User's Manual
For
GP3SRS
Medical Diagnostic Ultrasound Transducer Assembly

CE 0197

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Broadsound GP3SRS Medical Diagnostic Ultrasound Transducer Assembly

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CE 0197

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1. Introduction

1.1. Intended Use

Broadsound GP3SRS is the replacement ultrasound transducer intended to be used with standard ultrasound systems in diagnostic ultrasound imaging or fluid flow analysis of the human body and to be operated by or under the direction of a physician. Its specific indications for use are Cardiac, Pediatric, Abdominal.

1.2. Classification

Classification: IIa, Annex IX of the Directive 93/42/EEC
Subcategory: MD 1202 imaging devices utilizing non-ionizing radiation

1.3. Environmental Conditions

1.3.1. Operation Condition

Operate the transducer assembly under the following ambient conditions:
Ambient temperature: + 5 ℃ to + 40 ℃
Relative humidity: 30% to 85%

1.3.2. Storage Condition

Store or transport the transducer assembly under the following ambient conditions:
Ambient temperature: - 40 ℃ to + 50 ℃
Relative humidity: 30 % to 95%

Avoid rapid temperature change which may cause dew condensation.

Warning

Always use the probe in dried state. Dew condensation or waterdrops may appear by being moved from cold to warm place. Use without proper care can cause short-circuiting.

1.4. Contraindications, Warnings, and Precautions

1.4.1. Please read this user's manual before use; do not use this transducer assembly for any purpose other than its intended use.

Caution

Use the probe only for the purposes described above. This probe may injure the human body.

1.4.2. Handle this transducer assembly with care; do not drop or subject transducer assembly to any type of mechanical shock.
Impact may compromise transducer assembly operation, safety features or result in sharp edges that could damage the protective sheath and injure sensitive tissue.

Warning

When dropped or stuck against a hard surface, the probe may develop a defect that can not be located visually. If it is used without being checked first, the patient may be injured.

1.4.3. Prevent the transducer assembly from damage by placing it in its holder or carrying case when not in use.

1.4.4. Inspect acoustic lens, cable and housing before each exam. Avoid unnecessary stress or bending to the cable.

1.4.5. Do not use damaged transducer assembly. Injury to the operator or patient may occur if cracks, cuts, sharp edges or exposed wiring exist.
Cleaning and/or gel solutions may leak into the transducer assembly resulting in electrical shock. Discontinue use and notify the Broadsound service representative.

1.4.6. Do not twist, kink or pinch the cable. Excessive bending or stress on cable may result in damage to its insulating properties causing shock to the patient or operator.

1.4.7. Strictly follow the instruction provided in this manual when cleaning & disinfecting transducer assembly.

Caution

Using chemicals other than those specified in this manual may adversely affect the probe and reduce the disinfection effects. Use only the chemicals listed in Section 4.2.

1.4.8. Do not use coupling gels that contain lotions, mineral oil, olive oil, lanolin, polyethylene glycol, dimethylsilicone, methyl or ethyl parabens. (Recommended coupling gel: Aquasonic 100 Ultrasound Gel）

Caution

Using coupling gel other than those specified above may adversely affect the probe. Use only the coupling gel listed above.

1.4.9. Do not steam, heat autoclave or use ethylene oxide (EO) gas processes on general surface. Only use CIDEX OPA disinfectant.

Caution

The probe cannot withstand autoclave sterilization or disinfection at a temperature higher than 60^{o}C. Perform disinfection using chemical listed in Section 4.2.

1.4.10. Broadsound Corporation does not provide any biopsy guide device for GP3SRS, and GP3SRS transducer assembly is not intentionally designed to be compatible with any biopsy guide device.

1.4.11. For semi-critical and/or critical applications, the disinfected GP3SRS transducer must be used with a sterile sheath.

1.4.12. Do not use the transducer assembly with high frequency surgical equipment.

2. General Information

2.1 Content

When receiving the transducer assembly, unpack and check the following:
Transducer assembly: one unit
Carrying case: one
User's manual: one set

2.2. Geometry and Weight of Transducer Assembly

Scan head: 90 mm (length) *35 mm (width) *25 mm (height)
Cable: Approximate 2 meter (length) * 8 mm (diameter)
Connector: 120 mm (length) * 65 mm (width) * 30 mm (height)
Weight of probe: 0.9 kg

2.3. Device Name

Broadsound GP3SRS Diagnostic Ultrasound Transducer Assembly

2.4. Compatibility

Broadsound GP3SRS ultrasound transducer assembly is substantially equivalent to the predicate device GE 3S-RS transducer assembly. Both of them are similar to each other in terms of features and use parameters; as well, they are used on the same diagnostic ultrasound systems, such as GE logiqbook xp Series.

2.5. Acoustic Energy

The effects of acoustic energy on human tissue are currently under investigation. Therefore, it is recommended that diagnostic ultrasound output power be set to the lowest possible levels according to the principle of ALARA (As Low As Reasonably Achievable), especially during fetal examinations**.**
The acoustic output of Broadsound GP3SRS was tested and found to be statistically comparable to that of its predicate device GE 3S-RS.

Caution

Set the acoustic output to the lowest possible level. For details concerning acoustic output from the probe, refer to the instruction manual (Acoustic output power table) of compatible system GE logiqbook xp Series for relevant information.

2.6. Electromagnetic Compatibility

Broadsound GP3SRS ultrasound transducer assembly is substantially equivalent to the predicate device GE 3S-RS transducer assembly including the design of electromagnetic compatibility. Refer to the user's manual of compatible system GE logiqbook xp Series for relevant information.

3. Specification, Device description and Labeling

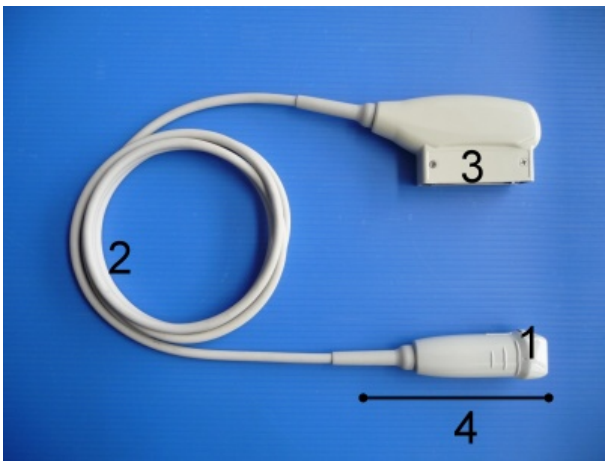
3.1. Specification

Array type: Phased
Nominal frequency: 2-4MHz
Sector angle/Field of view: 90 degree
Method of application: Apply transducer assembly to the surface of body
Application: Cardiac, Pediatric, Abdominal.

3.2. Device Description

Broadsound GP3SRS consists of piezoelectric crystals covered with an acoustic lens, a scan head that fits around the lens, a cable with strain relief devices on both ends, and a connector to attach the transducer assembly to the ultrasound console.

Figure 1 shows the name and function of each portion of transducer assembly, and the immersible region that is important in cleaning and disinfecting:



2. Cable

3. Connector

1. Scan Head

4. Immersible region

Figure 1. The name and function of each portion of transducer assembly

1. Scan Head
   The piezoelectric crystal converts electrical energy into ultrasound waves, which are transmitted to the human body. It also generates electrical signals when receiving the ultrasound echoes reflected from the tissues. The cover on the surface of the window is the acoustic lens.

2. Cable
   The cable conveys electrical signals back and forth between the scan head and connector of transducer assembly.

3. Connector
   This connects the transducer assembly to the ultrasound instrument console.

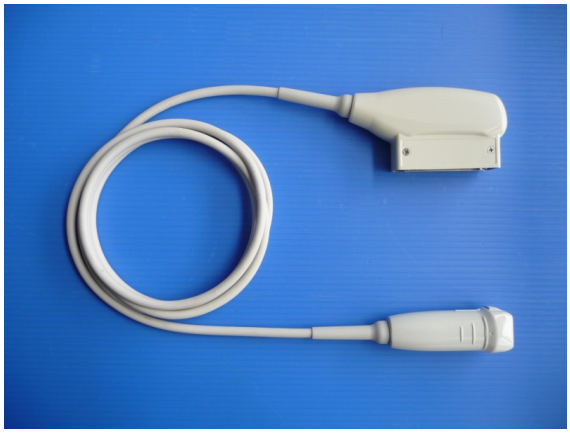
4. Lock Handle
   This locks the connector to the ultrasound instrument console.

5. Immersible Region

3.3 Labeling

3.3.1. Labels and Symbols

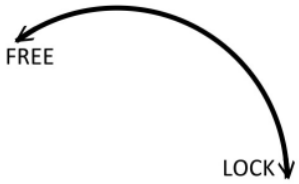
Safety-related labels and symbols are attached to the transducer assembly at the locations shown below:



3.3.2. Definition of Label and 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. The definition of the labels and symbols are shown below:

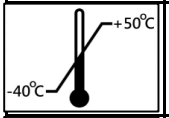
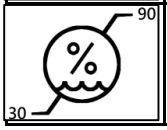
★ Connector Side:



ROHS

★ Scan-head Side:

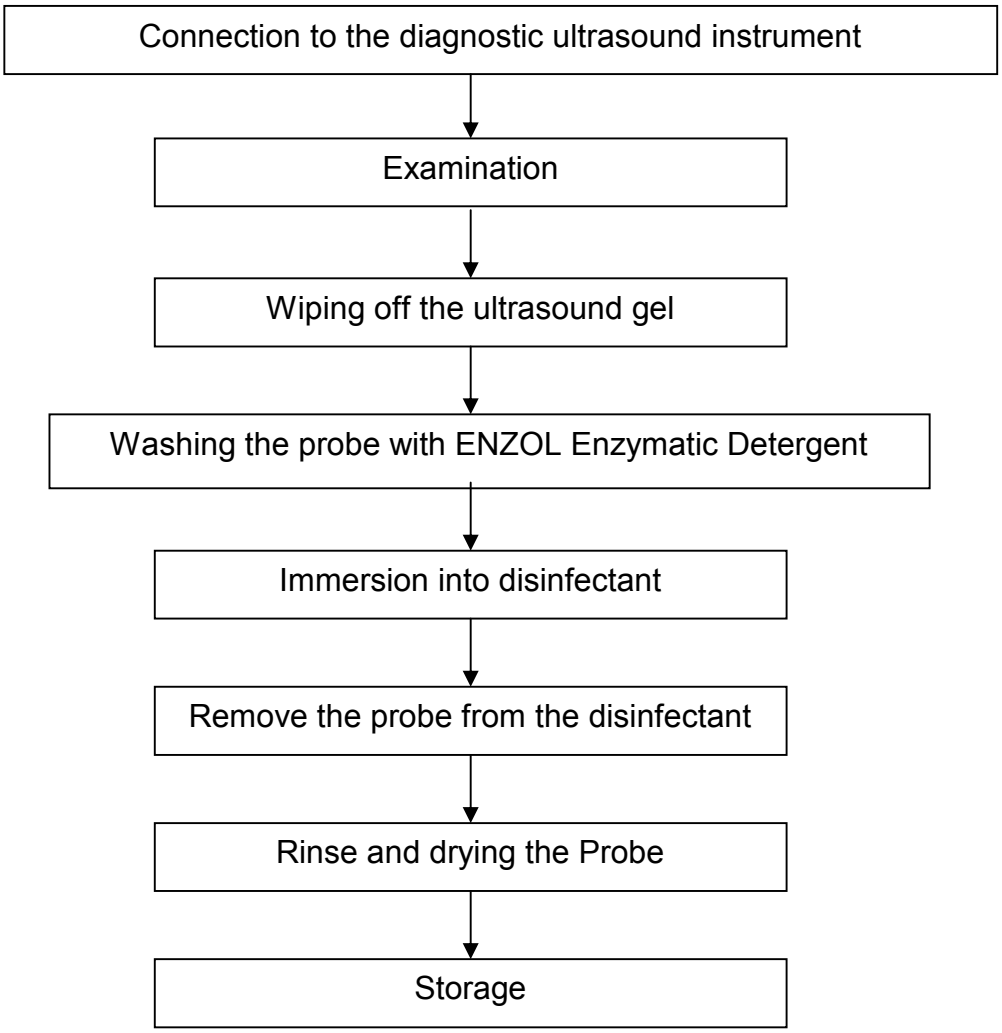
IPX7

Symbol	Description
CE 0197	The CE mark and Notified Body Registration Numbers, the requirement of Annex II article 3 from Medical Device Directive 93/42/EEC are met.
	Classification of applied part ,Type BF
	Follow instructions for use.
	Recycling symbol means that the end of the life of the ultrasound transducer you must dispose of it separately at an appropriate collection point and not place it in the normal domestic unsorted waste stream
GP3SRS	Model name of the transducer assembly
SN	Serial number of the transducer assembly
 Year/Month	Date of manufacture, “Year” denotes the year of manufacture, “Month” denotes the month of manufacture
LOT	Batch Code.
EC REP	Authorized representative in the European Community
	Manufacturer
IPX 7	Protection against ingress of water. An IPX7 designation means the probe housing can withstand accidental immersion in one meter of water for up to 30 minutes.
	Position of lock Handle
RoHS	Restriction of Hazardous Substances Directive 2002/95/EC
	Store or transport the transducer assembly under the following ambient conditions: Ambient temperature: - 40 ℃ to + 50 ℃
	Store or transport the transducer assembly under the following ambient conditions: Relative humidity: 30 % to 95%

4. Instruction for Use, Cleaning and Disinfection

4.1. Procedure of Operation

The probe should be used as described in the following procedure:



4.2. Preparation before cleaning, Cleaning, and Disinfection

Caution
The transducer assembly must be disconnected from the ultrasound system prior to clearning/disinfection.

Caution
Broadsound GP3SRS diagnostic ultrasound transducer assembly is supplied

Caution
When used in semi-critical and/or critical applications, the disinfected GP3SRS transducer must be covered with a sterile sheath

Caution
The scan head of transducer assembly must be cleaned and disinfected before each use or between uses. The other general surface of cable and connector can be cleaned with alcohol by using sterile gauze.

4.2.1 Preparation before cleaning

Caution
The transducer assembly must be disconnected from the ultrasound system prior to clearning/disinfection.

Caution
The scan head of transducer assembly must be cleaned and disinfected before each use or between uses.

4.2.2 Cleaning

Procedures for Cleaning:

1. The transducer assembly is disconnected from the ultrasound system .
2. Wipe off coupling gel and other foreign matter from the scan head with clean tissues.
3. Clean the scan head with ENZOL Enzymatic Detergent of Johnson & Johnson. Follow the labeling of the ENZOL Enzymatic detergent. Immersible region please refer to the picture shown in Section 3.2.
4. Wipe the scan head to remove residue.

Caution
Operate the transducer assembly under the following ambient conditions: Ambient temperature: + 5 ℃ to + 40 ℃

4.2.3 Procedures for Disinfection:

1. Follow the cleaning procedures to clean the transducer first.
2. Immerse the scan head into CIDEX OPA Solution, which is a high-level disinfectant manufactured by Johnson & Johnson. Follow the labeling of the CIDEX OPA disinfectant. The immersion time is at least 5 minutes and no more than 15 minutes.

   Immersible region please refer to the picture shown in Section 3.2.
3. Wipe off remaining residue on the transducer assembly with sterile gauze.

Caution
Operate the transducer assembly under the following ambient conditions: Ambient temperature: + 5 ℃ to + 40 ℃

Caution
Do not immerse the whole transducer assembly into disinfection fluid.

Caution
Do not dry the transducer assembly by heating.

Caution
Only use CIDEX OPA disinfectant. Do not steam autoclave or subject the transducer to Ethylene Oxide.

5. Setup before Use

5.1. Visual check

Visually check the cable and the tip and acoustic lens area of the probe. If any holes, dents, cracks, deformation, or other abnormal states are detected, do not use the probe.

Warning
If any an abnormal state is found, stop using the probe, and notify the Broadsound service representative.

5.2. Verification of cleaning and disinfection

Verify that cleaning and disinfection have been conducted. Note that the probe was not factory-disinfected before shipment.

Warning

Use of the contaminated probe may result in infection. In accordance with the procedure described in section 4.2, cleaning and disinfection the probe before using it.

5.3. Verification of operation

Connect the probe to the equipment and make sure that the indication the selected connector matches that the image (Linear indication) and the frequency. For viewing the image, refer to instruction manual provided by Original

Caution

If the indications do not match, the probe may be faulty. Discontinue use of the probe and notify the Broadsound service representative.

6. Periodic Inspection

The transducer may be damaged during use or processing, so it must be checked before use for cracks or irregularities in the surface.

Warning

Injury to the operator or patient may occur if cracks, cuts, sharp edges or exposed wiring exist. Cleaning and/or gel solutions may leak into the transducer assembly resulting in electrical shock. Discontinue use and notify the Broadsound service representative.

7. Disposal Instruction

When the transducer is scrapped at the end of its life, you must dispose of it separately at an appropriate collection point and not place it in the normal domestic unsorted waste stream. Within the EU, when you discard the transducer, you must send it to appropriate facilities for recovery and recycling. Please consult local health authorities for proper disposal methods.

Warning

For contaminated disposals such as transducer covers, follow disposal control policies established for your office, department or hospital.