

26-Aug-2024

Intended Use & Precautions

1. Intended Use

BroadSound AL6E124 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 Endocavity, Ob/Gyn, and Urology imaging applications.

2. Classification

Classification: IIa, Annex IX of the Directive 93/42/EEC

Subcategory: MD 1202 imaging devices utilizing non-ionizing radiation

3. Environmental Conditions

3.1 Operation Condition

Operate the transducer assembly under the following ambient conditions:

Ambient temperature: + 5 °C to + 40 °C

Relative humidity: 30% to 85%

3.2 Storage Condition

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

Ambient temperature: - 40 °C to + 50 °C

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.

4. Contraindications, Warnings, and Precautions

- 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.

- 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.

- 4.3. Prevent the transducer assembly from damage by placing it in its holder or carrying case when not in use.
- 4.4. Inspect acoustic lens, cable and housing before each exam. Avoid unnecessary stress or bending to the cable.
- 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.
- 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.
- 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.

- 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.

- 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°C. Perform disinfection using chemical listed in Section 4.2.

- 4.10. BroadSound Corporation does not provide any biopsy guide device for AL6E124, and AL6E124 transducer assembly is not intentionally designed to be compatible with any biopsy guide device.
- 4.11. For semi-critical and/or critical applications, the disinfected AL6E124 transducer must be used with a sterile sheath.
- 4.12. Do not use the transducer assembly with high frequency surgical equipment.

Copyright 2024 BroadSound Corporation
Printed in Taiwan