

26-Aug-2024

Compatibility & Safety

1. Device Name

BroadSound AL6E124 Diagnostic Ultrasound Transducer Assembly

2. Compatibility

BroadSound AL6E124 ultrasound transducer assembly is substantially equivalent to the predicate device Aloka UST-9124 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 Aloka SSD 3500 Series.

3. 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 AL6E124 was tested and found to be statistically comparable to that of its predicate device Aloka UST-9124.



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 Aloka SSD 3500 Series for relevant information.

4. Electromagnetic Compatibility

BroadSound AL6E124 ultrasound transducer assembly is substantially equivalent to the predicate device Aloka UST-9124 transducer assembly including the design of electromagnetic compatibility. Refer to the user's manual of compatible system

Aloka SSD 3500 Series for relevant information.

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.

5.1. 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 Manufacturer Equipment.

Caution

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

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