# Chapter 5: Checking and Maintaining Ultrasound Equipment

Ultrasound equipment requires regular checks and maintenance. Table 5 contains a list of required checks.

**NOTE:** *If you find any cracks or irregularities on the transducer, please contact your local BK Medical representative.*

| What to check | When to check |
|---|---|
| Transducer, connector, cable, remote control, attachments and reusable puncture guides for cracks and irregularities<br>See: *"Check of Equipment Between Each Use" on page 46.* | Between each use |
| Transducer for leakage<br>See: *"Checking the Transducer for Leakage" on page 48.* | See recommended frequency on page 48 |
| Watertight protection device and transducer plug's waterproof gaskets and seal for cracks and marks<br>See: *"Checking the Plug and Watertight Protection Devices Before Immersion" on page 47.* | Before immersing the transducer and/or the plug for cleaning or disinfection **OR** at least monthly (or more often in cases of heavy use) |
| Preventive maintenance and performance test of entire system<br>See: *"Yearly Preventive Maintenance and Performance Test" on page 51.* | Yearly |
| Type BF transducers to make sure they still comply with requirements<br>See: *"Yearly Check of Type BF Transducers" on page 52.* | |

*Table 5. Required checks of ultrasound equipment.*

## Check of Equipment Between Each Use

For reprocessing methods to be effective, external surfaces must be in good condition. Transducers (including connector, cable, remote control, attachments and reusable puncture guides) should be checked between each use for signs of damage.

How often

For critical-use and semi-critical applications, you should carry out a detailed check for damage between each use. For non-critical applications, this check can be performed daily. For a list of applications, please see the Recommended Leakage Testing Frequency table on page 49.

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| ⚠<br>Damage and reprocessing | **WARNING** Check-w2<br>Equipment may be damaged by use or reprocessing. It is important to check it at least once a month (or more often, if it undergoes sterilization) to ensure that it can be effectively reprocessed. If there are any pits or cracks on any equipment surfaces, reprocessing may not give a sterile or disinfected product. |

Damage signs

Check the transducer for the following signs of damage:

- Pits or cracks anywhere
- Deep scratches on any surfaces
- Splitting or peeling of the sealant around the front face (acoustic surface)
- Damage to the joint filler on the body of the transducer
- Damage to, or evidence of, contamination on the pins of the transducer plug
- Damage to the cable or cable bonding around the cable flex relief
- Deformation or other damage (to non-steel puncture guides) caused, for example, by autoclaving with excessive heat
- Blistering on the surface of the remote control

**NOTE:** *The front face (acoustic surface) must appear uniform and be fully attached to the rest of the transducer. It must not be swollen or peeling off.*

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| ⚠ Do not use damaged equipment | **WARNING** Check-w1<br>To ensure safe operation, do not use the equipment if you find any signs of damage. Contact your BK service representative.<br>If a transducer is dropped, and even if it shows no visible signs of damage, BK recommends that a High Voltage test is conducted before the transducer is used again. |

### Transducers 20R3, 8838 and 2052

Before you use one of these transducers, thoroughly inspect the connector plug and the rubber gasket on the plug (this refers to the small, round plug).

### Transducers 20R3, X14L4, 8838 and 2052

Damage to the surface of these transducers may lead to oil leaking from the transducer.

### Transducer 8666-RF, 8809, X18L5s and I12C4f

Before you use one of these transducers, inspect the flexible, black rubber next to the acoustic array, and the articulation joint on the flexible tip of the transducer to make sure that there are no defects in these areas.

### Checking the Plug and Watertight Protection Devices Before Immersion

To make sure that liquid does not get into a plug during immersion, the watertight protection device must be dry inside and it must make a tight seal with the plug[1].

Inspect the equipment for signs of damage to the plug, lid and the rubber sealing.

1. Some transducer types are not provided with a plug lid, and therefore the connector must not be immersed. See "Transducers Excluded from Leakage Testing" on page 49.

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| ⚠ Examine plug and waterproof protection for damage | **Caution** Plug-c4<br>Before you reprocess the transducer, inspect the watertight protection device and the transducer plug. If you find any signs of damage, do not immerse the plug. If liquid comes into contact with the plug connector pins, the transducer may be destroyed.<br>Examine the edges of the plug case that contact the lid and also the watertight protection device for cracks and marks. Examine the rubber seal of the plug lid. Look for deep scratches and grooves, holes or tears, brittleness, and looseness anywhere.<br>The transducer or watertight protection device must be checked by a BK service representative if you find signs of damage. |

## Checking the Transducer for Leakage

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| ⚠ Do not use damaged equipment | **WARNING** Check-w1<br>To ensure safe operation, do not use the equipment if you find any signs of damage. Contact your BK service representative.<br>If a transducer is dropped, and even if it shows no visible signs of damage, BK recommends that a High Voltage test is conducted before the transducer is used again. |

Before you immerse a transducer, check the transducer for cracks and irregularities. See “Check of Equipment Between Each Use” on page 46 for more information.

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| ⚠ Immersion: Cover plug – Lid ON | **Caution** Plug-c2<br>To prevent damage to the transducer, cover the plug with the watertight protection device before you immerse the transducer and plug in liquid. |

If the transducer is fitted with a watertight lid, it is recommended to use the appropriate leakage tester (UA1414 or UA1404) to verify that the transducer is watertight.

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| ⚠ Test for leaks before immersing | **Caution** Test-c1<br>You should use the leakage tester to test for leaks. If a transducer is not completely watertight, immersing it can seriously damage it. |

### Recommended Leakage Testing Frequency

Check transducers for leakage regularly, as a leakage may impair the performance and safety of the equipment. Recommended leakage testing frequency depends on the design and use of the transducer.

### Transducers Excluded from Leakage Testing

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| 8819<br>8830<br>8837<br>8670<br>2052<br>8838<br>20R3<br>5C1e<br>14L3e | Excluded due to transducer design or no immersible plug lid |

### Leakage Testing Table

| Transducer Classification | Applications | Before rinse and/or immersion | Leakage testing after each use | Minimum leakage testing frequency |
|---|---|---|---|---|
| Non-critical use | Abdominal<br>Adult Cephalic (Transcranial)<br>Cardiac Adult<br>Fetal, including Obstetrics<br>Musculoskeletal<br>Vessel (Peripheral Vessel)<br>Small Parts (also called Small Organs)<br>Neonatal Cephalic | Always | No | Recommended every 3 months |
| Semi-critical use | Transrectal<br>Transvaginal | Always | No | Recommended every 3 months |
| Critical use | Intraoperative<br>Intraoperative (Neuro) | Always | Yes | Recommended after each use |

### Leakage Testing Setup

After the transducer plug is covered with a special test lid, air is pumped into the transducer. The transducer and covered plug are then placed in a tank filled with water. If bubbles appear, it is a sign that the transducer, cable, or plug contains a hole and is not watertight.


*Figure 2. Example of a leakage testing setup with UA1414. Look for bubbles in the water.*

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| ⚠ Keep watertight plug lid dry | **Caution** Test-c4<br>Do not let the watertight plug lid get wet during the testing procedure. Keep it out of the tank.<br>If water gets inside the watertight plug lid, moisture can be transferred from the lid to the plug connector pins during reprocessing. This can damage the transducer. |

## Leakage Testing Procedure

**To test a transducer for leaks:**

1. Visually check the edge of the plug and the seal on the lid to make sure that they will fit tightly. Place the test lid on top of the plug with the locking pins unlocked (pointing at the open lock sign). Make sure that the lid is properly aligned and seated on top of the plug.
2. Firmly attach the test lid, as described in "Watertight Plug Lids" on page 54.
3. Pump slowly to increase the pressure up to a relatively stable level of 150 mm Hg. Keep pumping until the pressure is stable. If the pressure does *not* stabilize, look for obvious leaks before you submerge the transducer in the water. The purpose of submerging the transducer is to find small leaks that are not otherwise detectable.
4. Once 150 mm Hg is reached, observe the pressure for 45 seconds.

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| ⚠ Do not immerse if pressure drops | **Caution** Test-c3<br>If the pressure drops to zero after you use the pump, do not place the transducer in the tank. |

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| ⚠ Keep plug dry | **WARNING** T-w5<br>To prevent electrical shock and damage to the transducer, the connector pins in the transducer plug must always be completely dry before you connect to a system. |

5 If the pressure appears stable, place the transducer and covered plug in the water tank for 45 seconds. Water temperature should be between +10 °C and +40 °C.

6 With the transducer in the water tank, observe carefully to make sure that no bubbles escape from the transducer.
**NOTE:** *Some small, insignificant bubbles may escape from the housing/gasket interface when the transducer is placed in the tank - this is not a leak. A leak is indicated by a constant, steady stream of escaping bubbles.*

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| ⚠ If you see bubbles, do not release pressure | **Caution** Test-c5<br>If you see any bubbles, remove the transducer from the tank before you release the pressure. |

7 If you find a leak, contact your BK Ultrasound service representative to have the transducer repaired.

8 When leakage testing is finished, dry the transducer and connector before releasing the pressure and removing the test lid.

9 If the transducer will be further processed in liquid (for example, cleaned manually), attach the watertight plug lid (not the test lid) properly.

## Leakage Testing Kits

There are two leakage testing kits, UA1404 and UA1414.

Check your product's Product Data Sheet for the appropriate leakage testing kit.

It is not likely that the tester will need cleaning, but you can wipe the lid with a mild detergent, then wipe it with tap water, and then dry with a soft cloth. Do not try to clean the pump.

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| ⚠ Do not use test lid for reprocessing | **Caution** Test-c2<br>The lid part of the leakage tester is for testing only. Do not use it when you reprocess the transducer. |

### Yearly Preventive Maintenance and Performance Test

To ensure proper performance of the entire ultrasound system, preventive maintenance of the system, including a performance test, should be carried out once a year by a BK Ultrasound technician or a suitably qualified engineer.

Follow local procedures or consult your BK Ultrasound service representative about how to perform this check.

Circles and shadows when imaging in air

When you observe the monitor image from an array transducer that is not contacting a surface, you may see circles (or lines) and shadows. The concentric circles (or lines) are caused by re-reflections within the transducer and may not be uniform; they disappear when you image tissue. The shadows are caused by variations in the

transducer elements and the structure of the transducer surface. They do not indicate that the transducer is beginning to fail, and they do not influence general image performance.

All the equipment necessary for carrying out system preventive maintenance can be obtained from BK Ultrasound.

## Yearly Check of Type BF Transducers

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| ⚠ Check of Type BF transducers | **WARNING** Check-w3<br>To prevent electrical shock, all transducers that comply with Safety Standard EN60601-1 (IEC60601-1) Type BF must be checked once a year to ensure that they still comply with the requirements of this standard. Transducers that need to be checked have the letters BF or the symbol printed on them. This check must be carried out by qualified personnel. Contact your BK service representative if you need any help checking your transducers. |