User's Manual
For
GP3SRS
Diagnostic Ultrasound Transducer

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CE 0197

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Broadsound E.C. Distributed by:

1. Contraindications, Warnings, and Precautions

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

1.2. 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.

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

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

1.5. 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.

1.6. 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.

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

1.8. 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）

1.9. Do not steam, heat autoclave or use ethylene oxide (EO) gas processes on general surface.

1.10. 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.

1.11. Do not dry the transducer by heating.

1.12. Only use recommended disinfectant. Do not steam autoclave or subject the transducer

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

2. Content

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

3. Device Name

Broadsound GP3SRS Diagnostic Ultrasound Transducer Assembly

4. 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, Abdominal, GYN Transcranial..

5. 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.

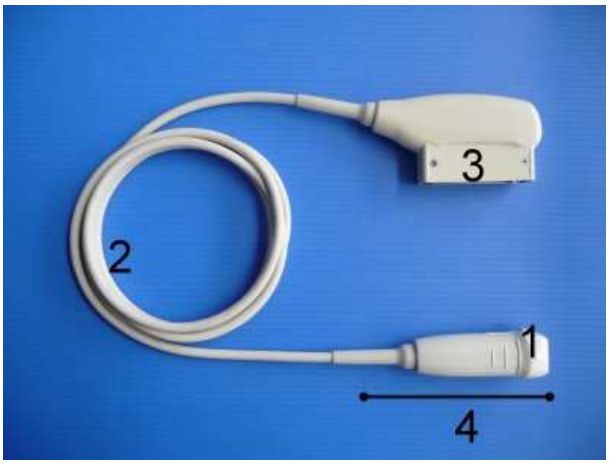
6. Acoustic Energy

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.

7. 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.

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



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.

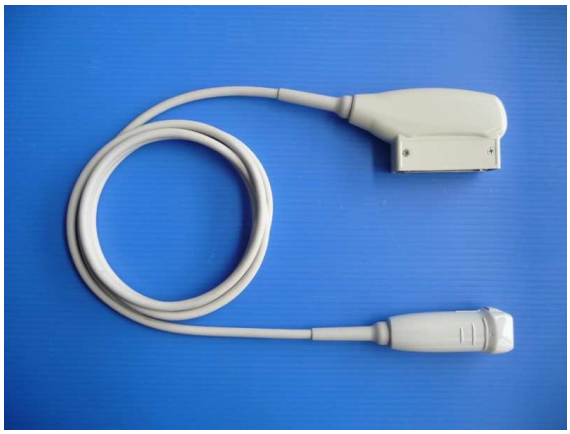
3. Connector
   This connects the transducer assembly to the ultrasound instrument console.

4. Immersible Region

8. Labeling

8.1. Labels and Symbols

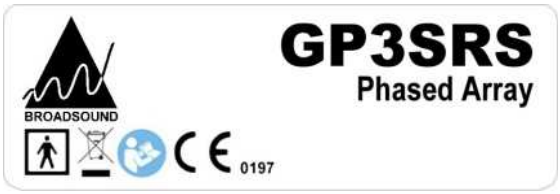
Safety-related labels and symbols are attached to the transducer assembly at the connector location shown below:



8.2 Definition of Label and Symbols

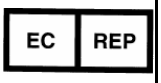
The International Electrotechnical Commission (IEC) has established a set of symbols for medical electronic equipment that classify a connection or warn of potential hazards. The definition of the labels and symbols are shown below:

★ Connector section:



★ Scan head section:

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.
	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.

9. Specification

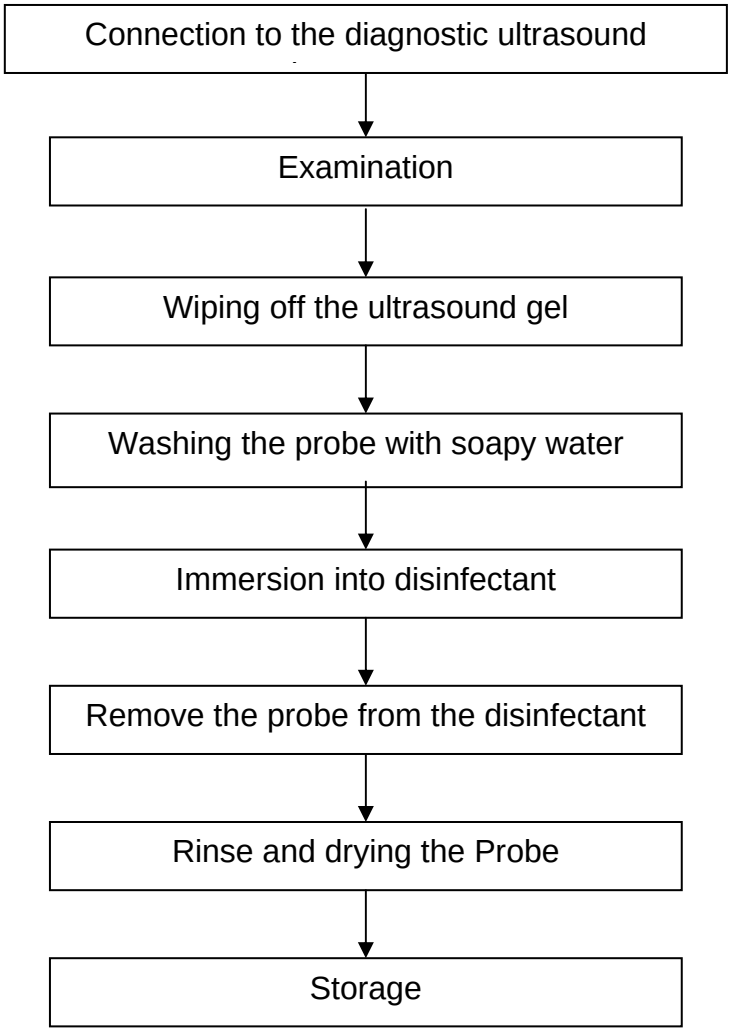
Array type: Phased
Nominal frequency: 2-4MHz
Sector angle/Field of view: 90 degree
Method of application: Apply transducer assembly to the surface of body
Application: Cardiac, Abdominal, GYN Transcranial..

10. 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

11. Procedure of Operation

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



12. Instruction for use

Broadsound GP3SRS diagnostic ultrasound transducer assembly is supplied non-sterile.

The recommended high-level disinfectant is the CIDEX OPA Solution.

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

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.

Recommended Procedures for Cleaning:

1. Wipe off coupling gel and other foreign matter from the scan head with clean tissues.
2. Clean the scan head with ENZOL Enzymatic Detergent of Johnson & Johnson. Follow the labeling of the recommended detergent.
3. Wipe the scan head to remove residue.

Recommended 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 recommended disinfectant. Do not immerse the whole transducer assembly into disinfection fluid.
3. Wipe off remaining residue on the transducer assembly with sterile gauze. Do not dry the transducer assembly by heating.
4. Only use recommended disinfectant. Do not steam autoclave or subject the transducer to Ethylene Oxide.

* Immersible region please refer to the picture shown in Section 7.

13. Operation Condition

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

14. Storage

Store or transport the transducer assembly under the following ambient conditions:

Ambient temperature: - 40 ℃ to + 50 ℃
Relative humidity: 30 % to 95 %

15. 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 for relevant information.