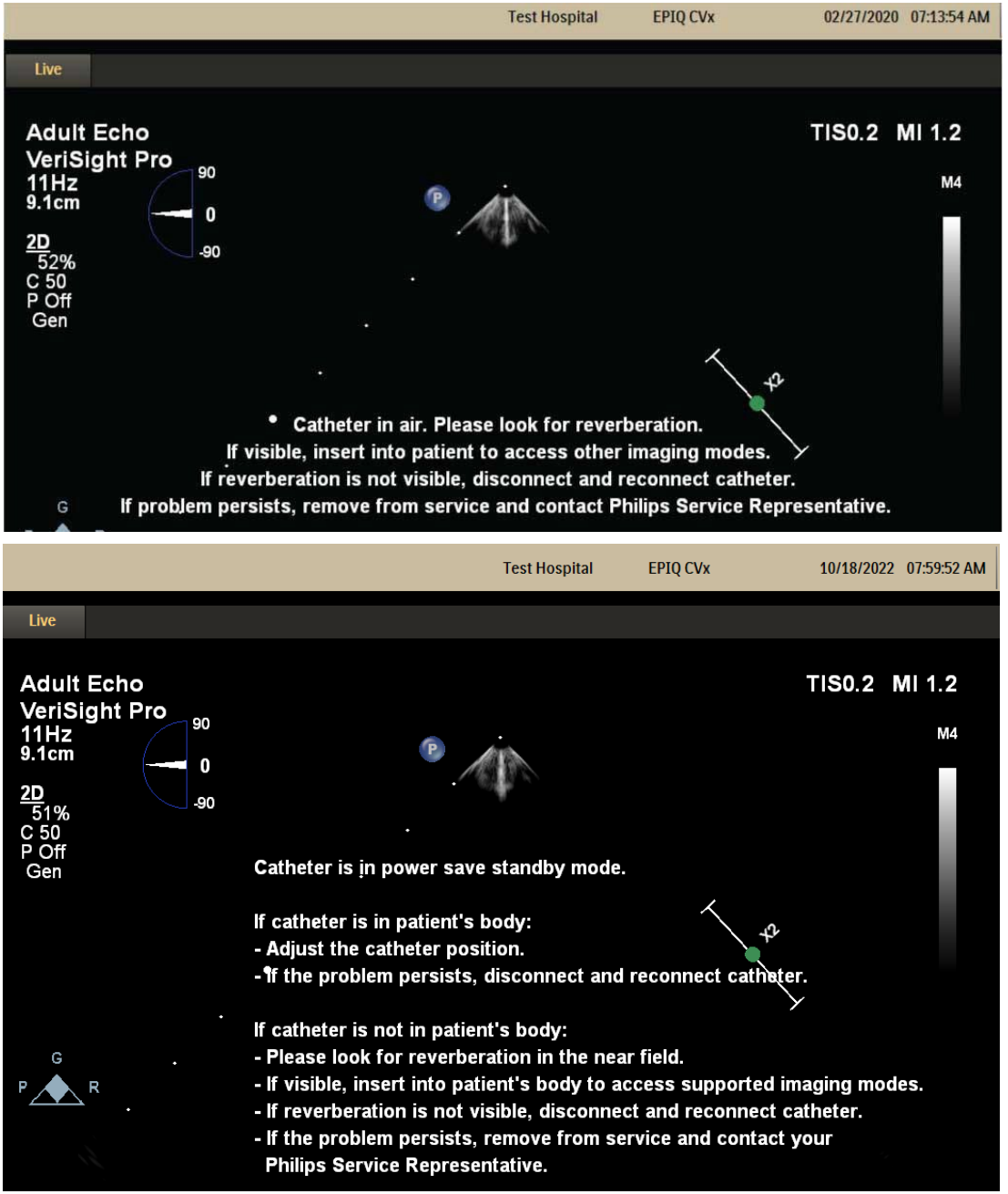
To avoid damage to the ICE catheter, do not disconnect the catheter or the Patient Interface Module (PIM) until after the ultrasound system has activated the catheter and begun imaging.

1. Connect the PIM to the ultrasound system and select it on the touch screen.
2. Connect the ICE catheter to the PIM (see “Connecting an ICE Catheter to the PIM” on page 12).
3. Do one of the following:
   - If the catheter is the only transducer connected to the system, the system begins 2D imaging in the default preset. If you want a different preset, touch the preset name.
   - If other transducers are connected to the system, touch **PIM** to select the catheter, and touch a preset. The system begins 2D imaging.
4. Verify the message, “Catheter is in power save standby mode.” Or “Catheter in air.” appears on the EPIQ main display as seen in the image below.

Note: Depending on the software version installed, user will see one of the following messages on the screen:

3000 031 06971_I / MAR 2024

Philips

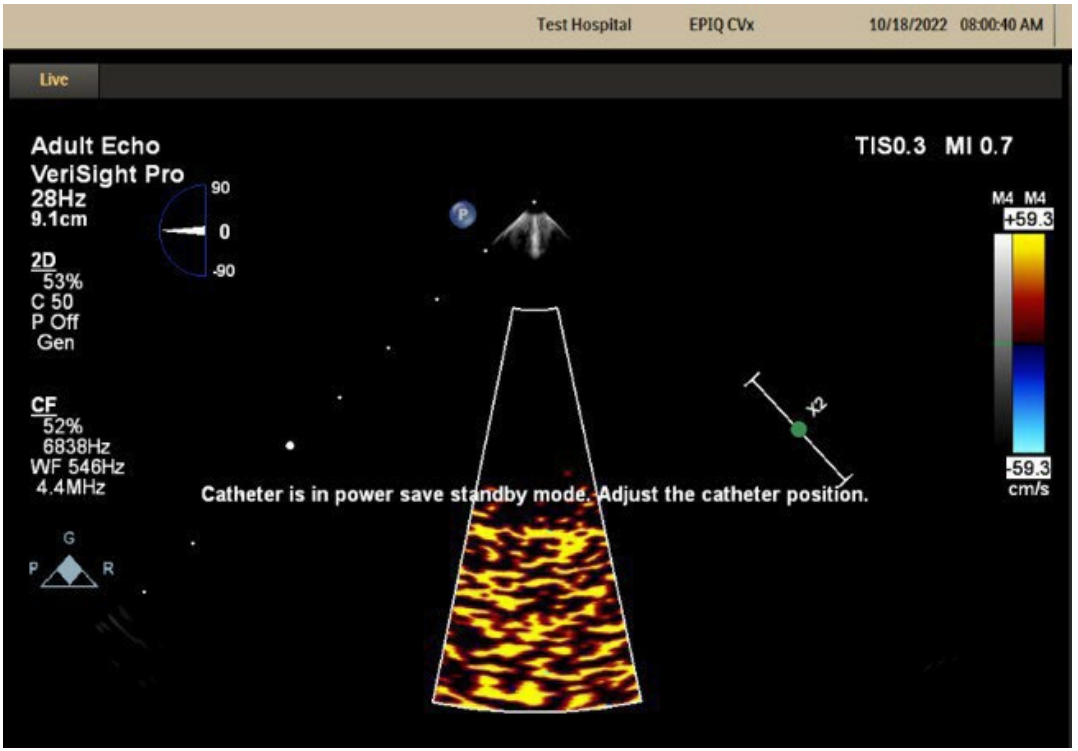


Reverberation on the Imaging Display

3000 031 06971_I / MAR 2024

Philips

5. While imaging in 2D Color, xPlane and 3D Zoom Preview Echo or Color, if “Catheter is in power save standby mode. Adjust the catheter position.” message appears as in the image below, adjust the catheter position.



In 2D Color, xPlane and 3D Zoom Preview Echo and Color Imaging Modes

6. If the system displays a power or thermal-monitoring error message, disconnect the PIM from the ultrasound system, disconnect the ICE catheter from the PIM, and then see “Responding to Connection Errors” on page 24. Also see “Avoiding Temperature Elevation in the Catheter Tip” on page 16.
7. Adjust the image plane with the seek angle controls. For more information, see “Seek Angle” on page 16.
   - To set the seek angle to -45, 0, or 45 degrees, touch **Quick Angle**.
   - To make fine adjustments to the seek angle, turn **Seek Angle**.
   - To reset the seek angle to 0 degrees, press the middle trackball button.

NOTE

While imaging with the ICE catheter in Live xPlane imaging, tilting laterally to the maximum allowed range degrades the extreme left or right sides of the lateral image (right image) at certain angles of left and right planes

3000 031 06971_I / MAR 2024

Avoiding Temperature Elevation in the Catheter Tip

When the ICE catheter is connected to the ultrasound system and in open air (outside the patient), do the following, to avoid increasing the temperature of the catheter tip:

1. If imaging modes other than 2D are active, switch the system to 2D mode only.
2. Press **Freeze**.

Access to imaging modes other than 2D is disabled until the catheter is inserted in the patient. For more information about tip temperature, see “ICE Catheter Temperature Sensing” on page 18.

Seek Angle

The **Seek Angle** touch screen control sets the image plane by adjusting the angle of the sound wave as it moves away from the transducer. The displayed image plane icon shows the current angle of the sound wave, in degrees. The ICE catheter's optimal image quality setting is -60 to 60 degrees.

NOTE

For best image quality, limit the seek angle to a maximum of 60 degrees. Imaging at angles greater than 60 degrees causes the seek angle indicator arrow to become red or gold, indicating the potential for degraded lateral image quality. (Color depends on the software version installed.)

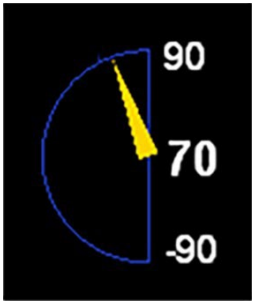


Image Plane Icon Displaying an Angle Greater Than 60 Degrees

3000 031 06971_I / MAR 2024

Philips

You can define seek angle and tilt in custom protocols using the following rules:

- The ultrasound system processes angles from 0 to 90 degrees as positive angles and angles from 0 to -90 degrees as negative angles.
- The ultrasound system converts positive angles above 90 degrees into values that are compatible with the limits of the ICE catheter.

Auto Focal Zone Tracking

When you adjust the image depth, automatic focal zone tracking adjusts the focal zone to the closest default zone. This feature is unavailable on zoomed images. You can also manually adjust the focal zone.

Foot Switch Option

If the foot switch is installed on your system, you can use it to rotate the 2D image plane and the xPlane secondary plane while imaging with an ICE catheter.

Catheter	Left Pedal	Center Pedal	Right Pedal
VeriSight	Decrease scan angle	• Modes except spectral Doppler: Resets the seek angle to 0 degrees • Spectral Doppler mode: Switches between live 2D and live Doppler	Increase scan angle
VeriSight Pro	Decrease scan angle	xPlane On/Off	Increase scan angle

3000 031 06971_I / MAR 2024

5 ICE Catheter Temperature Sensing

The ICE catheters contain a built-in temperature sensor near the distal tip. The sensor monitors the catheter tip temperature to prevent potential over-heating of vascular or heart tissue. The surface temperature of the distal tip appears as the **TEMP** on the imaging display.

The patient's temperature is required to accurately estimate the distal tip temperature. By default, the system assumes that the patient temperature is 37°C (98.6°F). You must manually enter the actual patient temperature, which appears as the **PAT T** on the imaging display.

The Auto-Cool feature operates as follows:

- At 41.0°C (105.8°F), a system message indicates that Auto-Cool is imminent.
- At 42.5°C (108.5°F), a system message indicates that Auto-Cool is in progress, and the system automatically freezes (stops scanning).
- At temperatures greater than 43.5°C (110.3°F), the ultrasound system stops imaging, removes the ICE catheter selection from the touch screen, and displays a warning. Disconnect the PIM from the ultrasound system, allow the ICE catheter to cool, and then reconnect the PIM to resume imaging.

WARNING

If the patient temperature is above 37°C (98.6°F) and the Pat Temp control is set below the actual patient temperature, then the system can underestimate the temperature of the ICE catheter's distal tip. This can expose patients to excessive temperatures. If the patient temperature is at or near 37°C (98.6°F) and the Pat Temp control is set above the actual patient temperature, then the system can overestimate the temperature of the distal tip. This can prematurely trigger the Auto-Cool feature.

3000 031 06971_I / MAR 2024

Philips

Patient Temperature

Entering a patient's temperature enables the Auto-Cool feature to calculate tip temperature more accurately, which can prevent unnecessary interruptions while scanning. If a patient's temperature is above normal, entering a temperature can avoid exposing the patient to excessive temperatures.

Always check the patient's temperature before inserting the ICE catheter. If it is above normal, whether from fever or therapeutic heating from a cardiac bypass heart-lung machine, perform the procedure in "Entering Patient Temperature" on page 20 before inserting the ICE catheter. Also, follow that procedure if a patient's temperature rises during a study.

Measure the patient's core temperature. For patients undergoing surgery, determine the temperature by direct measurement or by monitoring the temperature of blood returning from the bypass pump heat exchanger.

For closed-chest situations, rectal temperature is the best estimate of core temperature. You can also use oral temperatures, even though they can be one degree lower than the core temperature. If you measure an axillary temperature, which can be two degrees lower than the core temperature, add one or two degrees.

3000 031 06971_I / MAR 2024

Philips

Entering Patient Temperature

1. If you have not already done so, select the ICE catheter.
2. Turn **Pat Temp** to enter the patient's measured temperature.

NOTE
Each time you turn off or reset the system, or enter a new patient ID, the system assumes that the patient temperature is 37°C (98.6°F).

Using the Temperature Display

Both the patient temperature (assumed or entered) and the ICE catheter temperature appear in the lower left corner of the display when enabled. On the display, the patient temperature is labeled **PAT T**, and the ICE catheter temperature is labeled **TEMP**.

A less-than sign (<) after **TEMP** indicates that the ICE catheter's distal tip temperature is below the patient temperature (**PAT T**) assumed by the system, which is either 37°C (98.6°F) or the temperature you entered.

1. Connect the ICE catheter and select the preset.
2. If necessary, swipe the touch screen to display **Temp Display**.
3. Touch **Temp Display** to display or hide the temperature display.
4. Touch **Temp Units** to switch the temperature scale between Fahrenheit and Celsius.

3000 031 06971_I / MAR 2024

Philips

6 ICE Catheter Disposal and PIM Cleaning

The VeriSight and VeriSight Pro catheters are single-use devices. After use, discard the catheters according to your local medical-waste disposal regulations.

To clean and disinfect the Patient Interface Module (PIM), use the following procedures.

WARNING
Always use protective eyewear and gloves when cleaning or disinfecting any equipment.

CAUTION
Do not immerse the Patient Interface Module (PIM) or use it if it appears wet. Moisture trapped between the PIM and the ICE catheter can damage the catheter and the PIM, causing a possible loss of imaging capability.

CAUTION
When cleaning and disinfecting the Patient Interface Module (PIM), do not allow any fluid to enter the connector through the electrical contacts, strain reliefs, or connector housing. When wiping or spraying the connector housings, wipe or spray only the outer surfaces. If available, place a connector-cover splash guard over the electrical contacts to help prevent fluid from entering the connector housing. Damage due to fluids in these areas is not covered by the warranty or your service contract.

Cleaning the PIM

Clean the PIM after each use. It is an essential step before effective disinfection.

a. Gather the following supplies:
   - Soft moist cloth or non-abrasive sponge
   - Compatible cleaners or cleaning wipes for the cable and connector. See “Approved Cleaners and Disinfectants” on page 23.
   - Soft, dry, lint-free cloth

3000 031 06971_I / MAR 2024

Philips

b. Disconnect the PIM from the system. Push the connector cover, if available, onto the connector to protect against fluid splashing onto the contacts.

c. To remove any foreign material on the PIM cable or connectors, use a soft cloth lightly dampened in a mild soap and water solution.

d. To remove any remaining particulate and cleaning-solution residue on the PIM cable or connectors, use cleaning wipes (according to the manufacturer's instructions), or wipe thoroughly with water. Do not immerse or rinse the PIM.

e. Air dry or use a soft cloth to dry the PIM.

f. Examine the PIM for damage such as cracks, splitting, sharp edges, or projections. If damage is evident, discontinue use of the PIM and contact your Philips representative.

Low-Level Disinfecting the PIM

NOTE
The Patient Interface Module (PIM) can be disinfected using the wipe method only if the product labeling of the compatible disinfectant that you are using indicates that it can be used with a wipe method.

1 Gather the following supplies:
- Soft moist cloth or non-abrasive sponge
- Compatible low-level or intermediate-level disinfectants for the cable, strain relief, and connectors. See “Approved Cleaners and Disinfectants” on page 23.
- Soft, dry, lint-free cloth

2 Clean the PIM (see “Cleaning the PIM” on page 21). Observe all warnings and cautions.

3 Wipe or spray the cable, strain relief, and connectors with the disinfectant, following disinfectant label instructions for temperature, wipe durations, and duration of disinfectant contact. Ensure that the disinfectant solution does not enter the device or the connector.

When disinfecting the connector housings, wipe or spray only the outer surfaces; do not allow any type of fluid to enter through the strain relief or electrical contacts.

3000 031 06971_I / MAR 2024

Philips

4. Air dry or use a soft, dry, lint-free cloth to dry the PIM.
5. Examine the PIM for damage, such as cracks, splitting, fluid leaks, or sharp edges or projections. If damage is evident, discontinue use of the PIM and contact your Philips representative.

Approved Cleaners and Disinfectants

Approved cleaners and disinfectants for the Patient Interface Module are products that have "T,C" in column 3 of the "Disinfectants and Cleaning Solutions Compatibility" table in the *Disinfectants and Cleaning Solutions for Ultrasound Systems and Transducers* document. That document is available with your system user information or on the "Transducer and System Care" website:

www.philips.com/transducercare

3000 031 06971_ I / MAR 2024

Philips

7 Responding to Connection Errors

If one of these error messages appears during connection or use of the ICE catheter, perform the following procedure.

- Disconnect the PIM from the ultrasound system. Disconnect the catheter from the PIM. Remove current catheter from service. Reconnect PIM and connect another catheter. If problem persists, contact your Philips Service Representative.
- Disconnect the PIM from the ultrasound system. Disconnect the catheter from the PIM. Let cool. Reconnect PIM and then catheter. If problem persists, contact your Philips Service Representative.
- Disconnect the PIM from the ultrasound system. Disconnect the catheter from the PIM. Reconnect PIM and then catheter. If problem persists, contact your Philips Service Representative.

Note: Depending on the software version installed, user will see one of the following messages when an expired or unrecognized catheter is used for imaging.

- Catheter cannot be used for imaging. Disconnect, connect another catheter and reselect for imaging. If problem persists, contact your Philips representative.
- Catheter has expired. Disconnect and remove current catheter from service. Connect another catheter and reselect for imaging. If the problem persists, contact your Philips Service Representative.
- Catheter cannot be recognized. Disconnect and remove current catheter from service. Connect another catheter and reselect for imaging. If the problem persists, contact your Philips Service Representative.

1. Click **OK** to close the error message.
2. Disconnect the Patient Interface Module (PIM) from the ultrasound system.
3. Disconnect the ICE catheter from the PIM.

3000 031 06971_I / MAR 2024

Philips

4. Reconnect the PIM to the ultrasound system, and wait until a system message prompts you to connect the catheter.

CAUTION
Connect the ICE catheter to the Patient Interface Module (PIM) only after you have connected the PIM to the ultrasound system and the system has displayed the message that prompts you to connect the catheter.

5. Connect the ICE catheter to the PIM.
6. Begin imaging with the ICE catheter. If the catheter continues to malfunction, replace it.

3000 031 06971_I / MAR 2024

Philips

8 Acoustic Output Tables

The acoustic output tables are organized by transducer model and operating mode. The output display indices are calculated with the precision and accuracy described in *Acoustic Output Tables* on your *EPIQ User Information* disc.

Acoustic Output Default Tables

VeriSight ICE Catheter

Preset	Mode	Default TI Label	Default TI	Default MI	Default MI_F
Adult Echo	2D	TIS	1.0	1.2	--
	Duplex CW Color	TIS	0.1	0.0	--
	Duplex Doppler Color	TIS	0.7	0.5	--
	Duplex CW TDI	TIS	0.4	0.7	--
	Color	TIS	0.5	0.7	--
	Color M-mode	TIS	0.7	0.7	--
	Elevation Compounding	TIS	1.0	1.2	--
	THI	TIS	0.7	1.2	--
	iSCAN CW	TIS	0.1	0.0	--
	iSCAN PW	TIS	0.7	0.5	--
	M-mode	TIS	0.9	1.2	--
	Doppler	TIS	0.7	0.5	--
	Steered CW Doppler	TIS	0.1	0.0	--
	TDI	TIS	0.9	1.2	--

3000 031 06971_I / MAR 2024

Philips

VeriSight Pro ICE Catheter

Preset	Mode	Default TI Label	Default TI	Default MI	Default MI_F
Adult Echo	2D	TIS	1.0	1.2	--
	Duplex CW Color	TIS	0.1	0.0	--
	Duplex Doppler Color	TIS	0.7	0.5	--
	Duplex CW TDI	TIS	0.4	0.7	--
	Cardiac TrueVue	TIS	1.7	1.1	--
	Color	TIS	0.5	0.7	--
	Color M-mode	TIS	0.7	0.7	--
	Color xPlane	TIS	0.6	0.7	--
	Elevation Compounding	TIS	1.0	1.2	--
	THI	TIS	0.7	1.2	--
	iSCAN CW	TIS	0.1	0.0	--
	iSCAN PW	TIS	0.7	0.5	--
	M-mode	TIS	0.9	1.2	--
	Full Volume 3D Color	TIS	0.7	0.7	--
	Live 3D Color	TIS	0.7	0.7	--
	3D Zoom Color	TIS	0.7	0.7	--
	Full Volume 3D	TIS	1.7	1.1	--
	Live 3D	TIS	1.7	1.1	--
	3D Zoom	TIS	1.6	1.0	--
	Doppler	TIS	0.7	0.5	--
	Steered CW Doppler	TIS	0.1	0.0	--

3000 031 06971_I / MAR 2024

Preset	Mode	Default TI Label	Default TI	Default MI	Default MI_F
	TDI	TIS	0.9	1.2	--
	xPlane	TIS	1.0	1.2	--

IEC Standardized Acoustic Output Tables

All table entries have been obtained at the same operating conditions that give rise to the maximum index value. Due to the complexities of the system user interface, it may be difficult to exactly replicate the declared condition. For more information, contact Philips.

For descriptions of the symbols used in the tables, see *Acoustic Output Tables* on your *EPIQ User Information* disc.

3000 031 06971_I / MAR 2024

Philips

Transducer Model: VeriSight and VeriSight Pro, Operating Mode: 2D & 2D+M-Mode

Index label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			1.46	1.15	1.15	1.18	1.18	(b)
Index Component Value				1.15	1.15	B: 0.67 M: 0.34	B: 0.67 M: 0.50	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(Mpa)	3.26					
	P	(mW)		33.3	33.3	B: 19.5 M: 9.70	B: 19.5 M: 9.70	(b)
	P_{1x1}	(mW)		33.3	33.3	B: 19.5 M: 9.70	B: 19.5 M: 9.70	
	z_s	(cm)			0.00			
	z_b	(cm)					0.00	
	z_{MI}	(cm)	0.40					
	$z_{pii,a}$	(cm)	0.68					
	f_{awf}	(MHz)	4.96	7.24	7.24	B: 7.26 M: 7.29	B: 7.26 M: 7.29	(b)
Other Information	*prr*	(Hz)	1090					
	srr	(Hz)	90.8					
	n_{pps}		12.0					
	$I_{pa,a}$ at $z_{pii,a}$	(W/cm^2)	312					
	$I_{spta,a}$ at $z_{pii,a}$ or $z_{sii,a}$	(mW/cm^2)	421					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	522					

3000 031 06971_I / MAR 2024

Index label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
	p_r at z_{pii}	(Mpa)	3.01					
Operating Control Conditions	Control 1		MI					
	Control 2			TIS	TIS			
	Control 3					TIB	TIB	
	Control 4							
	Control 5							
	Control 6							

Notes:

(a) This index is not required for this operating mode.

(b) This probe is not intended for adult transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

(d) The maximum index value is less than 1.0.

Control 1: Adult Echo, M-mode, Frame Rate 91, 2D Depth 0.0-9.1 cm, 2D Opt HRES, 2D Res/Speed RS, 2D Zone Depth 8.0 cm, 2D PRF High, 2D Elevation Compounding Off, TAC Off, Trapezoid Off

Control 2: Adult Echo, 2D, Frame Rate 72, 2D Depth 0.0-12.1 cm, 2D Opt GEN, 2D Res/Speed S_TWO, 2D Zone Depth 5.0 cm, 2D PRF High, 2D Elevation Compounding Off, TAC Off, Trapezoid Off

Control 3: Adult Echo, M-mode, Frame Rate 33, 2D Depth 0.0-9.1 cm, 2D Opt GEN, 2D Res/Speed RS, 2D Zone Depth 5.0 cm, 2D PRF High, 2D Elevation Compounding Off, TAC Off, Trapezoid Off

3000 031 06971_I / MAR 2024

Transducer Model: VeriSight and VeriSight Pro, Operating Mode: 2D+Color & Color M-Mode

Index label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			1.03	1.04	1.04	1.69	1.69	(b)
Index Component Value				B: 0.22 rD: 0.33 B: 0.16 rD: 0.33	B: 0.22 rD: 0.33 B: 0.16 rD: 0.33	B: 0.03 rD: 0.08 M: 0.03 D: 0.56	B: 0.03 rD: 0.08 M: 0.08 D: 1.50	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(Mpa)	2.54					
	P	(mW)		B: 7.25 rD: 16.8 B: 5.47 rD: 16.8	B: 7.25 rD: 16.8 B: 5.47 rD: 16.8	B: 1.34 rD: 3.63 M: 1.54 D: 26.1	B: 1.34 rD: 3.63 M: 1.54 D: 26.1	(b)
	P_{1x1}	(mW)		B: 7.25 rD: 16.8 B: 5.47 rD: 16.8	B: 7.25 rD: 16.8 B: 5.47 rD: 16.8	B: 1.34 rD: 3.63 M: 1.54 D: 26.1	B: 1.34 rD: 3.63 M: 1.54 D: 26.1	
	z_s	(cm)			0.00			
	z_b	(cm)					0.67	
	z_{MI}	(cm)	0.49					
	$z_{pii,a}$	(cm)	0.57					
	f_{awf}	(MHz)	6.10	B: 6.24 rD: 4.13 B: 6.25 rD: 4.12	B: 6.24 rD: 4.13 B: 6.25 rD: 4.12	B: 4.26 rD: 4.52 B: 4.25 rD: 4.52	B: 4.26 rD: 4.52 B: 4.25 rD: 4.52	(b)
Other Information	*prr*	(Hz)	238					
	srr	(Hz)	5.18					

3000 031 06971_I / MAR 2024

Index label			MI	TIS At Surface	TIS Below Surface	TIB At Surface	TIB Below Surface	TIC
	n_{pps}		46.0					
	$I_{pa,a}$ at $z_{pii,a}$	(W/cm^2)	261					
	$I_{spta,a}$ at $z_{pii,a}$ or $z_{sii,a}$	(mW/cm^2)	178					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	231					
	p_r at z_{pii}	(Mpa)	2.65					
Operating Control Conditions	Control 1		MI					
	Control 2			TIS	TIS			
	Control 3					TIB	TIB	
	Control 4							
	Control 5							
	Control 6							

Notes:

(a) This index is not required for this operating mode.

(b) This probe is not intended for adult transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

(d) The maximum index value is less than 1.0.

Control 1: Adult Echo, Color M-mode, Frame Rate 5, 2D Depth 0.0-9.1 cm, 2D Opt PEN, 2D Res/Speed R_ONE, 2D Zone Depth 2.0 cm, 2D PRF High, Color Box Depth 0.0-9.1 cm, Color Focal Zone Depth 8 cm, Color Scale -15.4-15.4 cm/s, Coronary OFF, Freq Opt High, Color Line Density Medium, Color Box Steering Angle 0.0 degrees, 2D Elevation Compounding Off, TAC Off

Control 2: Adult Echo, Color, Frame Rate 39, 2D Depth 0.0-12.1 cm, 2D Opt PEN, 2D Res/Speed RS, 2D Zone Depth 8.0 cm, 2D PRF High, Color Box Depth 0.0-1.6 cm, Color Focal Zone Depth 4 cm, Color Scale -15.4-15.4 cm/s, Coronary OFF, Freq Opt Low, Color Line Density Low, Color Box Steering Angle 0.0 degrees, 2D Elevation Compounding Off, TAC Off, Trapezoid Off

Control 3: Adult Echo, Color M-mode, Frame Rate 12, 2D Depth 0.0-9.1 cm, 2D Opt HPEN, 2D Res/Speed R_ONE, 2D Zone Depth 8.0 cm, 2D PRF High, Color Box Depth 2.1-3.7 cm, Color Focal Zone Depth 4 cm, Color Scale -59.3-59.3 cm/s, Coronary OFF, Freq Opt Med, Color Line Density Medium, Color Box Steering Angle 0.0 degrees, 2D Elevation Compounding Off, TAC Off

3000 031 06971_I / MAR 2024

Transducer Model: VeriSight and VeriSight Pro, Operating Mode: PW Doppler

Index label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.79	0.88	0.88	2.13	2.13	(b)
Index Component Value				0.88	0.70	0.88	2.13	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(Mpa)	1.76					
	P	(mW)		40.4	40.4	40.4	40.4	(b)
	P_{1x1}	(mW)		40.4	40.4	40.4	40.4	
	z_s	(cm)			0.71			
	z_b	(cm)					0.71	
	z_{MI}	(cm)	0.49					
	$z_{pii,a}$	(cm)	0.68					
	f_{awf}	(MHz)	4.98	4.57	4.57	4.57	4.57	(b)
Other Information	*prr*	(Hz)	4433					
	srr	(Hz)	4433					
	n_{pps}		1.00					
	$I_{pa,a}$ at $z_{pii,a}$	(W/cm^2)	99.4					
	$I_{spta,a}$ at $z_{pii,a}$ or $z_{sii,a}$	(mW/cm^2)	241					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	314					
	p_r at z_{pii}	(Mpa)	1.44					

Index label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Operating Control Conditions	Control 1	MI					
	Control 2		TIS	TIS			
	Control 3				TIB	TIB	
	Control 4						
	Control 5						
	Control 6						

Notes:

(a) This index is not required for this operating mode.

(b) This probe is not intended for adult transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

(d) The maximum index value is less than 1.0.

Control 1: Adult Echo, PW Doppler, PW Doppler Sample Volume Size 3.0 mm, PW Doppler Sample Volume Depth 0.2 cm, PW Doppler Scale -34.1-34.1 cm/s, PW Doppler Steering Angle 0.0 degrees, Trapezoid Off

Control 2: Adult Echo, PW Doppler, PW Doppler Sample Volume Size 1.5 mm, PW Doppler Sample Volume Depth 4.3 cm, PW Doppler Scale -106.3-106.3 cm/s, PW Doppler Steering Angle 0.0 degrees, Trapezoid Off

3000 031 06971_I / MAR 2024

Philips

Transducer Model: VeriSight and VeriSight Pro, Operating Mode: CW Doppler

Index label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.02	0.14	0.14	0.28	0.28	(b)
Index Component Valu e				0.14	0.13	0.14	0.28	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(Mpa)	0.05					
	P	(mW)		7.51	7.51	7.51	7.51	(b)
	P_{1x1}	(mW)		7.51	7.51	7.51	7.51	
	z_s	(cm)			0.48			
	z_b	(cm)					0.48	
	z_{MI}	(cm)	0.31					
	$z_{pii,a}$	(cm)	1.49					
	f_{awf}	(MHz)	4.00	4.00	4.00	4.00	4.00	(b)
Other Information	prr	(Hz)	cwD					
	srr	(Hz)	cwD					
	n_{pps}		cwD					
	$I_{pa,a}$ at $z_{pii,a}$	(W/cm^2)	0.04					
	$I_{spta,a}$ at $z_{pii,a}$ or $z_{sii,a}$	(mW/cm^2)	36.9					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	56.0					
	p_r at z_{pii}	(Mpa)	0.05					

3000 031 06971_I / MAR 2024

Index label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Operating Control Conditions	Control 1	MI					
	Control 2		TIS	TIS			
	Control 3				TIB	TIB	
	Control 4						
	Control 5						
	Control 6						

Notes:

(a) This index is not required for this operating mode.

(b) This probe is not intended for adult transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

(d) The maximum index value is less than 1.0.

Control 1: Adult Echo, CW Doppler, CW Doppler Sample Volume Depth 1.9 cm

Control 2: Adult Echo, CW Doppler, CW Doppler Sample Volume Depth 5.0 cm

3000 031 06971_I / MAR 2024

Transducer Model: VeriSight and VeriSight Pro, Operating Mode: TDI

Index label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			1.45	1.10	1.10	1.10	1.10	(b)
Index Component Value				B: 0.32 B: 0.78	B: 0.32 B: 0.78	B: 0.32 B: 0.78	B: 0.32 B: 0.78	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(Mpa)	3.59					
	P	(mW)		B: 9.38 B: 22.3	B: 9.38 B: 22.3	B: 9.38 B: 22.3	B: 9.38 B: 22.3	(b)
	P_{1x1}	(mW)		B: 9.38 B: 22.3	B: 9.38 B: 22.3	B: 9.38 B: 22.3	B: 9.38 B: 22.3	
	z_s	(cm)			0.00			
	z_b	(cm)					0.00	
	z_{MI}	(cm)	0.49					
	$z_{pii,a}$	(cm)	0.57					
	f_{awf}	(MHz)	6.16	B: 7.26 B: 7.28	B: 7.26 B: 7.28	B: 7.26 B: 7.28	B: 7.26 B: 7.28	(b)
Other Information	*prr*	(Hz)	190					
	srr	(Hz)	38.0					
	n_{pps}		5.00					
	$I_{pa,a}$ at $z_{pii,a}$	(W/cm^2)	513					
	$I_{spta,a}$ at $z_{pii,a}$ or $z_{sii,a}$	(mW/cm^2)	349					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	436					

3000 031 06971_I / MAR 2024

Index label			MI	TIS At Surface	TIS Below Surface	TIB At Surface	TIB Below Surface	TIC
	p_r at z_{pii}	(Mpa)	2.65					
Operating Control Conditions	Control 1							
	Control 2			TIS	TIS			
	Control 3					TIB	TIB	
	Control 4							
	Control 5							
	Control 6							

Notes:

(a) This index is not required for this operating mode.

(b) This probe is not intended for adult transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

(d) The maximum index value is less than 1.0.

Control 1: Adult Echo, TDI, Frame Rate 76, 2D Depth 0.0-12.0 cm, 2D Opt PEN, 2D Res/Speed R_TWO, 2D Zone Depth 2.0 cm, 2D PRF High, Color Box Depth 0.0-12.0 cm, Color Focal Zone Depth 2 cm, Color Scale -6.5-6.5 cm/s, Coronary OFF, Color Line Density High, Color Box Steering Angle 0.0 degrees, 2D Elevation Compounding Off, TAC Off

Control 2: Adult Echo, TDI, Frame Rate 33, 2D Depth 0.0-12.0 cm, 2D Opt GEN, 2D Res/Speed R_TWO, 2D Zone Depth 5.0 cm, 2D PRF High, Color Box Depth 0.0-12.0 cm, Color Focal Zone Depth 5 cm, Color Scale -1.5-1.5 cm/s, Coronary OFF, Color Line Density High, Color Box Steering Angle 0.0 degrees, 2D Elevation Compounding Off, TAC Off

3000 031 06971_I / MAR 2024

Philips

Transducer Model: VeriSight Pro, Operating Mode: 3D

Index label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			1.43	1.79	1.79	1.79	1.79	(b)
Index Component Value				1.79	1.79	1.79	1.79	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(Mpa)	3.53					
	P	(mW)		51.6	51.6	51.6	51.6	(b)
	P_{1x1}	(mW)		51.6	51.6	51.6	51.6	
	z_s	(cm)			0.00			
	z_b	(cm)					0.00	
	z_{MI}	(cm)	0.57					
	$z_{pii,a}$	(cm)	0.57					
	f_{awf}	(MHz)	6.13	7.29	7.29	7.29	7.29	(b)
Other Information	prr	(Hz)	276					
	srr	(Hz)	21.2					
	n_{pps}	12.0	13.0					
	$I_{pa,a}$ at $z_{pii,a}$	(W/cm^2)	517					
	$I_{spta,a}$ at $z_{pii,a}$ or $z_{sii,a}$	(mW/cm^2)	492					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	611					
	p_r at z_{pii}	(Mpa)	3.97					

3000 031 06971_I / MAR 2024

Philips

Index label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Operating Control Conditions	Control 1	MI					
	Control 2		TIS	TIS	TIB	TIB	
	Control 3						
	Control 4						
	Control 5						
	Control 6						

Notes:

(a) This index is not required for this operating mode.

(b) This probe is not intended for adult transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

(d) The maximum index value is less than 1.0.

Control 1: Adult Echo, Live 3D Echo Full Volume, Frame Rate 21, 2D Depth 0.0-3.0 cm, 2D Opt PEN, 2D Res/Speed S_TWO, 2D Zone Depth 2.0 cm, 2D PRF High, 2D Elevation Compounding Off, TAC Off, 3D Opt 1 Beat

Control 2: Adult Echo, Live 3D Echo Full Volume, Frame Rate 23, 2D Depth 0.0-8.1 cm, 2D Opt GEN, 2D Res/Speed RS, 2D Zone Depth 5.0 cm, 2D PRF High, 2D Elevation Compounding Off, TAC Off, 3D Opt 1 Beat

3000 031 06971_I / MAR 2024

Transducer Model: VeriSight Pro, Operating Mode: 3D Color

Index label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.86	1.28	1.28	1.28	1.28	(b)
Index Component Value				B: 0.19 rD: 1.09	B: 0.19 rD: 1.09	B: 0.19 rD: 1.09	B: 0.19 rD: 1.09	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(Mpa)	1.91					
	P	(mW)		B: 8.09 rD: 46.1	B: 8.09 rD: 46.1	B: 8.09 rD: 46.1	B: 8.09 rD: 46.1	(b)
	P_{1x1}	(mW)		B: 8.09 rD: 46.1	B: 8.09 rD: 46.1	B: 8.09 rD: 46.1	B: 8.09 rD: 46.1	
	z_s	(cm)			0.00			
	z_b	(cm)					0.00	
	z_{MI}	(cm)	0.45					
	$z_{pii,a}$	(cm)	0.69					
	f_{awf}	(MHz)	4.96	B: 4.90 rD: 4.96	B: 4.90 rD: 4.96	B: 4.90 rD: 4.96	B: 4.90 rD: 4.96	(b)
Other Information	prr	(Hz)	23.1					
	srr	(Hz)	3.30					
	n_{pps}		7.00					
	$I_{pa,a}$ at $z_{pii,a}$	(W/cm^2)	107					
	$I_{spta,a}$ at $z_{pii,a}$ or $z_{sii,a}$	(mW/cm^2)	40.8					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	50.1					

Index label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
	p_r at z_{pii}	(Mpa)	1.92					
Operating Control Conditions	Control 1		MI					
	Control 2			TIS	TIS	TIB	TIB	
	Control 3							
	Control 4							
	Control 5							
	Control 6							

Notes:

(a) This index is not required for this operating mode.

(b) This probe is not intended for adult transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

(d) The maximum index value is less than 1.0.

Control 1: Adult Echo, Live 3D Color Full Volume, Frame Rate 3, 2D Depth 0.0-5.0 cm, 2D Opt HRES, 2D Res/Speed R_ONE, 2D Zone Depth 2.0 cm, 2D PRF High, Color Box Depth 0.0-5.0 cm, Color Focal Zone Depth 4 cm, Color Scale -86.0-86.0 cm/s, Coronary OFF, Freq Opt High, Color Line Density Medium, Color Box Steering Angle 0.0 degrees, 2D Elevation Compounding Off, TAC Off, 3D Color Opt 1 Beat

Control 2: Adult Echo, Live 3D Color Full Volume, Frame Rate 4, 2D Depth 0.0-5.0 cm, 2D Opt HRES, 2D Res/Speed R_TWO, 2D Zone Depth 5.0 cm, 2D PRF High, Color Box Depth 0.0-5.0 cm, Color Focal Zone Depth 4 cm, Color Scale -86.0-86.0 cm/s, Coronary OFF, Freq Opt High, Color Line Density Low, Color Box Steering Angle 0.0 degrees, 2D Elevation Compounding Off, TAC Off, 3D Color Opt 1 Beat

3000 031 06971_I / MAR 2024

Patient-Applied Part Temperature Measurements

Transducer	Surface Temperature, Still Air (°C)	Surface Temperature, Simulated Use (°C)
VeriSight	40.1	42.6
VeriSight Pro	40.1	42.6

3000 031 06971_I / MAR 2024

Philips

VeriSight and VeriSight Pro Catheters and ICE PIM Made in Costa Rica

Manufactured By:
Volcano Corporation
3721 Valley Centre Dr., Suite 500
San Diego, CA 92130 USA
(800) 228-4728
IGTD.CustomerInquiry@philips.com

www.philips.com/healthcare

Distributed By:
Philips Ultrasound, Inc.
22100 Bothell Everett Hwy
Bothell, WA 98021-8431
USA

Published in USA
300003106971_I / MAR 2024 - en-US