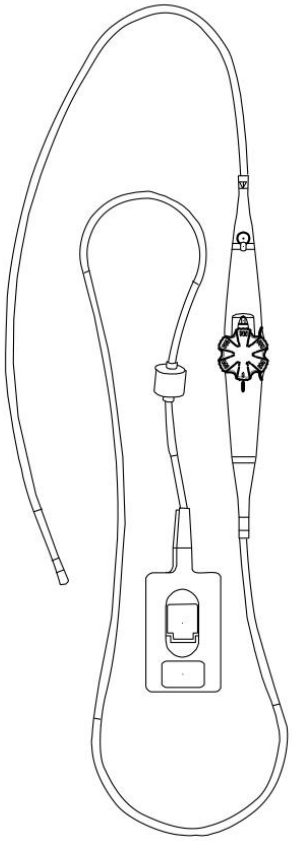
BC Group International Inc.
3081 Elm Point Industrial Dr.
St. Charles, MO 63301
1-314-638-3800
1-800-242-8428
Fax 1-314-638-3200
www.bcgroupintl.com
sales@bcgroupintl.com

ULT-2000 Series Product Overview

Are your TEE and other types of "invasive" ultrasound transducers safe?



Sonosite TEE Transducer
Courtesy of Sonosite, Inc.
Bothell, WA
www.sonosite.com

Or are you putting your patients needlessly at risk?

INDEX

APPENDICES

The Next Generation in TEE Transducer Testing is Here

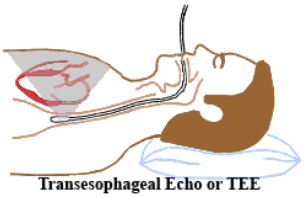
Until now, commercially available dedicated electrical leakage current testing systems for TEE and other types of "invasive" diagnostic ultrasound transducers have been limited to red light / green light testing[1]. If the test **Passes** according to the manufacturer of the test device, a green LED lights up. If the test results in a **Failure**, a red LED lights up. So what constitutes this Pass or Fail criteria? You have to dig into the product specifications of the particular test instrument to find that out, and once you find the information, you will notice that the exact same test protocol (test voltage, test voltage frequency, lower leakage current limit, and upper leakage current limit) is used for ALL types of ultrasound transducers tested, totally regardless of clinical application or the level of risk to the patient.

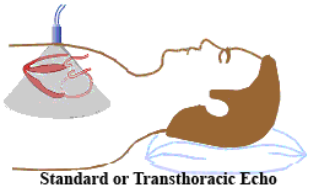
But what if the user really wants to know if the TEE or other type of diagnostic ultrasound transducer is "safe by a long shot" or if it passes just marginally? Is it getting worse or staying the same? Is it leaking more electrical current this time vs. the last time it was tested? Is the insulation barrier holding up or breaking down? Does the transducer display higher leakage values when flexed or strained in a particular way? Can the test results be printed out with a time and date stamp for formal documentation purposes? Until now, there was no real way to get the answers to these important questions with existing commercially available dedicated ultrasound electrical leakage current testing systems.

The BC Biomedical ULT-2000 Series of Ultrasound Transducer Leakage Current Testers (the ULT-2010 and ULT-2020 instruments) changes all of this and delivers the "next generation" in dedicated test devices for TEE and other diagnostic ultrasound transducers, with added functionality and flexibility never before seen in a commercially available and affordable tester.

Why Should You Test Your Transducers Anyway?

Many types of diagnostic ultrasound transducers come into "intimate" contact with the patient and should be tested regularly to evaluate the integrity of the insulation barrier between the inner wiring of the transducer and the outside world. But because of their proximity to the heart during typical clinical application, TEE (Transesophageal Echocardiography) ultrasound transducers are of paramount concern regarding electrical safety and the containment of potentially harmful electrical leakage currents. A tiny bite hole from a previous TEE procedure can leave the next patient at risk to elevated and potentially harmful levels of electrical leakage currents, with such currents actually being introduced by the TEE transducer into the patient's thoracic cavity, within a few centimeters of the heart muscle.


Transesophageal Echo or TEE


Standard or Transthoracic Echo

Major diagnostic ultrasound system manufacturers such as **GE Healthcare**, **Philips Medical Systems**, **Siemens Medical Solutions**, **Sonosite, Inc**. and **Toshiba America Medical Systems** highly recommend electrical leakage current testing of TEE transducers prior to each clinical application (or at least between clinical

[1] This methodology commonly refers to the Dale Technology DALE800, the Fluke Biomedical ULT-800, and the Siemens Medical Solutions DALE800A product that is purchased under private label agreement with Fluke Biomedical.

applications). TEE transducers such as the Acuson V510B and V705B, GE Healthcare 6T, Philips Medical Systems miniMulti, OmniPlane III, S7-3t, MPT- 7-4, Siemens Medical Solutions V5M, V5Ms, V7M, Sonosite TEE/8-3, and Toshiba America Medical Systems PEF 510SB are just a few examples of transducers that should be regularly tested for electrical leakage currents per manufacturer recommendations.

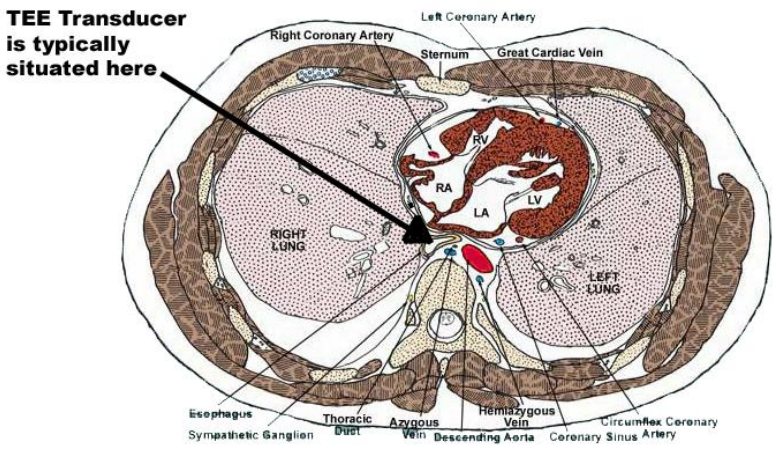


Figure 1
Cross-Section of the Human Thoracic Cavity Showing Proximity of a TEE Transducer to the Heart

Sonosite, Inc. (Bothell, WA) has been an advocate of electrical leakage current testing for TEE transducers since the introduction of their own TEE transducer. In their **TEE Transducer User Guide** (pages 31-33) they highly recommend periodic electrical safety testing. Language from this publication (top of page 31) is as follows:

> *"The electrical leakage current test should be performed on the TEE transducer after taking it out of the box and prior to each exam, alternatively, if the bite-hole inspection test is done prior to each exam, then the electrical leakage current test should be done yearly at a minimum."*

The "bite hole inspection test" referred to in the **Sonosite, Inc. TEE Transducer User Guide** publication involves setting up a water bath with a liquid medium that is electrically conductive to a specified level (water mixed with 50g NaCl/liter of water), using a Digital Multimeter calibrated to NIST traceability, and a copper or aluminum sheet with an area of at least 25 cm^2. The TEE transducer is then submersed in the water bath with the endoscopic shaft placed into the liquid up to the 40 cm mark. Readings are taken and compared to desired results. This test is recommended as a possible alternative to the electrical safety test (described in detail below using the BC Biomedical ULT-2000 Series), but it would actually be more time consuming than the electrical safety test described below, and could not be combined with the normal disinfection process. Also, because this test utilizes a simple digital multimeter, it is a DC-only low voltage test, and it will not capture capacitive electrical leakage currents that may be present during normal use of the ultrasound transducer with the ultrasound system powered by a customary AC power system at 50 or 60 Hz.

The Sonosite **TEE Transducer User Guide** publication can be downloaded from the Sonosite, Inc. company website at the following location: http://www.sonosite.com/content/view/55/439/ . Simply scroll to the bottom of the page to find it. You can also see Appendices D, E. and F of this document for detailed information, or simply follow this embedded link to access the file at the Sonosite web site.

Since early 2006, Sonosite, Inc. has purchased and offered for resale to their customers as an accessory item to their TEE transducers, the Fluke ULT-800 instrument for electrical safety testing.

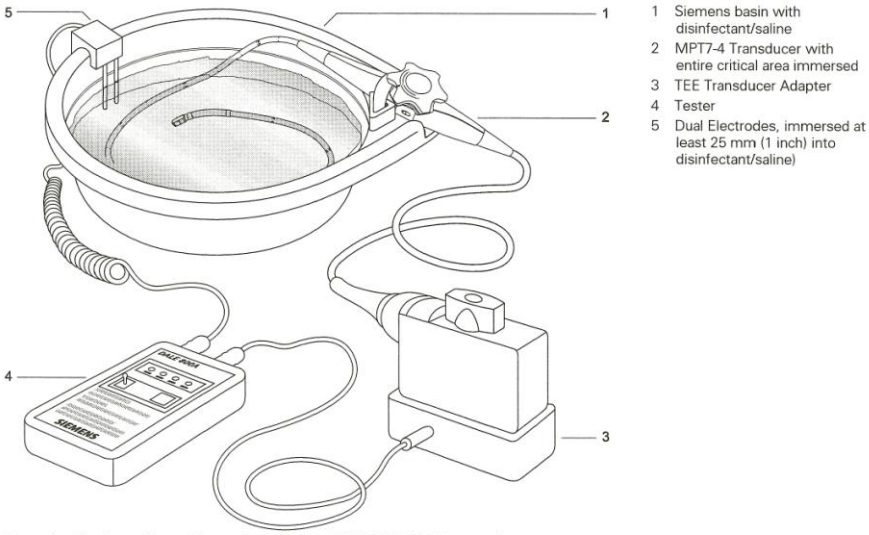
Siemens Medical Solutions is probably the most pro-active diagnostic ultrasound manufacturer in the market today when it comes to advocating TEE transducer electrical leakage current testing. Since April, 1993, Siemens Medical Solutions (Mountain View, CA) has been offering the DALE 800A TEE Transducer Leakage Current Tester to its TEE transducer customers as an accessory item, under the Siemens Medical Solutions brand label. In the Siemens **DALE 800A TEE Transducer Leakage Current Tester Instruction Manual**, the testing method outlined is exactly the same as that shown in Figure 2 below. The following language appears in the Siemens manual:

> *"The hand-held battery-operated Tester is designed for use during the routine transducer cleaning procedure conducted between patient examinations."*

The illustration in Figure 2 below is the recommended test setup that Siemens Medical Solutions gives to their customers in the **DALE 800A TEE Transducer Leakage Current Tester Instruction Manual:**

Instruction Manual

Sample Setup for the SONOLINE G60 S System's MPT7-4 Transducer



Example of Leakage Current Tester Setup for the SONOLINE G60 S system's MPT7-4 TEE Transducer.

Figure 2

Recommended TEE Transducer Test Setup Specified by Siemens Medical Solutions

As of the release date of this document, Siemens Medical Solutions markets the DALE800A TEE Transducer Leakage Current Tester on a worldwide basis and strongly endorses TEE electrical leakage current testing with its customers, as well as the specific testing methodology outlined in this document. See Appendix A for product specifications on the Siemens Medical Solutions DALE 800A instrument.

GE Healthcare is another pro-active ultrasound system manufacturer when it comes to advocating electrical leakage current testing of their TEE transducers. For example, in the GE Service Note # SN76018 (October 2, 2000), they outline an electrical safety testing protocol that is very similar to the one described in detail in this document. On page 2 of this service note, the following is stated:

> *"The electrical leakage current in the probe can alternatively be measured in a simplified test without the access to the ultrasound scanner, by using the procedure*

described below. The test described below is not a complete safety test. It is focused on the most important insulation test for this product".

The test setup outlined in this GE service note can be seen in Appendix G of this document. In this same service note, GE Healthcare states the following on page 4 relative to electrical leakage current testing on TEE transducers in general:

"GE Vingmed Ultrasound AS recommends that leakage current testing be carried out on a regular basis to obtain the best possible patient safety. Also, a leakage current test should be conducted prior to the use of the probe in any surgical procedure."

PHILIPS
HP / ATL Agilent

Philips Medical Systems has a history of recommending routine electrical leakage current testing of their TEE transducers that dates back to the Hewlett Packard and Agilent days. It was Hewlett Packard that initially established a working relationship with Dale Technology, Inc. of Thornwood, NY in the late 1990's regarding the use and recommendation of the DALE800 to their ultrasound customers. At that time, the DALE800 was the only commercially available dedicated ultrasound transducer electrical leakage current testing solution. Currently, Philips continues to advocate electrical leakage current testing on their TEE transducers with their customers, as part of an ultrasound "system" approach. In their **TEE Proper Care and Handling Manual** (Publication # 4535 611 90271 Rev B), they have the following comments regarding electrical safety concerns with TEE transducers:

"Cuts in the transducer cable or cracks in the housing can destroy the electrical safety features of the transducers."

"Bites can cause electrical hazards or mechanical malfunction."

"Cuts in the transducer insulation can result in current leakage and may lead to serious patient electrical hazards. In addition, fluid that enters the gastroscope via the cut will cause electrical and mechanical operational problems."

In some of their latest ultrasound system user manuals (specifically, manuals that are involved with systems that utilize TEE or other "invasive" types of ultrasound transducers), Philips Medical Systems includes detailed electrical safety testing instructions that are highly recommended to help determine of there is a hole of any kind in the transducer outer insulating barrier. Bite holes or cuts in this insulation barrier could lead to elevated levels of electrical leakage currents, consequently putting the patient at risk. Philips Medical Systems also warns against conducting transducer electrical safety tests by making simple DC measurements on their transducers, and further claims that such testing procedures yield inaccurate results regarding electrical leakage currents in transducers. The prescribed testing method offered by Philips Medical Systems involves the immersion of the TEE and/or other type of "invasive" ultrasound transducer in a saline solution, typically described within this document.

TOSHIBA
Leading Innovation

Toshiba Medical America is yet another advocate of routine electrical leakage current testing of their TEE transducers with their customers. In their TEE transducer Operation Manuals, Toshiba recommends an electrical leakage current test prior to each clinical procedure involving the transducer. They have an electrical leakage current testing solution in place (the Hioki Model 3451 Digital Megohm Insulation HiTester[2]) and they include this tester with each TEE transducer that they sell. A diagram of the recommended test setup for the Toshiba line of TEE transducers, utilizing the Toshiba supplied tester appears in Figure 3 below.

[2] The Hioki 3451 Digital Megohm HiTester is a DC Insulation Tester and it tests the transducer insulation barrier with DC voltage only. It will not pick up any capacitive electrical leakage currents that may exist in the transducer during actual use on a conventional AC power systems running at 50 or 60 Hz.

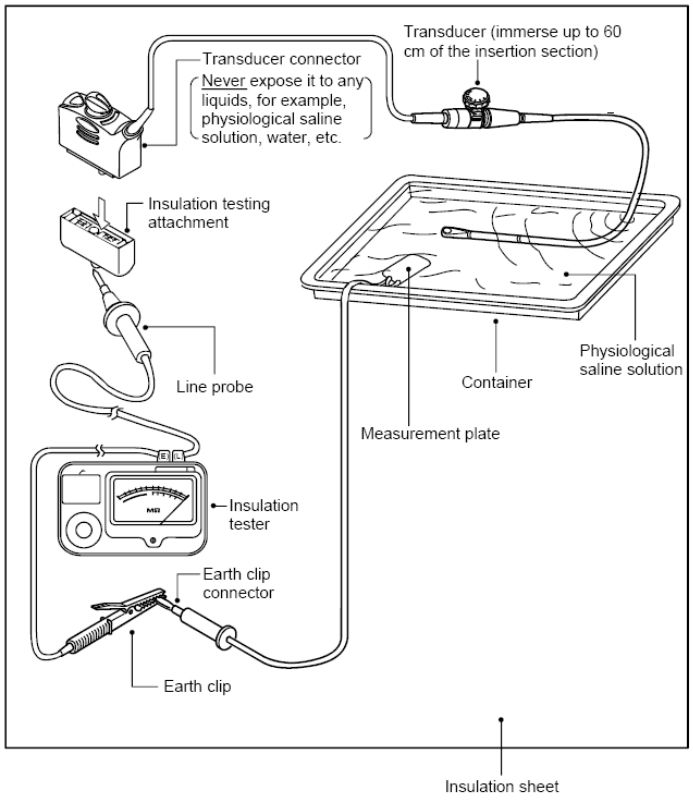


Figure 3

Recommended TEE Transducer Test Setup for Toshiba TEE Transducers Using the Toshiba Tester (Hioki Model 3451 Digital Megohm Insulation HiTester)[3]

Toshiba Medical lists the following safety recommendation in their **Operation Manual For Multiplane Transesophageal Transducer Model PET-510MB (2B701-591E*G):**

"Checks Before Use… Checks before system power ON… Electrical Safety Inspection (inspection using the safety kit)… Perform electrical safety inspection using the safety kit to check for damage to the transducer which may not be visible."

In general, this level concern over transducer electrical leakage currents is slowly but surely expanding to other types of "invasive" ultrasound transducers such as those used during laparoscopic procedures. Other major medical device manufacturers in the ultrasound arena are also beginning to make such recommendations to their customers concerning not only TEE but other types of invasive ultrasound transducers, and the need for electrical leakage current testing on them. Once again, the typical clinical application of these types of transducers finds them having been inserted at least several inches into a body cavity or through some type of an incision in the body, thus violating the human body's natural protection (the outer layers of otherwise dry skin) from electrical macroshock and microshock conditions.

The effects of even the smallest levels of electrical leakage currents on the heart muscle and other internal organs has been studied for over thirty years, and the potential risks are still viewed as critical ones, especially with such currents in close proximity to the heart, as in the typical application of a TEE transducer.

How Can Ultrasound Transducers Be Easily Tested?

TEE and other types of diagnostic ultrasound transducers can be easily tested as part of the routine disinfection process following each clinical procedure[3]. There is no need to make a big deal over testing and there are no elaborate test setups required. There are two basic approaches that can be taken, depending on the method commonly used to disinfect ultrasound probes at the medical facility in question.

Facilities that utilize a disinfecting agent such as Cidex® in a "soak tray" can use this same setup to test the ultrasound transducer for electrical safety during the disinfecting process. A typical test setup is illustrated in Figure 4 below. The most commonly used soak tray has historically been a Cidex® 2032 Tray. A Cidex® 2032 compatible tray is available from BC Group International (BC Part # BC20-42200).

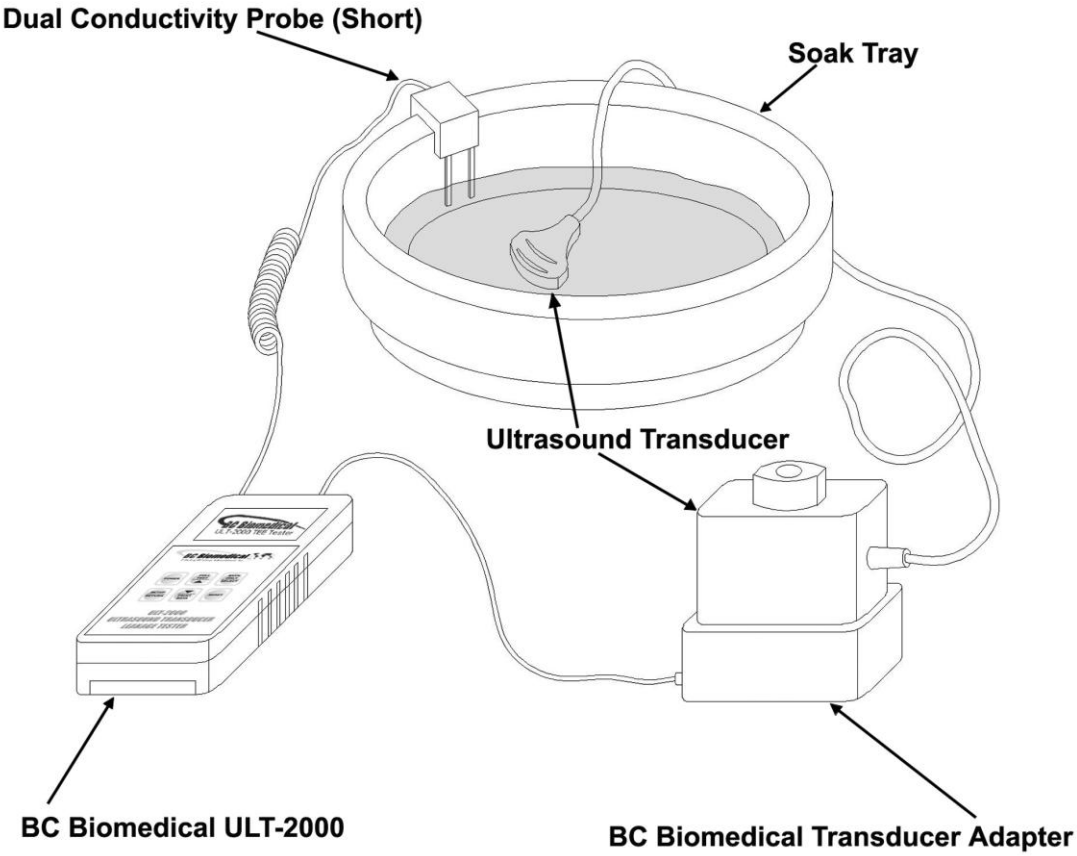


Figure 4
Typical Electrical Leakage Test Setup Using a Soak Tray[3]

Cidex® is characteristically an electrically conductive medium that works extremely well for electrical leakage testing of ultrasound transducers, including TEE transducers. If Cidex® or another disinfecting agent is used in the setup above, a Cidex® compatible soak tray such as the BC Biomedical # BC20-42200 must be used.

This same test setup can be used as a simple test procedure (without the disinfecting function) by using a saline solution or a mixture of tap water with dissolved table salt. The bath conductivity test function of the BC Biomedical ULT-2000 Series will assist in setting up a bath solution that is suitably conductive to electrical currents for this test. In such a test, a Cidex® compatible soak tray is not required.

The BC Biomedical ULT-PC-10 Dual Conductivity Probe is typically used in the soak tray testing solution as pictured above. This is the shorter of the two dual conductivity probe types available from BC Group International for the ULT-2000 Series.

[3] The soak tray and commercial disinfecting system immersion test procedure outlined in this document should only be conducted on those types of transducers that are approved by the original medical device manufacturer for immersion in a disinfecting agent bath. Consult with the manufacturer of your transducer to see what transducers are applicable to this procedure.

Where a commercially available ultrasound transducer disinfecting system such as the Automated TD 100® TEE Probe Disinfector manufactured by CS Medical is used (shown in Figure 5 below), the BC Biomedical ULT-2000 Series can also be easily utilized before or after the disinfecting process, for a combination disinfecting and electrical leakage current testing process with such systems.

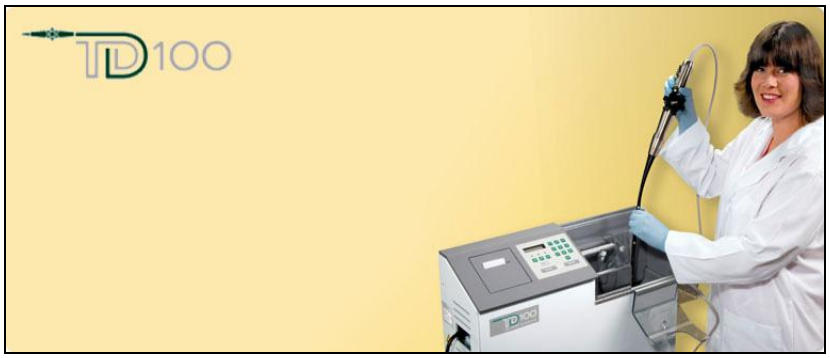


Figure 5
CS Medical TD 100® Disinfecting System

The special-purpose BC Biomedical ULT-PC-20 Dual Conductivity Probe is typically used in this type of application. A generic setup using a commercially available disinfecting station is illustrated in Figure 6 below.

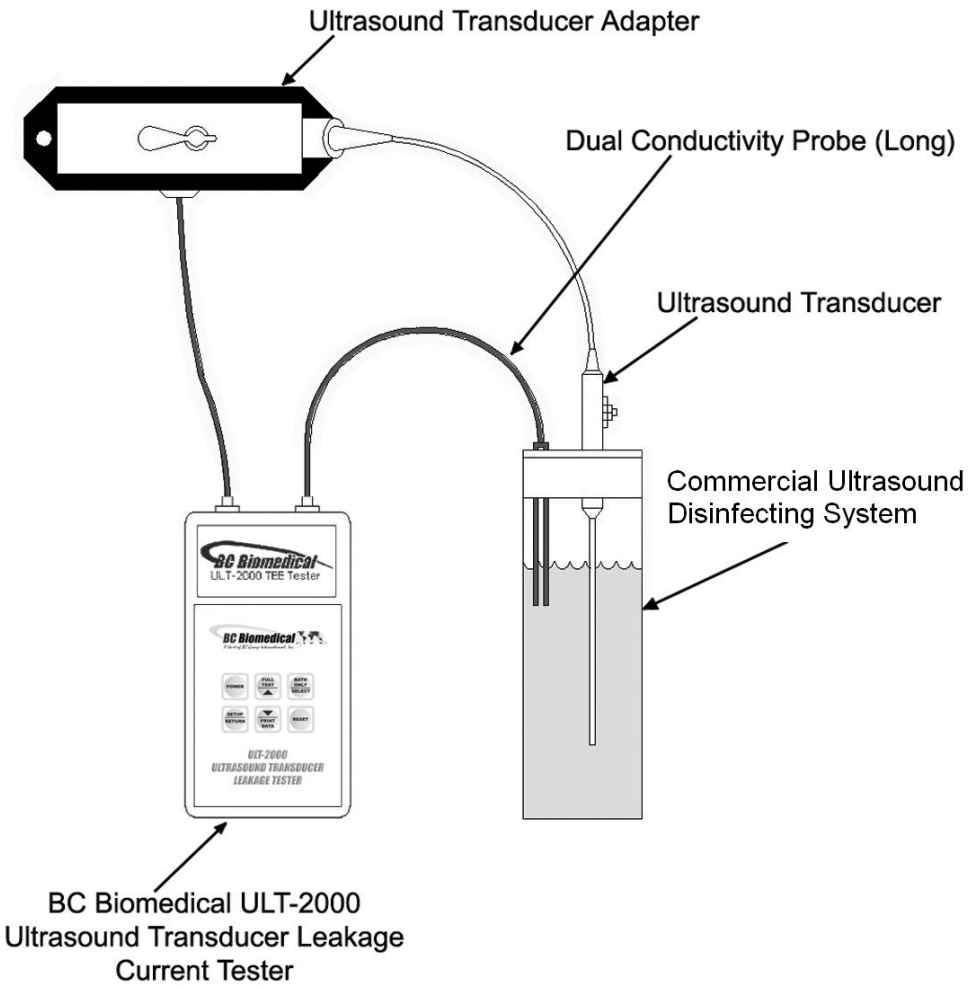


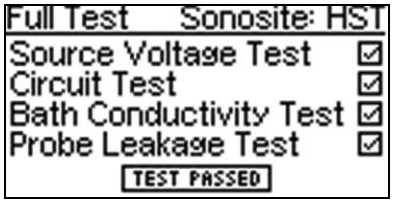
Figure 6
Generic Functional Diagram of a Typical Electrical Leakage Test Setup Using a Commercial Disinfecting System

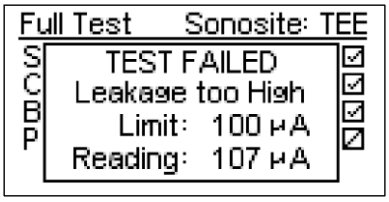
No matter which of the above setups is used, the actual testing is performed in the same manner. The ultrasound transducer to be tested is connected to the test device (BC Biomedical ULT-2000 Series) through a dedicated

ultrasound transducer adapter (as shown in Figures 4 and 6), also available from BC Group. The leakage current test is performed after the patient contact or "application" end of the transducer is immersed in the bath solution (typically Cidex® or saline solution). As soon as the ULT-2000 instrument is turned on, an automatic instrument self-test is performed. A test load is switched into the output circuit. The voltage is measured and internal circuitry is confirmed to be working correctly. This same test is performed prior to each electrical leakage test, to ensure test accuracy and quality. To further ensure a quality electrical leakage current test, the conductivity of the bath medium is tested immediately prior to each electrical leakage current test. If the bath conductivity is sufficient, then the electrical leakage current test is performed according to the desired test voltage and frequency (typically specified by the ultrasound manufacturer but the ULT-2000 Series also supports generic test setups as part of the basic instrument firmware). The actual test results are compared to the limits for the transducer being tested (or to the generic limits also supplied in the instrument) and a Pass / Fail indication is given. If the ULT-2000 Series instrument was initially set up to display actual leakage current readings, these readings will also be shown.

Can Non-Technically Oriented Personnel Perform These Tests?

Yes. Electrical safety testing of TEE and other types of diagnostic ultrasound transducers does not require the user to know anything about electrical leakage currents or electrical safety testing protocols. Anyone that can read and properly interpret the words "Pass" and "Fail" can adequately perform a proper electrical safety test on a transducer with the BC Biomedical ULT-2000 Series.

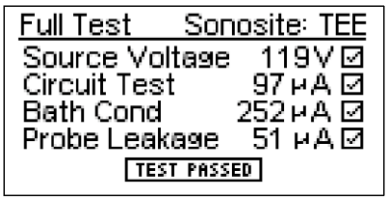


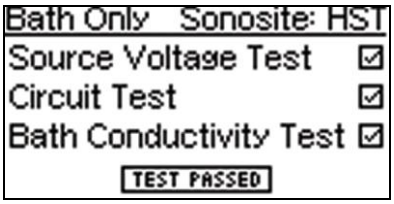


Whether the instrument is set up (by the user) to provide actual numeric values or not, the ULT-2000 Series instrument clearly reports a Pass or Fail result that is easily interpreted by anyone. It's that simple!

Can Technically-Oriented Personnel Get Important Measurement Data?

Yes. The user can select from two modes of operation in the ULT-2010 instrument (compared to three modes offered by the ULT-2020 instrument). The Pass / Fail mode as outlined above is intended for non-technical users such as ultrasound sonographers, central sterile supply technicians, etc. For biomedical and clinical engineering professionals, the Numeric Test Results mode reports the actual test results and leakage current limits in addition to the Pass / Fail results. The Metering mode of the ULT-2020 instrument allows the user to constantly monitor electrical leakage currents in real time to assess the impact of probe movement, flexing, straining, etc.





Competitive Product Comparison[4]

A brief overview of the BC Biomedical ULT-2000 Series as compared to the leading competitive products on today's market is as follows:

Feature / Product	BC ULT-2010	BC ULT-2020	DALE800[5]	Siemens DALE800A[6]	Fluke ULT-800[7]
User-selectable operating modes	Yes	Yes	No	No	No
User-selectable test voltages	Yes	Yes	No	No	No
User-selectable leakage current limits	Yes	Yes	No	No	No
User selectable test voltage frequency	Yes	Yes	No	No	No
Pass / Fail test results	Yes	Yes	Yes	Yes	Yes
Numeric test results data displayed	Yes	Yes	No	No	No
On-board storage of test results	No	Yes	No	No	No
Manufacturer & Model probe database	Yes	Yes	No	No	No
Ability to print test results report	Yes	Yes	No	No	No
Real-time continuous metering mode	No	Yes	No	No	No
Single 9-volt battery operation	Yes	Yes	Yes	Yes	Yes
AC power operation for long term testing	Yes	Yes	No	No	No
RS232 communications port	Yes	Yes	No	No	No
Download stored test results to PC	No	Yes	No	No	No
Large graphical display with backlighting	Yes	Yes	No	No	No
Real-time clock & calendar function for time and date stamping test results	Yes	Yes	No	No	No
Utility PC software available	Yes	Yes	No	No	No
Accurate and reliable readings down to 0.5 microamps	Yes	Yes	No	No	No
Accurate and reliable readings up to 500 microamps	Yes	Yes	No	No	No
Bath conductivity test	Yes	Yes	Yes	Yes	Yes
Aggressive bath conductivity test[8]	Yes	Yes	No	No	No
Compatibility with Dale / Fluke adapters and probes	Yes	Yes	Yes	Yes	Yes

The Difference Starts with the Bath Conductivity Test

From the start, the BC Biomedical ULT-2000 Series does it better than other commercially available dedicated testing solutions. Prior to the ULT-2000 Series, commercially available test systems simply tested the liquid medium bath at a single voltage level and reported a Pass result at a relatively low conductivity level. Typical values at the fixed point 120 VAC, 60 Hz bath conductivity test for a Pass result range from 133 microamps to 246 microamps. This amounts to a bath resistance level of 0.902 Megohms to 0.488 Megohms, respectively, for those Ohm's Law enthusiasts out there. More will be stated on why these levels are not adequate for reliable testing below.

The BC Biomedical ULT-2000 Series pushes the limit and ensures adequate bath conductivity to catch all transducer leakage current limits, no mater how big or small. The ULT-2000 conductivity test is performed at the minimum user-selectable voltage of 90 VAC. The test also looks for a minimum of 500 microamps of current flow at this voltage, in order to establish a Pass status for the bath conductivity test. This calculates to a bath resistance of 0.180 Megohms, which is 2.7 times better than the best case scenario and 5 times better than the worst case scenario of the other commercially available testers. What does this all mean and why is it important?

[4] Competitive product information presented is based upon all available information in the public sector, including but not limited to the following sources; product specification documents, product data sheets, product operator manuals, product information as found on the manufacturer's website.
[5] Product specifications can be seen in Appendix C.
[6] Product specifications can be seen in Appendix A.
[7] Product specifications can be seen in Appendix B.
[8] Defined as testing the bath conductivity at the minimum user-selectable test voltage while testing for at least 500 microamps of current flow through the bath medium

For the technically savy user…

First, here is the explanation for those technically-inclined Ohm's Law enthusiasts referred to above. Consider the simple series equivalent circuit below as being representative (functionally equivalent) of our soak tray test setup.

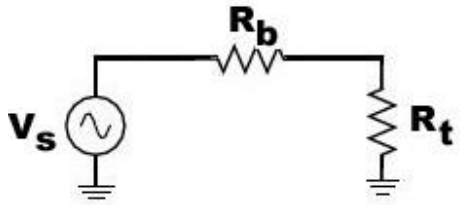


Figure 7
Simple Series Equivalent Circuit of Bath Resistance and Transducer Insulation Barrier Resistance

Consider V_s to be the test instrument voltage, R_b as the bath resistance, and R_t as the transducer under test insulation barrier resistance. Consider the current flow in the circuit to be the leakage current. This example is a little over-simplified, but it will work for this analysis. Use V_s = 120 volts. Using Ohm's Law (V = IR), the total current flow through the circuit will be the following:

$$I = V_s / (R_b + R_t) \quad \text{or} \quad I = 120 / (R_b + R_t)$$

For the simple series circuit in Figure 7 above, we essentially want the resistance of the bath (R_b) in the soak tray to be as low as possible, and much lower than the equivalent resistance of the insulation barrier of the transducer (R_t). Otherwise, it will interfere with the leakage current readings and may result in a false Pass / Fail test status.

If we use a 100 microamp Pass / Fail limit for any given transducer, then at leakage currents (series circuit current flow) above 100 microamps, we have a Fail condition and at currents below 100 microamps we have a Pass condition. This would calculate to a transducer insulation barrier equivalent resistance (R_t) of 1.2 Megohms as the borderline between the Pass and Fail conditions. **For the sake of this example, let's set the actual value of R_t to 1 Megohm**. In our simple series circuit above, and in an ideal, non-real world example, R_b would ideally be 0 ohms. Thus the current flow in the circuit would be 120 microamps, which constitutes a Fail condition (remember, the Pass / Fail threshold is 100 microamps). Now let's get back to the real world and add the R_b value of 0.180 Megohms that the ULT-2000 Series looks for to give the bath conductivity test a Pass status. The current flow in our simple series circuit is now 101.69 microamps. The ULT-2000 Series would report a Fail test status in this example.

Now let's look at how the competitive instrument that simply looks for a 133 microamp conductivity level to report a Pass status on the bath test does. From the explanation above, at this level of bath conductivity, the equivalent resistance of the bath can be calculated as 0.902 Megohms. This is our new value for R_b. Adding this value of R_b to the R_t value of 1 Megohm results in a series circuit current flow of 63.09 microamps! The test result is a Pass! But the real current (leakage current) is more like 120 microamps. What happened? The low conductivity (high resistance) of the bath (R_b) got in the way and reported a false Pass condition on a bad transducer!

Finally, let's look at how the competitive instrument that looks for a 246 microamp conductivity level to report a Pass status on the bath tests does. Again, from the explanation above, at this level of bath conductivity, the equivalent resistance of the bath can be calculated as 0.488 Megohms. This is our new value for R_b. Adding this value of R_b to the R_t value of 1 Megohm results in a series circuit current flow of 80.65 microamps! The test result is still a Pass! But once again the real current (leakage current) is more like 120 microamps. What happened? Once again, the low conductivity (high resistance) of the bath (R_b) got in the way and reported a false Pass condition on a bad transducer!

This example may be over-simplified but it certainly illustrates the role of the test bath conductivity level in the reporting of Pass / Fail results on transducers. In the example above, the BC Biomedical ULT-2000 Series reports the results correctly, while the competitive instruments report false Pass conditions, based solely on the role of the bath resistance. The much more aggressive bath conductivity test of the ULT-2000 Series instruments goes a long way to help ensure more accurate and more reliable test results, as compared to other commercially available testers.

For the non-technically oriented but interested users out there…

If you have no idea what Ohm's Law is and you don't care to find out, as we have already stated, the much more aggressive bath conductivity test of the ULT-2000 Series instruments goes much further in ensuring the accuracy and reliability of the test results on your TEE and other types of ultrasound transducers. In the specific example illustrated above, the transducer was bad, as it had approximately 120 microamps of electrical leakage at a 120 volt test voltage. The ULT-2000 Series instrument properly reported this Fail status. Based upon this analysis, the other commercially available testers would probably have falsely reported Pass results for this same transducer!

Dealing With Real World Parameters

The fact is that ultrasound manufacturers specify the following parameters in their detailed specifications on their ultrasound transducers, relative to electrical safety testing:

- Test voltage
- Test voltage frequency
- Lower leakage current limit (actual test value must exceed this value to Pass)
- Upper leakage current limit (actual test value must be less than this value to Pass)

Unlike other commercially available dedicated testers, the BC Biomedical ULT-2000 Series deals with all of these "real world" variables. Test voltage can be set by the use in the range of 90 to 275 volts at either 50 or 60 Hz. This capability is in response to customer demands in countries other than North America, where nominal line voltages are higher (e.g. 230 volts) and the frequency is different from North America (50 Hz instead of 60 Hz). There are some customers that even argue that the test voltage should be 10% above the nominal line voltage. The ULT-2000 Series responds to all of these demands.

There are some ultrasound manufacturers out there that have transducers with characteristic leakage currents that are as high as 300 to 400 microamps! These are the actual manufacturer specifications for select transducers. The current systems on the market do not address these real-world examples of transducers that have higher levels of electrical leakage currents when tested according to the prescribed means as illustrated in this document. The ULT-2000 Series instruments address these specific transducers with an upper-end range of 500 microamps.

Lower (low-end) leakage current limits are also a reality of manufacturer specifications. Transducers are "validated" by a minimum leakage current level as low as 2 microamps. The ULT-2000 Series instruments will measure reliably and accurately down to 0.5 microamps. The currently available competitive instruments on the market cannot accurately or reliably resolve leakage current levels less than approximately 20 microamps. One of these manufacturers has actually had to supply some of its customers with leakage current "dummy loads" designed to fool their instrument into thinking there was a higher amount of leakage than was actually present at this low-end with a specific type of transducer, just to get it to Pass the lower limit leakage current test. Is this how you want your leakage tester to work?

Finally, in order to make life even easier for the users of the ULT-2000 Series instruments, there is a manufacturer and model specific transducer database on board in the instrument that contains all of these "real world" variables for each transducer entered into the database. BC Group International has actually been working with several ultrasound manufacturers on supplying actual manufacturer specifications regarding characteristic leakage currents and set limits for Pass / Fail results according to these specifications. This work will continue well into the future.

Why Test With AC Voltages Instead of DC Voltages?

The ULT-2000 Series tests at AC voltages rather than DC for two main reasons. First, the capacitive leakage currents that will be present in an ultrasound system and transducer that is normally powered at AC line voltage will be present and will be detected in the test. At DC voltages, they will not be present nor will they be read by the tester. This would be a false test. Secondly, testing at DC voltages could set up a voltaic cell[9] condition, with

[9] See Appendix H for additional information on a voltaic cell.

the metal of the transducer and test electrode in the Cidex® or salt bath forming the two electrodes and an electrolyte. This condition would result in inaccurate readings

Can Test Results Be Archived for Legal Liability Purposes?

Yes. Unlike other commercially available dedicated testing systems, the BC Biomedical ULT-2000 Series offers the ability to print test results to an accessory printer that is attached to the RS232 communications port of the ULT-2000. A ruggedized serial printer is available from BC Group International as an optional accessory item to the ULT-2000 Series under Part # BC20-42300.

This printer will work with either the ULT-2010 or ULT-2020 instruments. With the ULT-2020 and the PC Utility Software for the ULT-2000 Series, the user can actually print test results form the PC as well.

Test results printed from the ULT-2000 Series instrument will have the date and time of the test listed, thanks to the real-time clock and calendar function of the ULT-2000 Series. Stored test records will also contain the date and time of test as part of the stored data. A sample printout of these test results can be seen in Appendix I.

Test results can also be archived via the ULT-2000 Series PC Utility Software to a PC (ULT-2020 only), and can be printed at any time from the PC to any Windows® compatible printer.

PC Utility Software Makes It Easy

The BC Biomedical ULT-2000 Series PC Utility Software is a special Visual Basic software utility for the ULT-2000 Series that makes it easy to perform functions like adding or editing information in the transducer manufacturer and model database (both ULT-2010 and ULT-2020), configuring the instrument (ULT-2010 and ULT-2020), operating the tester remotely (ULT-2020 only), and downloading stored test results (ULT-2020 only).

Ultrasound Transducer Adapter Compatibility

Users of competitive instruments such as the Dale Technology DALE800, the Fluke Biomedical ULT-800, and the Siemens Medical Solutions DALE800A, who have already invested substantially in a library of dedicated ultrasound adapters, will find the BC Biomedical ULT-2000 Series to be 100% compatible with the adapters previously purchased. These users can take full advantage of the advanced level of features and functionality offered by the ULT-2010 and ULT-2020 instruments by simply purchasing one of these instruments and using it with existing adapters. Users who need additional adapters will also find that the adapters available from BC Group International are at a significant cost savings compared to those available from our competitors.

Available Transducer Adapters

At the time of publication of this document, the following complement of dedicated ultrasound transducer adapters is available from BC Group International for use with the BC Biomedical ULT-2000 Series, as well as with competitive dedicated testing systems that utilize these types of adapters:

Ultrasound Transducer Manufacturer	Ultrasound Platform	Transducer Compatibility	BC Biomedical Part #
Sonosite	180/180+, Titan	ICT7-4, ITC8-5, C60, etc.	ULT-PA-11
Siemens/Acuson	Sequoia	V5M (TEE), V7M (TEE), EV8-C4, etc.	ULT-PA-10
Siemens	Antares	EC9-4, etc.	ULT-PA-12
Siemens/Acuson	128XP	156-pin Transducers	ULT-PA-13
Philips/ATL	HDI-3000/3500/5000	C9-5, C8-4v, MPT7-4 (TEE), etc.	ULT-PA-17
Philips/ATL	le33/iU22	S7-2 (TEE), S7-3t (TEE), C8-4v, C9-5, etc.	ULT-PA-17
GE	LogicQ & Vivid	6T (TEE), 9T (TEE), E8C, etc.	ULT-PA-16
GE	LogicQ & GE P9603AU	Other	ULT-PA-16

For an up-to-date listing of transducer adapters available from BC Group International, simply go to www.bcgroupintl.com.

Advanced Features for Advanced Users

Independent ultrasound service companies like Echoserve of Golden, CO[10] (www.echoserve.com), that use the BC Biomedical ULT-2000 Series product, will find some of the advanced and special features of the BC Biomedical ULT-2000 (available in the ULT-2020 Model) extremely useful. The special "Monitoring Mode" of the ULT-2020 (the advanced testing model of the ULT-2000 Series) allows real-time continuous testing for electrical leakage currents while the ultrasound probe cable is flexed and bent in order to evaluate whether positioning or stress on the cable has any effect on electrical leakage currents.

The ability to store up to 99 sets of test results in the ULT-2020 adds to the flexibility of the instrument. Test results can be printed to the optional printer immediately following the leakage test or they can be recalled from memory at a later time and printed then.

The ULT-2000 Series PC Utility Software allows remote control of the ULT-2020 and allows the user to transfer the stored test results form the instrument to the PC for printing or archiving.

Competitive Product Cost Comparison

Even with all of the added features and functionality of the BC Biomedical ULT-2000 Series, system cost is not something that our customers will find to be prohibitive in any way. A fully-functional test system for both the BC Biomedical ULT-2000 Series and the leading competitive unit could easily include the following items:

- TEE Leakage Current Tester
- Conductivity Test Probe
- Two (2) dedicated ultrasound transducer adapters
- Soak Tray

The "system cost"[11] of the leading competitive unit[12], with all of the items specified above, could be as high as $ 2,529, depending upon the transducer adapters selected. The comparable system, utilizing the BC Biomedical

[10] Echoserve is a customer of BC Group International and uses the ULT-2000 Series instruments in their business.
[11] Based upon U.S. List Price of individual part numbers at the time of publication of this document..
[12] Fluke Biomedical ULT-800 pricing is referenced in this comparison.

ULT-2000 Series product and the adapters for the same transducers would cost $ 2,190. That's a savings of 13%, even with all of the added functionality of the BC Biomedical ULT-2000 Series.

Conclusion

The evidence regarding the need for electrical leakage current testing between patient applications of TEE and other "invasive" types of ultrasound transducers, as gathered from the major diagnostic ultrasound system medical device manufacturers represented in this document, is compelling. This testing is clearly prescribed at the end-user level. Some manufacturers even go as far as recommending suitable test setups[13]. Accordingly, end-users of these TEE and other types of "invasive" types of transducers are strongly advised to comply with these original manufacturer recommendations in order to: 1) enhance the quality of patient care and safety, and 2) avoid legal liability implications in the case of a patient treatment event in the process of using such a transducer. The only logical conclusion would be to perform these electrical safety tests on these transducers prior to each clinical procedure. The easiest and most efficient way to perform these tests would be to implement the test methodology illustrated within this document, utilizing the "next generation" BC Biomedical ULT-2000 Series instruments.

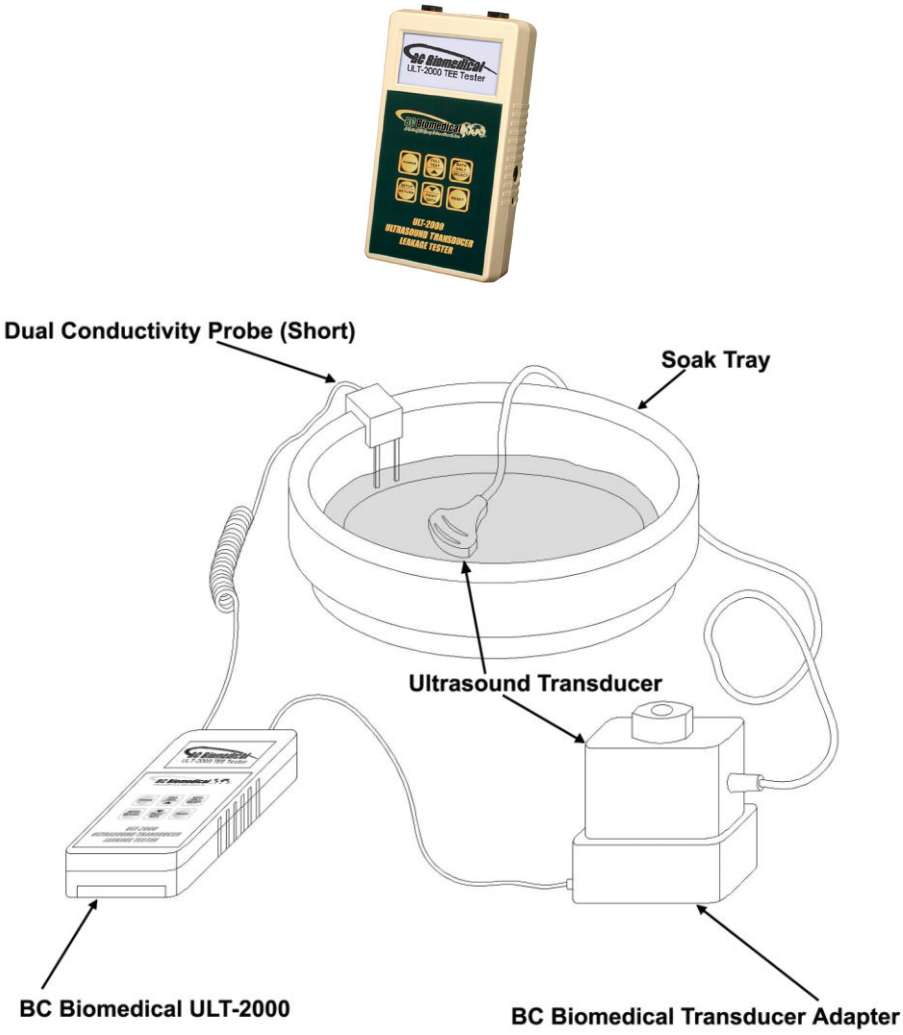
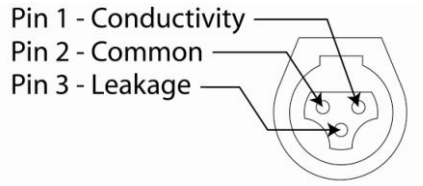
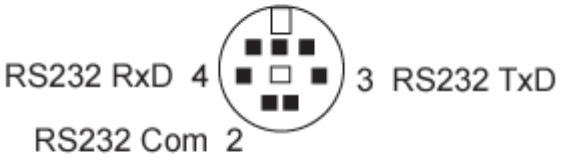


Figure 8
Typical Electrical Leakage Test Setup Using a Soak Tray[14]

[13] See Figures 2 and 3, and Appendices for manufacturer recommended test setups.
[14] The soak tray and commercial disinfecting system immersion test procedure outlined in this document should only be conducted on those types of transducers that are approved by the original medical device manufacturer for immersion in a disinfecting agent bath. Consult with the manufacturer of your transducer to see what transducers are applicable to this procedure.

ULT-2000 Series Product Specifications[15]

SOURCE, LEAKAGE AND CONDUCTIVITY	
SOURCE (CHALLENGE) VOLTAGE	90 - 275 VAC, ± 1% FS 500 µA Max Load
SOURCE (CHALLENGE) FREQUENCY	50 or 60 Hz, ± 0.5 Hz
LEAKAGE CURRENT MEASUREMENT	0.50 - 10.00 µA, ± 0.5 µA 10.0 - 250.0 µA, ± 1% Range 250.0 - 500 µA, ± 1% Range
CONDUCTIVITY CURRENT MEASUREMENT	0.5 - 500 µA, ±1% FS
CONNECTIONS	 Note: As Viewed From Unit Exterior

ELECTRICAL AND MISC.		
BATTERY	9V Lithium Battery (ANSI/NEDA 1604LC or equivalent)	
BATTERY ELIMINATOR	10 VDC, 300mA ⊖⊙⊕ BC20-21103 (USA Version) BC20-21106 (EURO Version)	
POWER CONSUMPTION	ON	< 300 mA
	OFF	< 250 uA
BATTERY LIFE	CONTINUOUS	> 100 Full Tests
	OFF	1 year
RS-232 COMMUNICATIONS CONNECTOR	Seven (7) pin Mini-DIN Pinout: **RS232**  **NOTE: As Viewed from Unit Exterior**	

[15] Specifications are accurate as of the date of release of this document. Specifications are subject to change without prior notice.

ELECTRICAL AND MISC. (continued)		
RS-232 COMMUNICATIONS SETTINGS	BAUD	115200
	DATA BITS	8
	START BITS	1
	STOP BITS	1
	PARITY	none
	HANDSHAKING	none

PHYSICAL & ENVIRONMENTAL		
DISPLAY	128 X 64 Pixels Graphical LCD, White LED Backlight	
MEMORY	SETUP	EEPROM, All parameters
	RETENTION	10 Years w/o Power
CONSTRUCTION	ENCLOSURE	ABS Plastic
	OVERLAY	Back-printed Lexan
SIZE	7.27 x 3.97 x 1.80 Inches (184.7 x 100.8 x 45.7 mm)	
WEIGHT	≤ 1.1 Lbs (0.50 kg)	
OPERATING RANGE	15 to 30 °C (59 to 86 °F)	
STORAGE RANGE	-40 to 60 °C (-40 to 140 °F)	

Technical References

- Sonosite TEE Transducer User Guide, Publication No. P05341-02 06/2005, Copyright Sonosite, Inc., Bothell, WA (Download file @ http://www.sonosite.com/Service-Support/support-documents.html)
- GE Healthcare Service Note # SN76018, October 2, 2000, Copyright GE Healthcare
- TEE Proper Care and Handling (Publication # 4535 611 90271 Rev B), Copyright 2004, Koninklijke Philips Electronics N.V.
- iE33 Ultrasound System User Reference (Publication # 4535 612 82431 Rev A), Copyright September, 2006, Koninklijke Philips Electronics N.V.
- Operation Manual for Safety Kit for Multi-Plane Transesophageal Transducer (2B701-753E), Toshiba Corporation, Copyright 2003
- Operation Manual for Multiplane Transesophageal Transducer Model PET-510MB (2B701-591E*G), Toshiba Medical Systems Corporation, Copyright 2002 - 2006
- Common Ultrasound Probe Failures (Copyright 2006) , Sonora Medical Systems (www.4sonora.com) , Author: G. Wayne Moore, B.Sc., MA
- Dale Technology DALE800 Product Overview Document, Fluke Biomedical, Author: Michael R. Erwine, Copyright June, 2003 (Download file @ www.daletech.com/main/**DALE800**ProductOverview-RevA.pdf)
- Siemens Medical Solutions DALE 800A TEE Transducer Leakage Current Tester Instruction Manual, Copyright April, 2003 (Co-authored by Michael R. Erwine)
- Dale Technology DALE800 Operator Manual (Out of production – no longer available), Copyright Dale Technology, Inc.
- Fluke Biomedical ULT-800 Operator Manual, Copyright Fluke Biomedical (Download file @ http://global.flukebiomedical.com/busen/support/manuals/default.htm)
- IEC 60601-1:1988 Medical Electrical Equipment–Part 1. General Requirements for Safety.
- UL 60601-1:2003, Underwriters Laboratories Medical Electrical Equipment-Part 1. General Requirements for Safety.

APPENDICES

All documents and information contained in the following Appendices have been obtained from various sources within the public sector, and do not represent confidential information or trade secrets of any kind. Recognition of ownership and copyright is hereby given to the companies and manufacturers whose product and other types of information are represented here in this document for informational purposes. Original ownership and copyright of this documentation remains with these companies.

APPENDIX A

Siemens DALE 800A Instrument Specifications

(Source: Siemens Medical Solutions DALE 800A Instruction Manual)

Specifications

Power:	9-volt alkaline battery	
Number of Uses:	Approximately 1,000 uses on a single battery	
Conductivity Threshold:	Limit to pass: greater than 246 µA ± 10 µA	
Leakage Threshold:	Limit to pass: less than 185 µA ± 2 µA and greater than 40 µA ± 10 µA	
Dimensions:	6.5 x 3.7 x 1.5 inches (17 x 10 x 4 cm)	
Weight:	340g	
Environmental Requirements:	Operational Temperature:	10° to 40° C
	Storage Temperature:	-40° to 60° C
	Relative Humidity:	90% Maximum

APPENDIX B

Fluke Biomedical ULT-800 Instrument Specifications

(Source: Fluke Biomedical ULT-800 Users Guide)

ULT800

Users Guide

Specifications

Power: 9 V Alkaline Battery

No. of Measurements: Approximately 1000 measurements on a single battery

Conductivity: Limit to pass: greater than 250 µA ±5 %

Leakage: Limits to pass: less than 100 µA ±5 % and greater than 20 µA ±5 µA

Dimensions: 6.5 x 3.7 x 1.5 in. (17 x 19 x 4 cm)

Weight: 12 oz (340 g)

Environmental

Operation Temperature: 15 ° to 40 ° C

Storage Temperature: 15 ° to 65 ° C

Relative Humidity: 90 % Max

APPENDIX C

Dale Technology DALE800 Instrument Specifications

(Source: Dale Technology, Inc. DALE800 Instruction Manual)

SPECIFICATIONS

Power:	9-Volt Alkaline Battery	
No. Of Uses:	Approximately 1,000 uses on a single battery	
Conductivity:	Limit to pass: greater than 133 µA ± 1%	
Leakage:	Limit to pass: less than 100 µA ± 1%	
Dimensions:	6.5 x 3.7 x 1.5 in (17 x 10 x 4 cm)	
Weight:	12 oz (340 g)	
Environmental:	Operation Temperature	15º to 40º C
	Storage Temperature	15º to 65º C
	Relative Humidity	90% Max

APPENDIX D

Sonosite TEE Electrical Safety Test Description

(Source: Sonosite TEE Transducer User Guide)

Electrical Safety

The electrical leakage current test should be performed on the TEE transducer after taking it out of the box and prior to each exam, alternatively, if the bite-hole inspection test is done prior to each exam, then the electrical leakage current test should be done yearly at a minimum.

Electrical Leakage Current Test

SonoSite ultrasound systems with accessories are designed to meet the requirements for patient safety described in IEC 60601-1:1988 Medical Electrical Equipment-Part1. General Requirements for Safety. To maintain patient safety it is important to have a low electrical leakage current in the product.

The endoscope shaft has no electrically conducting surfaces, and is covered with a layer of material, which permits neither fluids nor electricity to pass through it. Electrical safety is maintained for the transducer by keeping this material intact.Each TEE transducer is tested for electrical isolation and leakage current before it is shipped to a customer.

WARNING: To avoid injury to the patient, do not use the transducer if the insulating material has been punctured or otherwise compromised.

Checking the integrity of the insulating material cannot always be accomplished by visual inspections. A program for measuring the electrical leakage current on a regular basis should be established. As a minimum, leakage tests according to EN 60601-1/IEC 60601.1 §19 must be performed once a year, or as required by local regulation. The leakage limits associated with Type BF Applied Part must be met. The test requires access to the ultrasound system and to standardized test equipment. The transducer has to be immersed in a Normal Saline solution (50g NaCl per liter water) to above the 40 cm mark (but below the handle).

SonoSite recommends keeping a written log of the results.

WARNING: Measuring electrical leakage current should only be done by qualified personnel. Take all necessary precautions to avoid contact with non-insulated parts that have applied voltage.

Safety

APPENDIX E

Sonosite TEE Bite-Hole Test (1st page)[16]

(Source: Sonosite TEE Transducer User Guide)

Bite-Hole Inspection Test

Bite-holes or other damages of the endoscope surface can alternatively be detected by a simplified test without the access to the ultrasound system, by using the following procedure. The objective of this test is to detect bite-holes. It is safe and easy to perform, but is not an isolation or leakage current test as described in EN 60601-1. The test equipment is shown in Figure 2.

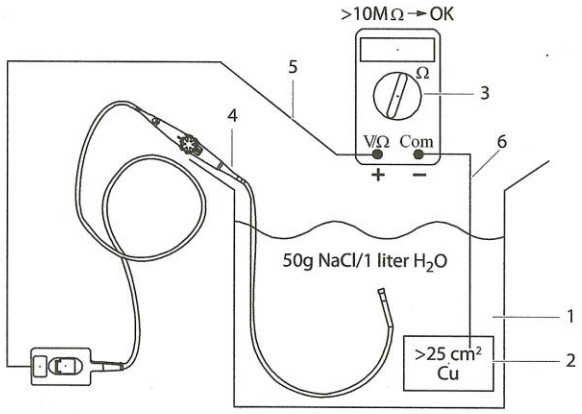


Figure 2 Equipment Used to Detect Bite-Holes in the Endoscope Shaft

Table 1: Equipment Used to Detect Bite-Holes in the Endoscope Shaft

Number	Description
1	Water bath
2	Copper or aluminum sheet
3	Multimeter
4	TEE transducer
5	Positive lead
6	Negative lead

[16] Because this test utilizes a simple digital Multimeter, it is a DC-only low voltage test, and it will not capture capacitive electrical leakage currents that may be present during normal use of the ultrasound transducer with the ultrasound system powered by a customary AC power system at 50 or 60 Hz.

APPENDIX F

Sonosite TEE Bite-Hole Test (2nd page)[17]

(Source: Sonosite TEE Transducer User Guide)

Test Setup	Assemble the following items for the test. • Water bath with a 1 Normal saline solution (50g NaCl/1 liter water) • Copper or aluminum sheet with an area of at least 25 cm^2 • Digital multimeter with 40 MOhm scale (calibrated to NIST).
Bite-Hole Test	1 Submerse the TEE transducer with the endoscope shaft in liquid to above the 40 cm mark (but below the handle). 2 Connect the leads of the multimeter. See Figure 2. *Note: The multimeter can be connected to transducer and copper or aluminum sheet using alligator clips.* • Connect the positive lead to the bare metal of the system connector housing. • Connect the negative lead to the copper or aluminum sheet in the salt-water bath. 3 Set the multimeter to measure resistance (range > 40 MOhms). 4 Wait at least 2 seconds and verify that the resistance is acceptable (greater than 10 MOhms). *Note: If there is a bite hole, the resistance may vary considerably during the measurement and between different multimeters.*

WARNING: To avoid injury to the patient, do not use the transducer if the resistance value is less than 10 MOhms. Endoscope insulation may be damaged and should be verified by a SonoSite representative.

To avoid injury to the patient, SonoSite recommends that leakage current measurements be carried out on a regular basis. In addition, a bite-hole inspection should be conducted prior to the use of the transducer in any surgical procedure.

Acoustic Output

See the ultrasound system user guide for acoustic output information.

Cleaning and Disinfectants

For cleaning and disinfectant information see the TEE Care Instructions.

Safety

[17] Because this test utilizes a simple digital Multimeter, it is a DC-only low voltage test, and it will not capture capacitive electrical leakage currents that may be present during normal use of the ultrasound transducer with the ultrasound system powered by a customary AC power system at 50 or 60 Hz.

APPENDIX G

GE Healthcare Simplified Leakage Current Setup

(Source: GE Service Note # SN76018)

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SN76018 **TEE Probes** **SN76018**

Measuring Electrical Leakage Current

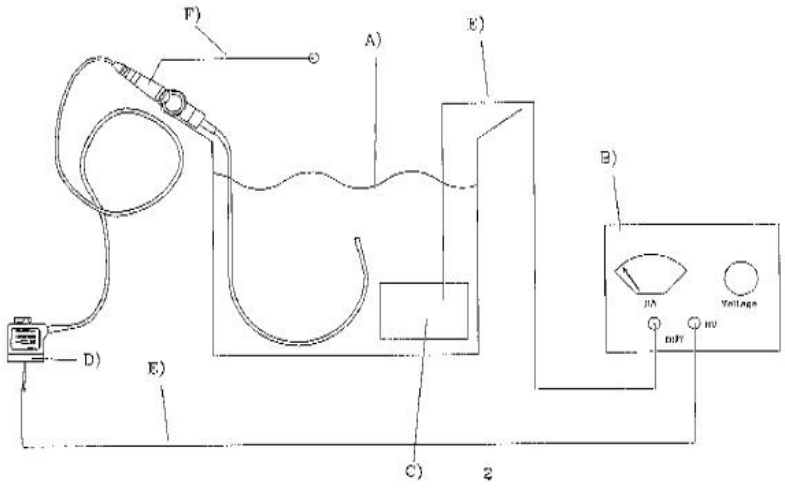


Figure 5-1

Simplified leakage current test set-up

For all references, see Figure 5-1

Required equipment:

A. Tank with Normal Saline solution, sufficiently large to cover the endoscope shaft. Normal Saline solution can be made of 50 grams NaCl pr. liter water
B. Leakage current tester, capable of 275 VAC and with 0 – 10 mA current meter
C. Copper or aluminum electrode, 625 cm2
D. Test connector, supplied with the probe
E. Test wires from probe connector
F. Test wire from the probe handle

1. Connect the equipment as shown in the figure. Connect the wire from the probe handle to the HV terminal.
2. Immerse the TEE Probe up to the 40-cm mark.
3. Increase the test voltage slowly to 275 VAC. Check that leakage current is less than 5 mA. Reduce the voltage to 0 V.
4. Connect the wire from the probe handle to the ground terminal.
5. Increase the test voltage slowly to 275 VAC. Check that leakage current is less than 5 mA. Reduce the voltage to 0 V.

APPENDIX H

Voltaic Cells

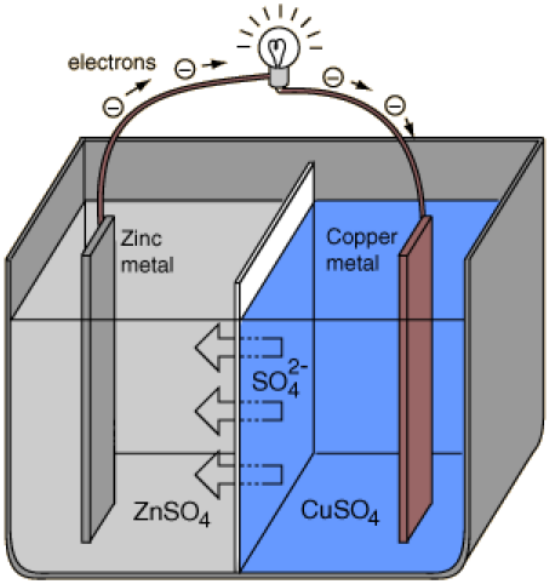
(Source: http://hyperphysics.phy-astr.gsu.edu/hbase/chemical/electrochem.html)

A Voltaic Cell is an electrochemical cell that causes external electric current to flow. It can be created by using two different metals since metals differ in their tendency to lose electrons. For instance, Zinc more readily loses electrons than copper, so placing zinc and copper metal in solutions of their salts can cause electrons to flow through an external wire which leads from the zinc to copper. The presence of this condition sets up a relative inaccuracy in a leakage current test setups as the one shown in this document, and should not be used to test TEE and other types of "invasive" diagnostic ultrasound probes.

Philips Medical Systems has the following to say in their iE33 Ultrasound System User Reference Manual (Publication # 4535 612 82431 Rev A) relative to DC voltage testing of TEE and others types of "invasive" transducers:

CAUTION

Do not make a DC measurement of impedance. This could set up a voltaic cell, with the metal of the transducer and a test electrode in the salt bath forming the two electrodes and an electrolyte. Such a voltaic cell produces inaccurate resistance measurements.



Example of a Simple Voltaic Cell

For additional information on Voltaic Cells, and to complete the analysis (explanation) started above, you can simply visit the following url:

http://hyperphysics.phy-astr.gsu.edu/hbase/chemical/electrochem.html

Or simply search the Internet for "voltaic cells" using your favorite search engine.

APPENDIX I

Sample Printout of Test Results from ULT-2000

Ultrasound Transducer Leakage Test Report

Test Instrument: BC Biomedical ULT-2020

TEST DATE: 10/05/09 TIME: 08:38 AM

TRANSDUCER: Generic, Generic

TRANSDUCER UNIQUE ID: ----------

TEST VOLTAGE: 125 VAC @ 60 HZ

TEST LIMITS: Manuf Deflt

TEST RESULTS: Failed-Conductivity too Low

BATH CONDUCTIVITY TEST

BATH CONDUCTIVITY TEST LIMIT:	500.00µA
BATH CONDUCTIVITY MEASURED:	0.00µA
BATH CONDUCTIVITY TEST STATUS:	FAIL

UPPER LEAKAGE CURRENT TEST

MAXIMUM LEAKAGE CURRENT LIMIT:	100µA
MAXIMUM LEAKAGE CURRENT MEAS:	0µA
UPPER LEAKAGE TEST STATUS:	N/A

LOWER LEAKAGE CURRENT TEST

MINIMUM LEAKAGE CURRENT LIMIT:	10µA
MINIMUM LEAKAGE CURRENT MEAS:	0µA
LOWER LEAKAGE TEST STATUS:	N/A

TESTED BY: ----------

* * * FAILED * * *

APPENDIX J

History of BC Group International, Inc.

BC Group was founded in 1988. In 2000, we began manufacturing our own product line under the now familiar Green and Gold "BC Biomedical" label.

In January of 2005, Lloyd Industries, the company that engineered and manufactured most of the BC Biomedical brand products, purchased BC Group. This acquisition has allowed our products and services to expand at an even faster pace. BC Group, under the "BC Biomedical" brand, is now the second largest manufacturer of Biomedical Test and Measurement Equipment in the world.

Our philosophy with BC Biomedical products runs counter to the current trend of "one-size-fits-all." We offer families of products that provide the users with a choice of models so they can pick the features they need at a price they can afford. We will very shortly be releasing software that will allow our ESU-2400 Electrosurgery Analyzer to not only record data from testing, but to actually run the ESU that it is testing.

BC Group has a major commitment to Quality at all levels of our operation. The entire company is ISO 9001:2008 and 13485:2003 Registered. Our Service Center is compliant with both ANSI Z540 and ISO 17025 with full traceability to NIST. We are Registered with and Inspected by the FDA and follow the Good Manufacturing Practices (GMP) as well as comply with the QSR (Quality Systems Regulation) 21CFR820.

Keep checking our website for the latest additions to the BC Biomedical Line.

BC Group
YOUR ONE-STOP BIOMED SHOP

Website: www.bcgroupintl.com
E-mail: sales@bcgroupintl.com