ImaCor
The hemodynamic ultrasound company.™

ImaCor

ClariTEE® Probe
User Manual
Model IFU-CLT-010

User Guide Conventions

Icons

⚠ **Caution or Warning:** Describes a procedure or precaution necessary to prevent injury to the patient or damage to the system.

Safety Feature: Highlights a safety feature.

ImaCor Innovation: Highlights a feature unique to the ImaCor ClariTEE Probe.

RoHS Compliance Statement

We declare that our product complies with The European RoHS Directive 2002/95/EC.

(Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment), which restricts the following substances in electrical and electronic medical equipment:

- Lead (Pb) < 1000 ppm
- Mercury (Hg) < 1000 ppm
- Cadmium (Cd) < 100 ppm
- Polybrominated Biphenyls (PBB) < 1000 ppm
- Hexavalent Chrome (Cr VI) < 1000 ppm
- Polybrominated Diphenyl Ethers (PBDE) < 1000 ppm

Exemption:

COMMISSION DELEGATED DIRECTIVE, Council of the EU of 18.10.2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards to an exemption for lead in solders on populated printed circuit boards used in Directive 93/42/EEC class IIa and IIb mobile medical devices other than portable emergency defibrillators.

ImaCor ClariTEE Probe

Overview

- The ImaCor ClariTEE® miniaturized transesophageal echocardiography (TEE) probe enables direct visualization of cardiac size and function and is designed specifically for episodic assessment in the critical care environment.
- Miniaturization of the probe permits an extended maximum dwell time of 72 hours.
- The probe is intended for single patient use only and is provided sterile and is disposable.

Prescription use: For use by qualified clinicians only.

Indications for Use

1. The ImaCor ClariTEE Probe is intended for the following applications: cardiac and transesophageal measurement and calculation packages that provide information of anatomical structures that may be used by a physician for clinical diagnosis purposes.
2. It is indicated for use in clinical settings including long term settings such as the ICU for an indwelling time not to exceed 72 hours.

Diagnostic Ultrasound Indication for Use Forms

ClariTEE PROBE

Intended Use: The episodic assessment of cardiac function using transesophageal echocardiography (TEE). It is indicated for use in clinical settings including long term settings such as the ICU for an indwelling time not to exceed 72 hours.

Table 1 ClariTEE Probe Indications

Clinical Application	Mode of Operation							
	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Other (Notes)
Ophthalmic								
Fetal								
Abdominal								
Intraoperative[1]								
Intraoperative Neurological								
Pediatric								
Small Organ[2]								
Neonatal Cephalic								
Adult Cephalic								
Cardiac								
Transesophageal	P				P			
Transrectal								
Transvaginal								
Transurethral								
Transcranial								
Peripheral Vascular								
Laparoscopic								
MSK Conventional								
MSK Superficial								
Vascular Access								
Nerve Block								
Other								

N = New Indication; P = Previously cleared under K080223, K100989

Table 2 ClariTEE Probe Indications

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Contraindications

The ImaCor ClariTEE Probe is contraindicated as follows: ***It is not for pediatric use (patients less than 18 years of age).***

⚠ **Warning**: Patients with known issues such as esophageal or stomach varices, obstructive esophageal pathology, recent surgery, or radiation therapy in the esophageal or gastric area, should be evaluated by a physician prior to having a TEE procedure.

Transesophageal Echocardiography (TEE) Use in Critical Care Settings

ImaCor Innovation

Miniaturization of the ClariTEE probe permits assessment of cardiac function episodically over an extended period of time, as the smaller probe should not require the use of general anesthesia.

The ImaCor ClariTEE Probe addresses the need in the critical care setting for a miniaturized TEE probe to assess important cardiac parameters that influence hemodynamics. The ImaCor ClariTEE ultrasound probe, when used with ImaCor ultrasound platforms, provides direct visualization of cardiac size and function, allowing intensive care clinicians to conduct episodic assessments of cardiac performance over an extended period.

Principles of Operation

ImaCor Innovation

The ImaCor single-use disposable probe can remain in place for up to 72 hours, enabling episodic assessment of the patient's cardiac function over that period at intervals determined by the physician.

Miniaturization of the ClariTEE probe enables direct visualization of the cardiac structures episodically over time. Direct visualization of the left ventricle permits improved assessment of intravascular volume status and cardiac function.

The ClariTEE disposable probe is for use with the ImaCor Handheld Scanner (ZHH) and can remain in place for up to 72 hours, enabling episodic assessment of the patient's cardiac function over that period at intervals determined by the physician. Episodic assessments typically occur up to six times over a 24-hour period.

Probe single usage is considered use for a single patient at a time duration not to exceed 72 hrs.

- The electrical insulating properties of the ClariTEE probe are unknown if the probe is used for greater than 72 hrs. Risk of an electric shock to the patient could result.
- The mechanical integrity of the ClariTEE probe is unknown if the probe is used for greater than 72 hrs. A mechanical risk to the patient, i.e., sharp edges could result.
- The ClariTEE probe is for single patient use only and is to be disposed after single patient use or if otherwise contaminated by blood, body fluids, or other biological materials. Do not re-sterilize or disinfect the ClariTEE disposable probe after single patient use.
- Reuse of the probe for a single patient, within 72 hrs., is considered in compliance with ClariTEE labeling. However, probe cleanliness in these situations is subject to HCP control. The probe is not to be sterilized (i.e., autoclave) or subject to high level disinfection like Cidex, and then used in another patient. However, it may be disinfected by wiping it with alcohol and stored in the protective sleeve between uses on the same patient for up to 72 hrs.

Episodic Assessment

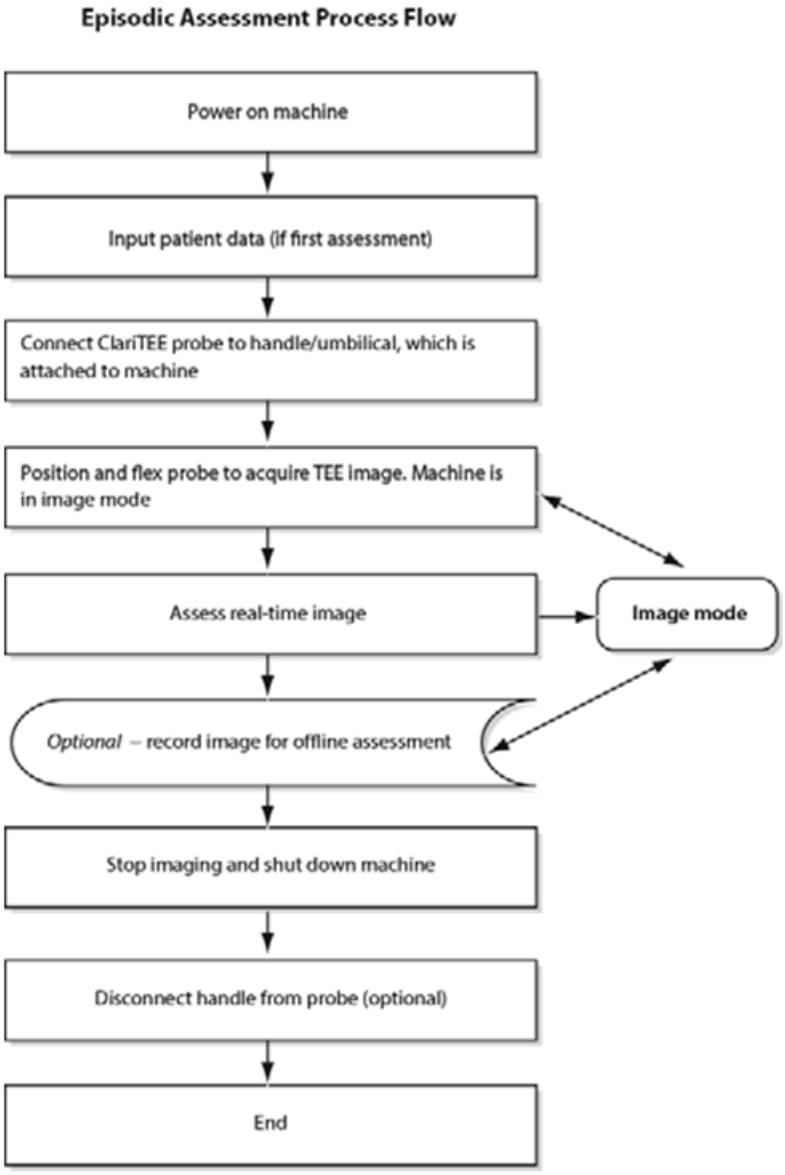

Figure 1 Process flow of one episodic assessment

Non-Imaging Mode

Safety Feature

During non-imaging intervals, no energy is delivered to the patient and the probe remains in a relaxed, unflexed position. As a result, the mucosal tissue is not subject to any mechanical or thermal stress.

The ClariTEE probe is designed for a maximum dwell time of 72 hours. Episodic assessments typically account for a fraction of total dwell time; therefore, during the majority of probe dwell time no imaging is taking place. During non-imaging intervals, no energy is delivered to the patient and the probe remains in a relaxed, unflexed position.

Cumulative Imaging Time

Caution

The ClariTEE Probe should be in imaging mode only when an episodic assessment is being conducted.

Cumulative imaging time is the total time over the course of probe dwell duration that the ZURA Imaging System is in imaging mode for the purpose of episodic assessment. The ClariTEE probe delivers energy to the patient only while in the imaging mode. Only in imaging mode is the ClariTEE probe mechanically flexed to obtain the tissue contact required for imaging.

Ultrasound Machine

The ImaCor ClariTEE Probe is for use with an ImaCor Zura ultrasound platform EVO, EVO-1, and Handheld. The platform includes a display and all the required system firmware and hardware except for the disposable ClariTEE probe.

Ultrasound TEE Probe

⚠ **Caution**
The ImaCor ClariTEE is for use **only** with the ImaCor Zura Platforms EVO, EVO-1, or Handheld (ZHH-010 and ZHH-011).
Flex the probe only when imaging.
Disconnect the probe from the handle when not conducting an episodic assessment.
The ClariTEE probe is designed for single patient use.
The maximum dwell time for the ClariTEE probe is 72 hours.
Do not use probe if packaging shows evidence of damage.
Caution – Prescription use only

The ClariTEE is a miniaturized disposable single patient use probe optimized for extended dwell-time, making it ideal for use in longer-term clinical settings such as the ICU. During imaging, the probe tip is flexed upward (anteflexed) or downward (retroflexed).

The indwelling portion of the ClariTEE probe is detachable from the system handle. The detachable handle enables one scanner to serve multiple patients.

ADAPTAFLEX™ TECHNOLOGY

The ClariTEE probe features ImaCor AdaptaFlex technology. This technology changes the flex point of the probe's adaptive section to accommodate the patient's anatomy. AdaptaFlex technology enables the operator to obtain an optimal view across patients of varying sizes.

Figure 2 ImaCor ClariTEE® probe connected to handle of Zura system

Getting Started

Connecting the Ultrasound Probe

1. When ready to attach the probe, take the probe from its sterile packing. Remove the cover from the disposable probe connector as shown. (Figure 3).

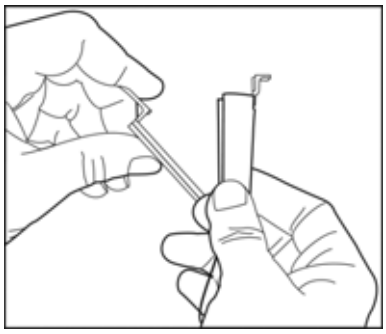

Figure 3 Remove the cover from the disposable probe

2. Position the probe connector and handle as shown in Figure 4.

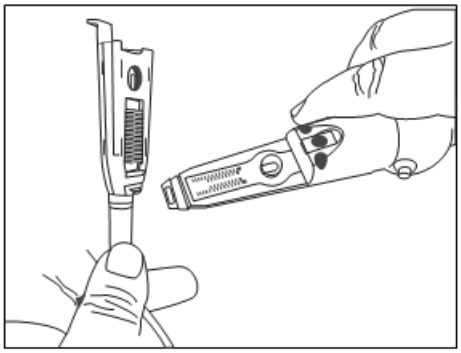

Figure 4 Position the probe connector and handle in hand

3. Align the probe with the handle.

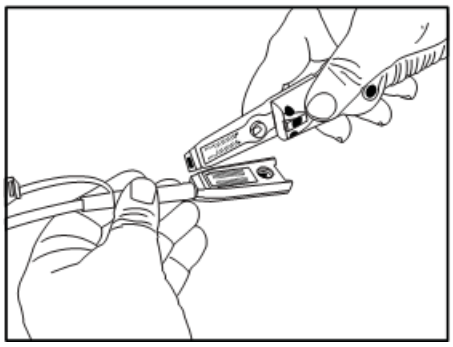

Figure 5 Align probe and handle

4. Insert the blue connector tab into the distal end of the handle (Figure 6).

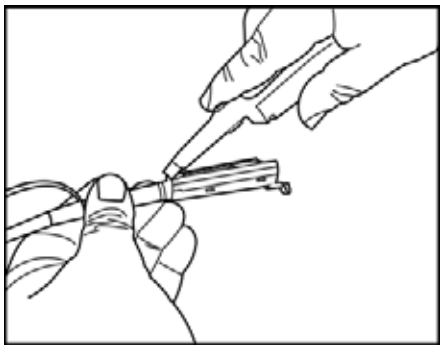

Figure 6 Insert connector tab into distal end of the handle

5. Gently press the probe connector over the handle; press the tab on the handle connector to assist with engagement (Figure 7). An audible click will indicate the probe is properly connected.

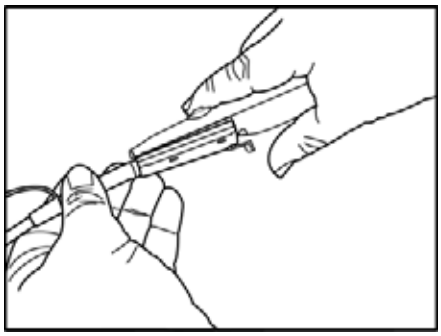

Figure 7 Press the probe connector over the handle

6. With the disposable probe locked into place, check articulation by moving level in each direction. The distal tip of the probe should flex in either direction.

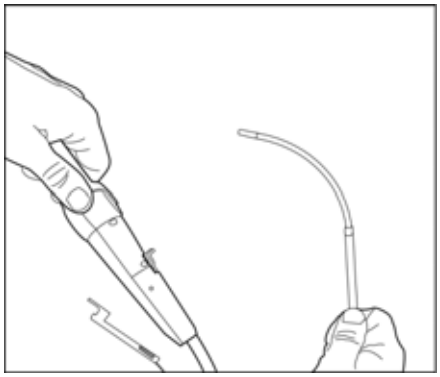

Figure 8 Check articulation of the probe

Note: Expect flex of 90 degrees in the forward direction (anteflex) and 20 degrees minimum in reverse direction (retroflex).

Specifications

Table 3 ImaCor System Specifications

Item	Specification
System dimensions	Content
Transducers (probes) TEE	Phased array Single-use, disposable, provided sterile
Imaging mode	Type B mode imaging Color Flow mode imaging (where available)
Sector Angle	70° and 90°
Application	TEE imaging. The probe is optimized for three views: • Transgastric short axis view of left ventricle • Midesophageal four chamber view to evaluate size and function • Super Vena Cava view to assess volume responsiveness
Resolution	128 Lines
Probe	Single use, TEE, disposable, provided sterile
Temperature, pressure, & humidity limits	Operating limits: Probe • 10-40°C (50-104°F), 15-95% R.H. noncondensing • 700 to 1060 hPa (0.7 to 1.05 ATM)
	Shipping/storage limits: Probe • -20-60°C (-4-140°F), 0-95% R.H. noncondensing • 500 to 1060 hPa (0.5 to 1.05 ATM) • For storage longer than 30 days, store at room temperature

Glossary

Terms

ClariTEE®	ImaCor miniature disposable TEE probe
ICU	Intensive Care Unit
Real-time imaging	Imaging occurring in the present moment
TEE	Transesophageal echo where the ultrasound transducer is placed in esophagus or stomach

Acronyms

ALARA	As low as reasonably achievable
FDA	Food and Drug Administration
hTEE	Hemodynamic transesophageal echocardiography
ICU	Intensive care unit
ISPPA	Intensity spatial-peak pulse-average
ISPTA	Intensity spatial-peak temporal-average
LV	Left ventricle
MI	Mechanical index
TEE	Transesophageal echocardiography
TGSAV	Trans-gastric short-axis view