# Acertara AmpSafe™

**Ultrasound Transducer Electrical Leakage Tester**

**User's Manual**

## Product Description

The AmpSafe™ is a microprocessor-based ultrasound transducer electrical leakage test device.  The AmpSafe™ measures both the conductivity of the cleaning/test medium and the leakage current of the ultrasound transducer.  The AmpSafe™ provides the following features:

- Bring Your Own Device (BYOD) operation: interact with the AmpSafe™ by using any device with a Web browser (PC, tablet, phone)
- Wi-Fi or USB connection to BYOD
- "Single mode" for single measurements of leakage current
- "Meter mode" for continuous measurement of leakage current
- Data save capability on device and/or on a Cloud endpoint
- Test report generation in HTML or PDF
- User-selectable test limits by transducer manufacturer and model
- 2.5% or ± 2.5µA, whichever is greater, FS measurement accuracy
- Automatic internal self-test
- Digital calibration
- Battery life display (0% to 100%)
- Soak timer

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⚠ **WARNING**

High voltages are generated when running AmpSafe™.  Avoid electrical shock.

**DO NOT** touch the ultrasound transducer or any surface that is in contact with AmpSafe™, including the liquid in the test basin, once you start a measurement.

**DO NOT** use AmpSafe™ in any patient occupied areas.

**DO NOT** connect any leads from patient to the AmpSafe™ or any transducer under test.

**DO NOT** operate the AmpSafe™ if water or other liquid has been spilled on the unit.  This can cause a shock hazard.  Call Acertara Acoustic Laboratories (Acertara) at the number listed in the Service and Technical Support section of this manual.

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🌡 **Caution**

AmpSafe™ is designed to be serviced only by authorized service personnel.  Contact Acertara at the number listed in the Service and Technical Support section of this manual for service.
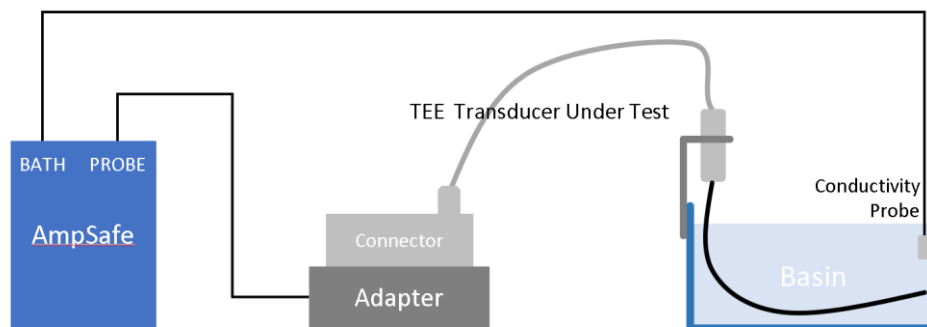
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## User Responsibilities

Users are responsible for testing ultrasound transducers according to the transducer manufacturer's instructions and using manufacturer identified pass/fail criteria. AmpSafe™ users are assumed to have a basic technical knowledge of ultrasonic systems, transducers, and the fundamentals of electronics. Users are responsible for reading and following all product labeling and product literature, and for heeding all warnings and cautions described in the labeling and literature.

## General Operating Overview

The AmpSafe™ is designed to test the electrical safety of all types of diagnostic ultrasound transducers, independent of the ultrasound systems on which they are typically used. Although the AmpSafe™ can test virtually any type of ultrasound transducer, it is especially recommended in the testing of TEE (Transesophageal Echocardiography) transducers prior to each use, as recommended by TEE ultrasound manufacturers. The AmpSafe™ tests the integrity of the outer insulation barrier of the transducer as well as the capacitive leakage currents that exist. Due to the proximity of the TEE transducer to the human heart during normal operation in a patient procedure, abnormally elevated electrical leakage currents can be hazardous to the patient and could induce micro-shock, resulting in cardiac fibrillation and death. It is therefore vital to routinely test TEE and other types of ultrasound transducers prior to their use on a patient.
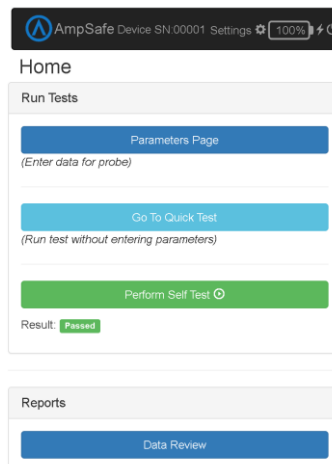
## Test Set Up

Set up AmpSafe™ leakage tester, probe and adapter, and basin as shown in the figure below. Ensure that the in-line conductivity probe is immersed in the conductive liquid medium.



To ensure the insertion tube is soaked for an appropriate amount of time AmpSafe™ has a timer function that allows the User to set the amount of soak time desired. When the selected soak time is reached, AmpSafe™ will provide a visual indication and emit an audible beep indicating to the User to begin the electrical leakage test.

## AmpSafe™ Set Up

The AmpSafe™ unit has a bi-color status LED that is solid red during startup.  After a successful startup and self-test the LED will indicate solid or blinking green.  Startup can take up to 60 seconds.  After startup, the user can connect to the device using the Web browser on a "Bring Your Own Device" (BYOD -- PC, tablet, phone).  Acertara offers a BYOD as an accessory if desired.  There are two primary connection methods: 1) wired and 2) wireless.  For the wired connection, insert one end of a USB cable into the AmpSafe™ unit (USB C connector) and the other end into the BYOD (commonly USB A).  After a few moments, the BYOD will recognize the AmpSafe™ device and the user can open a Web browser to operate the unit.  For the wired connection, enter http://sn00000.ampsafe in the Web browser's address bar, where "00000" should be replaced by the serial number of the unit which can be found on the unit's enclosure.  If this does not connect, enter the following numeric IP address: http://192.168.42.1.  For a wireless (Wi-Fi) connection, the user must configure Wi-Fi for *client* mode or *hotspot* mode (see "Settings Page" below).  In *client* wireless mode, enter http://sn00000.ampsafe where "00000" should be replaced by the serial number of the unit which can be found on the unit's enclosure.  If this does not connect , using the unit's numeric IP address in Wi-Fi client mode is usually not practical -- you can defer to a wired USB connection in this scenario.  In *hotspot* wireless mode, use the BYOD to display available Wi-Fi networks and select the network named "AmpSafe-SN0000" where "00000" should be replaced by the serial number of the unit which can be found on the unit's enclosure.  Once a wired or wireless connection is established and the URLs noted above are entered into the Web browser's address bar, the Home page will appear:



The Home page (and every page) displays the device serial number, a link to the settings for the device, the battery level, and a power on/off button as shown in the above screenshot.

## Power, Battery, and Charging

The battery is a rechargeable 2.3Ah Lithium-Ion. AmpSafe™ is charged via its USB port. The fastest way to charge AmpSafe™ is with the unit powered on. Charging AmpSafe™ while the device is off limits the USB current to 100mA and the battery will take much longer to charge. Also, unless the battery is fully discharged, the unit can be used and measurements made while the device is charging. Whenever the battery is charging a "lightning bolt" is displayed on the battery icon. Below a factory-defined battery level, a warning will be displayed to the user. After an extended period of inactivity AmpSafe™ will automatically power down. The default auto power down inactivity period is set to 60 minutes but this can be adjusted.
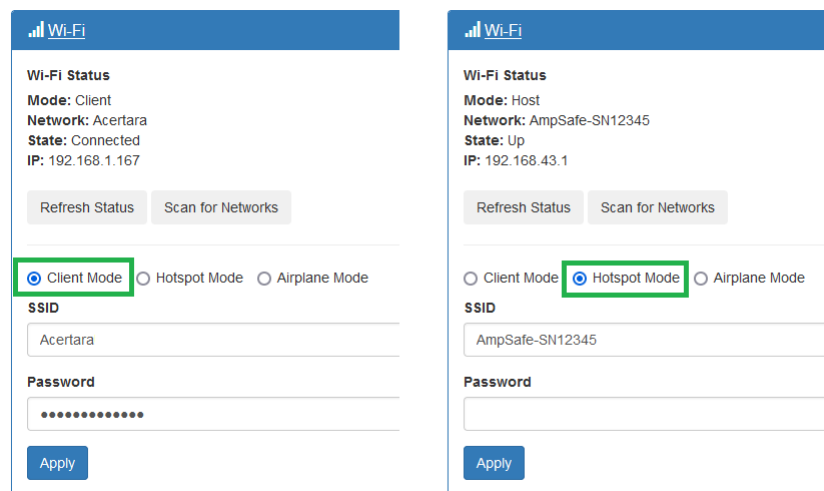
## Self Test

During power-up, the unit will perform a self-test and report the results as pass or fail. The user can invoke a self-test by clicking the "Perform Self Test" button as shown in the Home page screenshot above. Upon failure, it will indicate "failed". There are several possible reasons that a self-test may fail, but a common cause is low battery.

## Settings Page

The settings page allows the user to configure the following items: Wi-Fi, Email notifications, and software update as discussed in this section.

Wi-Fi can be configured in two ways: 1) as a *client* that connects to an existing network, and/or 2) as a *hotspot* that will appear in any list of available Wi-Fi networks shown on the BYOD. Wi-Fi mode (1) (*client*) is useful when the user wants the AmpSafe™ device to connect to their company's network. Wi-Fi mode (2) (*hotspot*) is useful when the user wants to operate the device wirelessly but does not want the device to connect to their company's network. The Wi-Fi settings are summarized in the screenshot below:
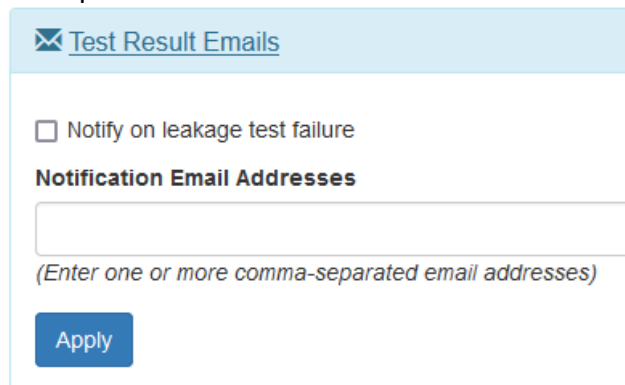
The information entered for Wi-Fi settings is as follows:
- For client mode: specify the SSID of the network to which you wish to connect and the password for that network.
- For hotspot mode: specify the SSID that you would like to assign to AmpSafe™ -- this SSID will be broadcast to the BYOD for connection.  Also specify a password that must be entered on the BYOD.

USB settings are currently fixed and not necessary but they appear for future expansion.

Email notifications can be sent for failing leakage tests by selecting the checkbox and entering one or more recipient email addresses:



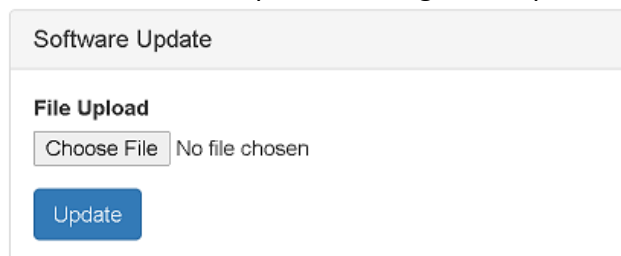Finally on the Settings page, a software update can be applied.  Software updates require an update image file to be sent from Acertara to the user via email or user download.  Once this file is obtained and copied to the BYOD, choose the update file by clicking "Choose File" and then click "Update" to begin the update:
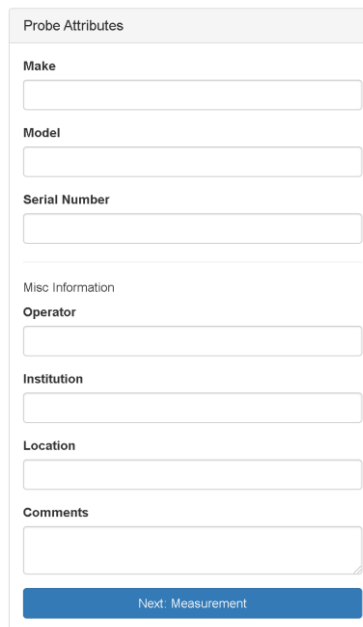
## Performing Leakage Tests

⚠ **WARNING** **High voltages are generated when running AmpSafe™. Avoid electrical shock. DO NOT touch the ultrasound transducer or any surface that is in contact with AmpSafe™, including the liquid in the test basin, once you start a measurement**

To conduct leakage tests, the user has two options from the Home page: 1) Full Test, or 2) Quick Test as discussed next.

### Full Test

A Full Test gathers information about the test conditions before conducting the leakage current measurement. Data from a Full Test can be digitally stored and retrieved. To begin a Full Test, click "Parameters Page" from the Home page which will allow you to enter test conditions as shown below:



Make, Model, and Serial Number are required to properly identify the measurement data as it is saved. After entering the test conditions, click "Next: Measurement" to show the Measurement page which will conduct the actual leakage current measurements (discussed in "Measurements Page" below).
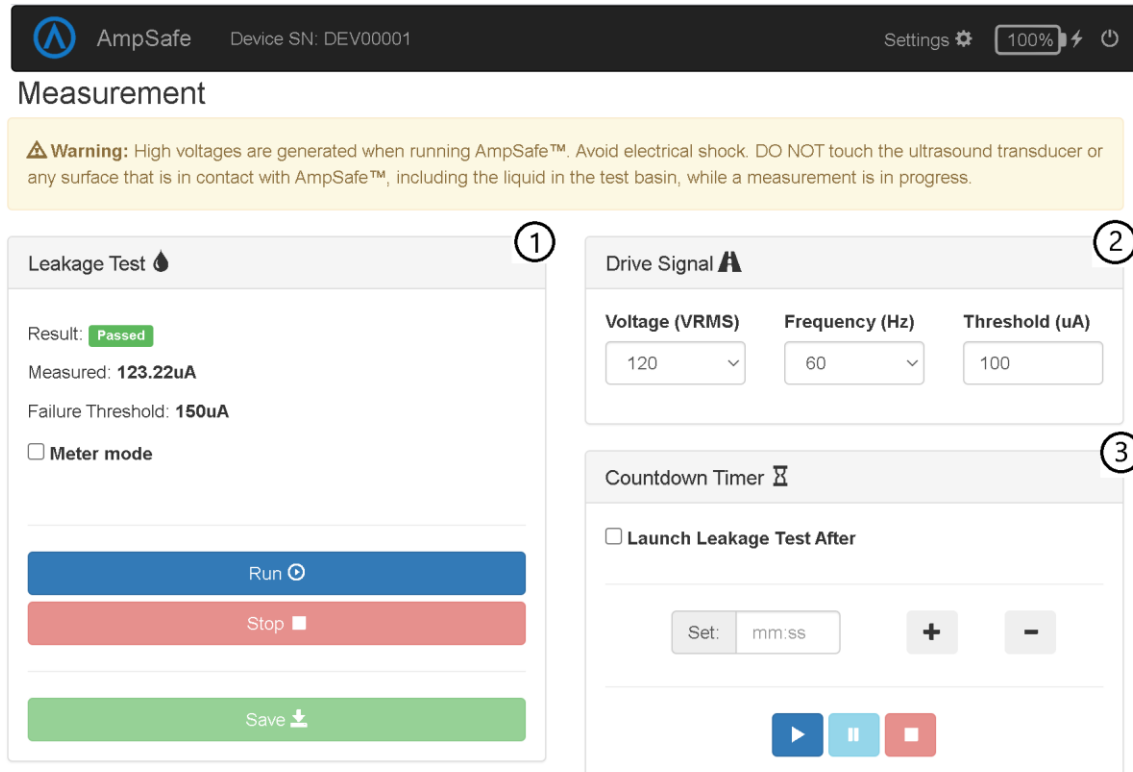
### Quick Test

A Quick Test does not require information about the test conditions before conducting the leakage current measurement. Data from a Quick Test cannot be digitally stored and retrieved. To begin a Quick Test, click "Go To Quick Test" from the Home page to

show the Measurement page which will conduct the actual leakage current measurements (discussed in "Measurements Page" next).

**Measurement Page**

The Measurement page is shown below.  The main features are annotated in the diagram as: 1) Leakage Test command and results, 2) Drive Signal configuration, and 3) Countdown Timer.



Verify the desired drive signal by selecting the voltage and frequency under "Drive Signal".  The user can run a test by clicking "Run" -- the leakage test will be performed and the result will be displayed under the "Result" heading.  Additionally, the actual measured current and the pass/fail threshold will be displayed below the pass/fail result.  Single measurements cannot be stopped mid-stream.  If the measurement produces very low current (below 3μA) for two or more measurements, the software allows you to ignore further warnings.  Warnings are ignored until the Measurement page is closed, the unit goes to sleep, if there is a measurement error, any measurement parameter is changed, or a good measurement is made (above 3μA).  When the Measurement page is entered via Full Test, the "Save" button is available which will save the test data to the device and it can be reviewed from the Data Review page (see section  "Data Review Page" below) .  Additionally, AmpSafe™ offers "Meter Mode" which is enabled by checking the box labeled "Meter mode".  Meter Mode will run a continuous leakage current measurement and the measured result is displayed live.  Meter Mode is executed in the following segments to help preserve battery life: 1)

30sec, 2) 60sec, 3) 120sec, etc.  Beyond segment three (3), each subsequent segment is 120sec.  Finally, the Measurement page provides a countdown timer which can be used for arbitrary countdowns or it can be configured to launch a leakage test after the countdown expires.

## Data Review Page

The Data Review page is accessible from the Home page by clicking the "Data Review" button.  The Data Review page is shown below:



Summary information and results are displayed in the list of measurements to allow for quick visual comparison between tests.  Click any entry in the data file list to view an HTML report for that measurement.  From the Web browser, select "Print to PDF" or "Save as PDF" to generate a PDF version of the report.  An example report is shown below:

## Maintenance and Calibration

Clean the outside of the AmpSafe™ system and the adapters with a damp cloth as needed to remove dust and dirt.  Do not open the AmpSafe™ case.  AmpSafe™ requires calibration and Acertara recommends annual calibration.  Call Acertara at (303) 834-8413 to arrange for calibration.

## Software Security

AmpSafe™ is an internet-enabled medical test and measurement device. With Internet connectivity comes added concerns about the security of the device and the network it is connected to.  AmpSafe™ provides the following features and security mitigations:

- Hosted Wi-Fi AP Mode (*hotspot* mode)
    - o AmpSafe™ can "host" a Wi-Fi network for the purposes of both configuration and normal use.
    - o This network is secured via WPA2 wireless encryption. It can also be disabled entirely.
- Client Wi-Fi Mode (*client* mode)
    - o AmpSafe™ can connect to a pre-existing wireless network for normal operation
    - o While the owner of that network is responsible for its security settings, AmpSafe™ is compatible with several varieties of wireless encryption to ensure that modern network configurations can be used.
    - o Client mode can also be disabled entirely.
- USB Mode
    - o A computer can be connected to AmpSafe™ via a USB-C cable.
    - o Communication with AmpSafe™ uses standard wired internet protocols over USB.
- Cloud Connectivity
    - o AmpSafe™ uses the internet to communicate with Acertara's servers to provide modern Cloud integrations (e.g. automatic emails, software updates). All of these communications utilize transport-layer security (TLS) and user data remains protected at every step of the transaction.

## Troubleshooting

| Symptoms | Possible Causes |
|---|---|
| Unit does not power-on | Ensure the battery is charged above the critical level of 5%. |
| Unit powers down by itself | If the unit is unused for an extended period of time (one hour by default), it will automatically power off; refer to the section "Auto Power Down" for more information. Additionally, the unit will automatically power-down when the battery is below 5%; ensure adequate battery charge. |
| Cannot perform a test | The unit will disallow measurements when the battery drops too low; ensure adequate battery charge. |
| Cannot save test data | Ensure that the Quick Test mode is not active and ensure that a Manufacturer, Probe Model, and Probe Serial Number have been selected before proceeding with a measurement. |
| Very low current measured during a test | Ensure the "Probe" connector is properly seated and connected at the AmpSafe™ unit and at the probe under test. |
| Bath fault encountered during a test | Ensure the "Bath" connector is properly seated and connected at the AmpSafe™ unit and in the test bath. |

## AmpSafe™ Specifications

| SPECIFICATIONS | |
|---|---|
| EXCITATION VOLTAGE | 120VAC or 240VAC |
| EXCITATION FREQUENCY | 50Hz or 60Hz |
| LEAKAGE CURRENT | ≤250µA, 2.5µA or 2.5% |
| CONDUCTIVITY CURRENT | 500 µA |
| DISPLAY | Bring Your Own Device |
| SETUP MEMORY | Micro SD, All Parameters |
| MEMORY RETENTION | 5 Years w/o Power |
| OPERATING RANGE Temp | 10 to 30 Degrees C |
| STORAGE RANGE Temp | -20 to 35 Degrees C |
| CONSTRUCTION | ABS Plastic |
| SIZE | 158 x 83 x 47 mm (L x W x D) |
| WEIGHT | 0.32 kg |
| POWER | LINE:  5V USB BATTERY:  Rechargeable Li Ion |
| POWER CONSUMPTION | ON:  less than 300mA OFF:  less than 60 µA |
| BATTERY LIFE/Charge | ≥ 100 tests |

## Service and Technical Support

Call Acertara at **(303) 834-8413** or email [AmpSafe@acertaralabs.com](mailto:AmpSafe@acertaralabs.com) with any questions you may have about your AmpSafe™ system.  Accessories may also be ordered by calling Acertara at the number above or via email at [sales@acertaralabs.com](mailto:sales@acertaralabs.com)

## Limited Warranty

Acertara warrants its new products to be free from defects in materials and workmanship under the service for which they are intended.  This warranty is effective for twelve months from the date of shipment.

Exclusions:   This warranty is in lieu of any other warranty expressed or implied, including, but not limited to any implied warranty of merchantability or fitness for a particular purpose.

Acertara is not liable for any incidental or consequential damages.

No person other than a corporate officer of Acertara is authorized to give any other warranty or assume any liability and must be in writing.

Remedies: The purchaser's sole and exclusive remedy shall be as follows: 1) the repair or replacement of defective parts or products without charge, 2) at the option of Acertara, the refund of the purchase price.