

ULT800 Ultrasound Leakage Tester

MAXIMIZING PATIENT SAFETY WITH THE ULT800 SYSTEM

Are your ultrasound transducers safe?



Are you putting your patients at risk?

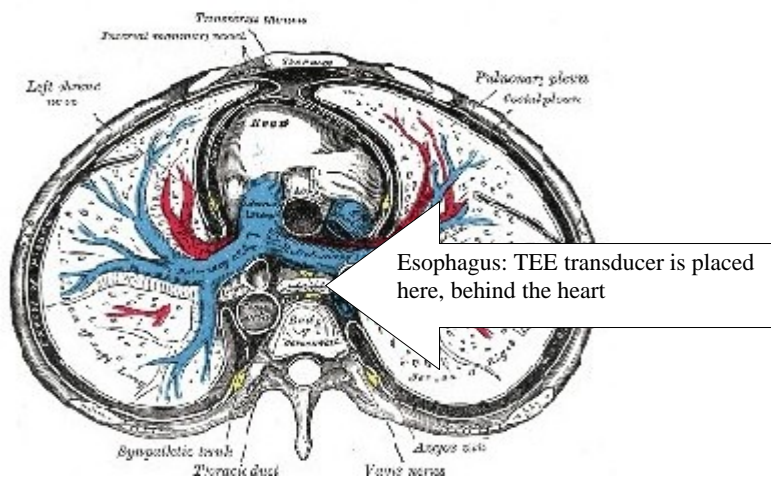
OPERATING OVERVIEW

Background: Diagnostic Ultrasound systems are abundantly present in healthcare facilities today and are an increasingly common modality used in many types of patient diagnosis. In addition to the ultrasound departments found in almost every acute care hospital worldwide today, there are literally tens of thousands of outpatient facilities and clinics, doctors offices, urgent care centers, surgical centers, etc. across the country (and many more around the world) that are utilizing diagnostic ultrasound on a routine basis. Over the past 20 years, this routine utilization has evolved into hundreds of thousands of diagnostic ultrasound transducers of many different types in use around the world today. Of particular concern are TEE (Transesophageal Echocardiography) transducers, which are routinely used in close proximity to the heart. Diagnostic ultrasound manufacturers are testing their ultrasound transducers at the factory to ensure patient safety. At least one leading manufacturer is actually shipping an ultrasound electrical leakage testing system as a value-added accessory to their customers with new TEE transducers. Is your facility continuing this all-important leakage testing vigilance with the transducers you use on patients on a daily basis? If not, you could be putting your next patient at considerable risk.

Situation: Transesophageal Echocardiography (TEE) is employed to diagnose certain cardiac diseases and conditions. TEE allows the physician to detect subtle findings within the heart. By positioning the transducer in the esophagus, which is just behind the heart, there is elimination of usual barriers to ultrasound created by the chest wall or lung fields. This allows enhanced resolution compared to standard imaging methods. This test is frequently ordered for assessment of valvular disease, aortic disease, endocarditis and cardiac source of emboli.

Figure 1
Cross-section of the human thoracic cavity

Problem: Because of its proximity to the heart when the TEE transducer has been properly positioned, the electrical insulation integrity of the transducer becomes of paramount concern. A transducer in which the electrical integrity has been compromised in any way can present a significant level of danger to the patient in the form of microshock hazard. Voltage levels within the transducer head are sufficient to create electrical leakage levels in excess of 100 μ amps through the compromised insulation barrier, thus putting the patient at significant risk.



Implication: Excessive leakage current is capable of producing a microshock hazard, thus causing ventricular fibrillation, and possibly leading to total cardiac arrest.

Prevention: Leakage current levels from the TEE transducer should be routinely tested. Ultrasound transducers (especially TEE transducers) should ideally be tested at the beginning of the day (prior to the first patient procedure), and between individual patient diagnostic procedures. This can be easily and quickly accomplished during the normal cleaning procedure for the transducer.

The Solution: The ULT800 Ultrasound Leakage Current Test Kit provides a complete testing solution for TEE transducers as well as other types of diagnostic ultrasound transducers. The ULT800 is so simple to use, non-technical medical personnel (e.g. Sonographers, Central Sterile Supply technicians, etc.) can actually perform this type of testing. Testing is most readily

accomplished during the routine disinfection/cleaning procedure for the transducer. Typically, this can be done while the transducer is soaking in a Cidex® bath. Fluke Biomedical offers a disinfecting/testing tray as an accessory item for the ULT800. This tray can also serve as a storage container for the ULT800 and up to four (4) individual ultrasound transducer test adapters (if ordered from Fluke Biomedical, your disinfecting/testing tray will come with a special fitted foam storage liner for the ULT800 system).

How it Works: The ULT800 Ultrasound Transducer Electrical Leakage Tester measures the electrical leakage current of ultrasound transducers, independent of their ultrasound machines. The hand-held battery-operated ULT800 is designed to be used during routine transducer cleaning and disinfecting procedures that are conducted between patient uses. A built-in self-test insures that the ULT800 is working properly each time you turn it on. A low battery warning indicator virtually eliminates the possibility of incorrect test result indications caused by a weak or significantly depleted battery.

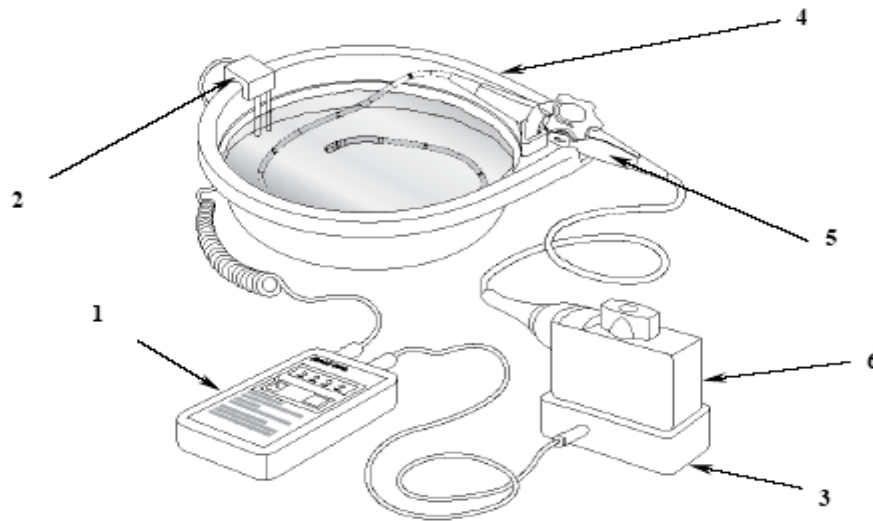
The ultrasound transducer to be tested is connected to the ULT800 via a unique ultrasound transducer adapter (see Figures 2,3,4). The measurement is performed when the transducer is immersed in a cleaning solution (e.g. Cidex® or saline). To insure that the electrical leakage test will be accurate, the conductivity of the cleaning fluid is first tested. A special dual element probe (600/212 or 600/220 Dual Conductivity Probe) is connected to the ULT800 and facilitates this conductivity test (see Figures 2,3,4). The results of the conductivity and leakage current tests are indicated either by green (PASS) or red (FAIL) indicators on the front panel of the ULT800. In addition to verifying that the ultrasound transducer is safe for patient use, the ULT800 makes it possible to reduce expensive repairs. Identifying transducers that exceed safe electrical leakage current levels early may allow for needed repairs to be made before a transducer becomes non-repairable due to damage related to leaks or damaged insulation barriers.

On the Technical Side: The ULT800 generates a pulsed 120-volt, 60 Hz signal from its internal 9-volt battery, and places this voltage potential across the insulation barrier of the transducer under test. One pole of this potential is applied to the outside of the transducer through the dual conductivity electrode and into the cleaning solution in which the transducer is immersed. The other pole is connected to the internal elements of the transducer via the special ultrasound transducer adapter into which the transducer under test is connected. The actual electrical leakage seen by the ULT800 is then compared to an internal PASS/FAIL threshold (set at 185µA, an extrapolation of the test requirements found in the IEC standards for diagnostic ultrasound transducer testing), and the appropriate PASS or FAIL indicator on the front of the ULT800 is illuminated. To insure operator safety during actual testing, the ULT800 is current limited to prevent any possibility of harmful electrical shock in the case where the operator may inadvertently come into contact with the electrical potential produced by the ULT800.

Kit or Ala Carte: The ULT800 can be ordered in two ways. It is available in kit form, combined with specific ultrasound transducer adapters for testing ultrasound transducers from select manufacturers. It can also be ordered "ala carte", with any combination of ultrasound transducer adapters required to fit your testing requirements. The following is a listing of the currently available ULT800 Kits:



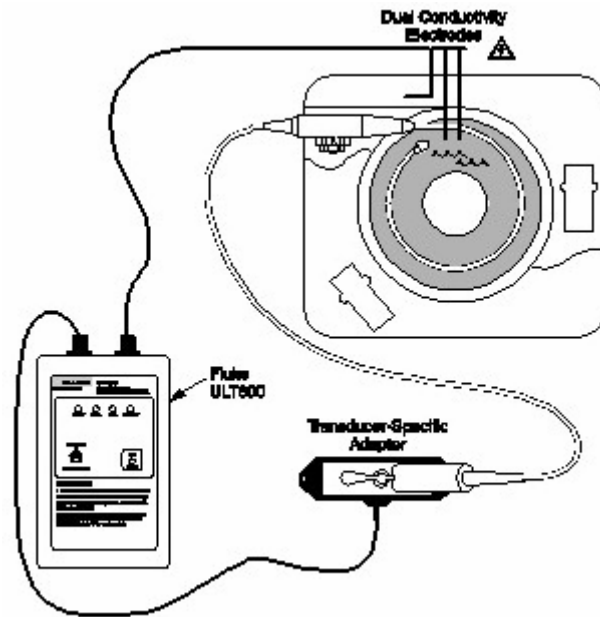
Figure 2



Using the ULT800 with a disinfecting/testing tray and the 600/220 Dual Conductivity Probe to test a TEE Transducer

- Component Key:**
- 1 = ULT800
 - 2 = 600/220 Dual Conductivity Probe
 - 3 = Ultrasound Transducer Adapter (to match the transducer being tested)
 - 4 = Disinfecting/testing tray
 - 5 = Ultrasound transducer under test
 - 6 = Ultrasound transducer connection block

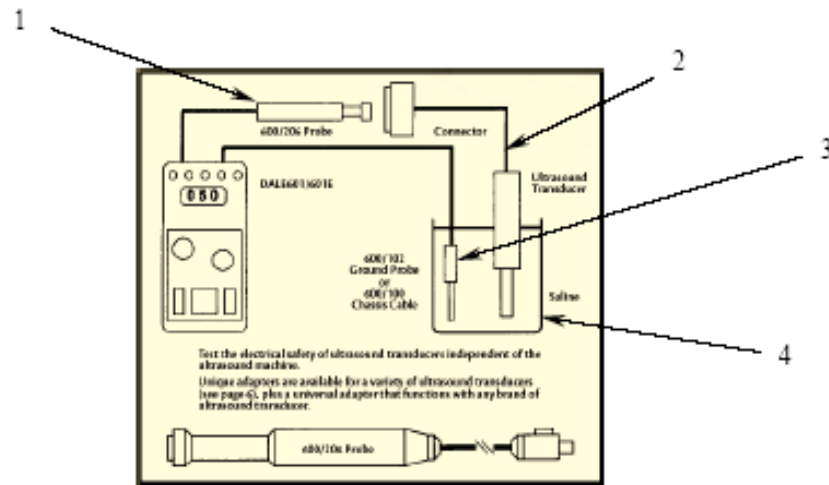
Figure 3



Overhead view of ULT800 with disinfecting/testing tray to test TEE Ultrasound Transducer

- Component Key:**
- 1 = ULT800
 - 2 = 600/212 Dual Conductivity Probe
 - 3 = Ultrasound Transducer Adapter (to match the transducer being tested)
 - 4 = Disinfecting/testing Tray
 - 5 = Ultrasound transducer under test

If you need actual numbers: If you are a biomedical engineer or simply a more technically inclined individual who needs actual readings, you can still measure ultrasound electrical leakage currents easily, and substitute actual μA numerical values for the PASS/FAIL indications of the ULT800. Below is a simple line diagram that can be implemented using the DALE601 or DALE601E electrical safety analyzers to measure ultrasound transducer electrical leakage currents. Of course, you will have to obtain actual readings and then make a judgment-call as to whether or not the readings obtained represent a safe level of electrical leakage for the ultrasound transducer under test. This method is not recommended for anyone without a technical electronics background and a thorough understanding of the principles of electricity.



Using the DALE601/601E to measure ultrasound transducer electrical leakage

- Component Key:**
- 1 = 600/206 Universal Ultrasound Probe or dedicated 600-series ultrasound transducer adapter
 - 2 = Ultrasound transducer under test
 - 3 = Use 600/102 Ground Probe or 600/100 Chassis Cable.
 - 4 = Any suitable container capable of holding the ultrasound transducer and conductive solution

To perform ultrasound transducer leakage test using the DALE601/601E:

1. Connect the transducer adapter to the External connector and either a ground probe or chassis cable to the Chassis connector.
2. Attach the appropriate transducer adapter to the Ultrasound transducer connector,
3. Place the ground probe or clip of the chassis cable in the bath, along with the transducer head.
4. Set the Function Switch to "External" and press the M.A.P. switch to apply mains voltage to the probe. The leakage reading should then be displayed on the LCD.

ULT800 Product Specifications

Power:	Single 9-volt Alkaline Battery
Number of uses:	Approximately 1,000 uses on a single battery
Conductivity:	Limit to pass: greater than $133 \mu\text{A} \pm 1\%$
Leakage:	Limit to pass: less than $185 \mu\text{A} \pm 1\%$ but greater than $20 \mu\text{A} \pm 1\%$
Dimensions:	6.5 x 3.7 x 1.5 inches (17 x 10 x 4 cm)
Weight:	12 ounces (340 grams)
Environmental:	Operating Temperature: 15° to 40° C
Storage Temperature:	15° to 65° C
Relative Humidity:	90% Maximum

The ULT800 can help ensure that the ultrasound transducers you are using on your patients are electrically safe. If you are not testing your ultrasound transducers for electrical safety, you may be putting your next patient at risk!