DALE TECHNOLOGY

DALE601 & 601E

Electrical Safety Analyzers

Operating Manual

DALE TECHNOLOGY

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Warnings

Disconnect all patient connections before connecting the device to be tested to the analyzer.

This device is sensitive to electromagnetic fields. If interference is encountered in measurements, reconfigure the test setup or contact the manufacturer.

Isolation test utilizes 120 or 240 VAC applied to patient leads or to external connections, which are accessible to the tester. Maintain care when making connections.

Although the voltage is current limited to 1 mA, and is safe for healthy intact skin contact, it can be felt and can result in a startled reaction.

Cautions

Be sure that the device under test power requirements are within the capabilities of the safety analyzer, labeled 15A at 120 V for the DALE601, and 10A at 240 V for the DALE601E.

While the analyzers are equipped with receptacle limiting access to devices of higher ratings, replacement cord set may have been installed incorrectly.

The DALE601/601E are not designed for continuous measurements. Do not leave the device under test connected and drawing high load current for extended periods.

To maintain its small hand held size, the analyzer was not designed to provide it's high current capability continuously and may overheat.

Be sure to pause in the OFF (Middle) position when switching polarity from normal to reverse.

Inductive loads of the device under test may create high voltage transients, when trying to reverse the direction of current flow instantaneously.

General Information

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Inside This Chapter

- Introduction
- Controls & Indicators
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- Maintenance & Calibration
- Accessories

Introduction

The **DALE601/601E Electrical Safety Analyzers** are highly versatile and portable instruments. They are used for the basic electrical safety evaluation of electrical systems, medical devices and physiological instrumentation. Their compact hand held size makes them an ideal addition to a service technician or engineer's toolbox for that "after service list" as well as serving as a bench top instrument for the laboratory. They do not sacrifice functions or accuracy and their low cost permits putting one on each bench.

The analyzers are simple to use. A single master function switch directly labeled with the test to be performed leads the user through a complete measurement procedure. A single range meter for each measurement avoids potential erroneous readings.

The analyzer utilizes simple, yet sophisticated electronics for true RMS measurement of current and voltage. Input impedance uses the AAMI ES1-1993 or IEC601-1 test load (manually selectable) to compensate for high frequency components in the measurement. Resistance measurements are made with a four-wire Kelvin bridge to eliminate errors due to cable length and connector resistance.

Unique to the **DALE601/601E Electrical Safety Analyzers** are the capability to make a broad range of external measurements. These include leakage current and/or voltage gradients and resistance between two points. Also, the analyzer provides the voltage and measuring provision for the independent measurement of the isolation current of a device. Thus the analyzer provides the additional versatility for evaluation of the electrical system, system installation and separately, isolation of probes and transducers in addition to the conventional leakage current measurements.

Key Features

- ❑ Hand held instrument
- ❑ Test power line integrity (DALE601 only)
- ❑ Mains Voltage
- ❑ Current Consumption
- ❑ Earth Resistance via four-wire method
- ❑ Selectable Test Load (AAMI or IEC)
- ❑ Earth Leakage Current
- ❑ Enclosure (chassis) current
- ❑ Patient (lead to ground) leakage current
- ❑ Patient (lead-to-lead) auxiliary current
- ❑ Mains on Applied Parts (sink) current
- ❑ External Voltage Gradient
- ❑ Device-to-Device Resistance
- ❑ Probe and Transducer Isolation current
- ❑ True RMS measurements
- ❑ Test Point

Controls and Indicators

Refer to Figure 1 (page 8) and Figure 2 (page 9)

1. **POWER CORD** supplies power to the DALE601/601E Electrical Safety Analyzers and to the device under test (DUT). The measurement circuits are energized when the power cord is plugged into an outlet. There is no on/off switch.

2. **TEST RECEPTACLE** for supplying power to the device under test (DUT). DALE601, 15 Amps at 125 V, Nema 5-15R, and DALE601E, 10 Amps at 230 V, Nema 6-15R.

3. **OUTLET INDICATORS** (DALE601 only) verify the polarity and wiring of the outlet to which the Analyzer is connected. Only correctly wired outlets should be used. *Not applicable to isolated systems.*

4. **OUTLET SWITCH** with center **OFF** position permits testing with both the **NORMAL** (forward) and **REVERSED** polarity of the line. *It is recommended that the switch is paused in the center OFF position before changing polarity.*

5. **L2 (Neutral) SWITCH** permits making leakage current measurements under the **OPEN** neutral **(L2)** condition as required by UL and IEC.

6. **LIFT GROUND / MAP** switch is a dual function switch. The **LIFT GROUND** position will open ground to the device for leakage current measurements. The **MAP** test position will energize the selected patient lead at mains voltage, current limited, to measure the isolation current when the function switch is in the **MAP** position. With the function switch in the **EXTERNAL** position, the isolation test voltage is supplied to the **EXTERNAL** connector for measuring the isolation current of a probe or transducer.

7. **FUNCTION SWITCH** provides direct one step selection of the measurement to be made.

These are, Mains voltage, instrument current, grounding (earth) resistance, earth and leakage currents and the patient lead currents. These include lead leakage, auxiliary current and mains on applied parts (M.A.P.) for isolation (sink) current. An external position is provided to measure leakage current between two points, or isolation current of probes and transducers, independent of their instruments.

8. **LEAD SWITCH** directs the selected patient lead measurement to the desired lead. When testing a 10 lead device, a second pass will be required for the C leads.

9. **METER** (display) is a large, ½ inch, high contrast 3½-digit display of the measured parameter. This will read 1999 with decimal points added where required

10. **UNIVERSAL PATIENT LEADS** provide means for the connection of the patient leads for leakage current measurement.

11. **TEST POINTS** of 0.15 ohms and 100 µA are provided to check the **DALE601/601E** Analyzers by clipping onto with the chassis cable and selecting appropriately, **RESISTANCE** or **ENCLOSURE LEAKAGE** via the function switch.

12. **CHASSIS CONNECTOR** provides means for inputting the chassis cable with its clip for connection to the DUT's chassis or enclosure. With the FUNCTION switch in the resistance position, the earth resistance is measured, and on the enclosure position, the enclosure leakage current is measured.

13. **EXTERNAL CONNECTOR** is for making external measurement of resistance, voltage gradient, leakage current or isolation current of probes and

transducers, when used in conjunction with the chassis cable for the other reference point.

14. **TEST LOAD** selector switch between IEC601.1 and AAMI

15. **CHASSIS CABLE** (not shown), black coil cord with black clamp, for measurement of enclosure leakage and earth resistance. One is supplied with each analyzer.

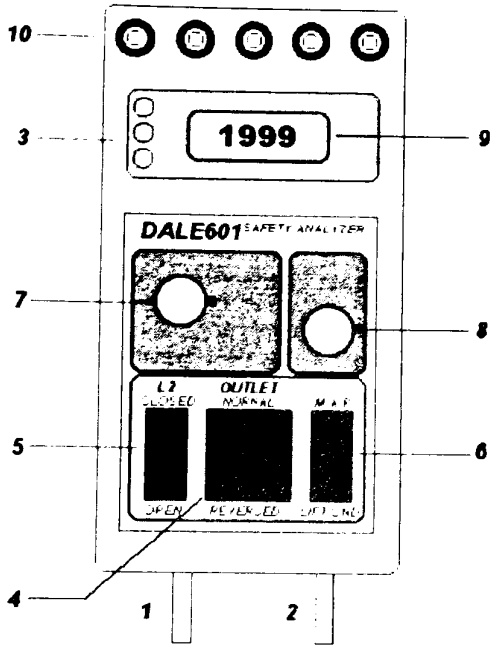

Figure 1

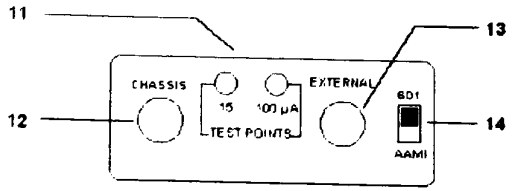

Figure 2

Specifications

Mains Voltage		
Range		Line Voltage
Accuracy		± 2% R, ± 1 digit
Current Consumption		
Range		0 – 19.99 Amps
Accuracy		± 5% R, ± 1 digit
Earth Resistance		
Range	0–19.99 Ohms	
Accuracy	± 1%R,±1 digit (0 – 1.99 Ohms)	
	± 2%R,±1 digit (2–19.99 Ohms)	
Current Source	10 mA DC (four wire bridge)	
Leakage Current		
Range		0 – 1999 µA
Accuracy		
DC and 25 HZ to 1 KHz		± 1% R, ± 1 digit
1.0 KHz to 100 KHz		± 2.5% R ± 1 digit
100 KHz to 1 MHz		± 5 %R ±1 digit
Type Measurement	True RMS	
Test Load	AAMI or IEC601 - 1 (selectable)	
Isolation Test (Mains on Applied Parts)		
Voltage		Mains voltage
Current		Limited @ 1 mA
Current Capacity		
DALE601		15 Amps
DALE601E		10 Amps
Environmental		
Operating Temperature		15º – 40º C
Storage Temperature		- 20º to 65º C
Relative Humidity		90% max

Maintenance and Calibration

The DALE601/601E needs little maintenance or special care. However, it is a calibrated instrument and should be treated as such. Avoid dropping or other mechanical abuse that could cause a shift in the calibrated settings.

CLEANING the analyzer should be done occasionally utilizing a damp cloth and a mild detergent. Care should be taken to avoid the entrance of liquids.

CABLES should similarly be wiped down with the same care and inspected for damage and deterioration of the insulation. The cable entrance to their connectors should be checked for integrity of the cable clamp and strain relief.

VERIFICATION of general performance can be observed by utilizing the two test points located in the back (top) of the instrument. Both the leakage current and resistance measurement circuits are checked for performance.

MAINS VOLTAGE can be verified with a multi-meter, although the reading itself is self-evident.

CURRENT is verified by connecting a lamp with a standard incandescent bulb to the DUT receptacle and switching the OUTLET switch to NORMAL. Display should read approximately as follows:

	Current (Amps)	
Bulb (watts)	120V line	230V line
60	0.50	0.30
75	0.63	0.35
100	0.83	0.45
150	1.25	0.70

RESISTANCE is checked my connecting the black chassis cable to the CHASSIS connector and clipping to the .15-ohm test point. The display should read 0.15 ± 0.02.

ENCLOSURE LEAKAGE. Connecting the black chassis cable to the **CHASSIS** connector and clipping to the 100-µA-test point checks the desired function. Display should read 100 ± 2.

PATIENT LEAD LEAKAGE is checked by clipping a clip lead to the 100-µA-test point and the other end to the LEAD snap selected. Display should read 100 ± 2.

PATIENT AUX. LEAKAGE is checked in the same manner as the one above.

M.A.P. (lead isolation current) is checked by connecting the black chassis cable to the **EXTERNAL** connector and the clip to the lead selected. Press **ISO TEST**. The display should read 1,000 ± 15%, depending on line voltage.

EXTERNAL operation can be quickly checked for leakage current measurement by connecting the read external cable to the **EXTERNAL** connector and clipping to the 100-µA-test point. Display should read 100 ± 2 counts.

To check for isolation measurements, clip the read external cable to the black chassis cable and press the **ISO TEST** switch. Display should read approximately 1,000 ± 15%, depending on the line voltage.

CALIBRATION of the DALE601/601E is best done at the factory on a yearly schedule, as we are equipped with the appropriate tools and reference instruments traceable to the National Institute of Standards and Technology (NIST).

Accessories

Description	Part Number
*CHASSIS CABLE For measurement of earth resistance and enclosure leakage current. Also used as reference lead for external measurement. Black coil cord, 8 ft extended length with clip.	600/100
CHASSIS CABLE Same as above, except 16 ft extended.	600/101
CHASSIS GROUND PROBE For measurement of earth resistance and Enclosure leakage current. Also used for grounding saline baths for isolation testing of probes and transducers. Black coil cord with copper needle probe for testing receptacles and for tight spaces. It is 8 ft long extended.	600/102
EXTERNAL LEAKAGE CABLE Standard auxiliary cable for external measurements of leakage current and voltage gradient between two conductive surfaces. Coiled cord is 8 ft. extended with red clip.	600/200
EXTERNAL LEAKAGE CABLE Same as above, except 16 ft extended.	600/201
*SOFT CARRYING CASE Case to protect the DALE601/601E when placed in a toolbox and to carry it's accessories.	100-030
HARD CARRYING CASE Case for carrying the DALE601/601E and it's accessories.	600/700
*OPERATING MANUAL This book	9508-0324

Accessories (cont.)

PROBE ADAPTOR CABLES. For making electrical contact with all terminals of an ultrasound probe's connector. This is needed for all isolation testing.

Description	Part Number
GEYMS probe (for GE product)	600/202
LOGIQ series probe (for GE product)	600/203
For Model 21369A probe (HP/Agilent product)	600/210
For Model 21364A probe (HP/Agilent product)	600/211

Check with Dale Technology for other applications.

UNIVERSAL Ultrasound Transducer Probe	600/206

*standard accessory

Using the DALE601/601E

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Inside This Chapter

- ❑ Preparing For Use
- ❑ Measuring Parameters
- ❑ External Measurements
- ❑ What is Being Measured

Preparing For Use

WARNING

TO ASSURE TOTAL SAFETY TO THE PATIENT, DISCONNECT ALL PATIENT CONNECTIONS TO THE DEVICE TO BE TESTED BEFORE STARTING.

As it is best to start from the same position each time, place the analyzer's switches in the following initial positions:

FUNCTION switch	Mains Voltage
NEUTRAL switch	Closed
OUTLET switch	Off (center)

Plug the DALE601/601E into an outlet properly rated. The analyzers are equipped with a hospital-grade power cord. Grounding reliability can only be achieved when the analyzer is connected to a power receptacle marked "Hospital Grade". Grounding is important for personal safety and to make some of the test offered by the analyzer.

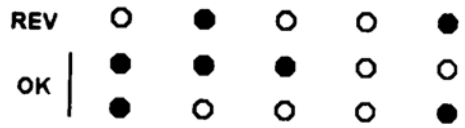
Do not circumvent for any reason.

Using the DALE601/601E

Verifying the Power Outlet Connections

Note: this section is not applicable to Isolated Power Systems, or to the 601E (220 volt version).

Three neon lamps provide indication of the polarity and condition of the outlet that is used, as determined by the following chart.



Note: Lamps do not check open neutral or neutral/ground reversal.

If the line checks OK, plug the device to be tested into the analyzer's line receptacle. If the line is found faulty, correct the problem before proceeding.

Measuring the Mains Voltage

From the recommended starting position, FUNCTION switch in the MAINS VOLTAGE position, the meter will display the mains voltage with a resolution of one (1) volt. Switching the OUTLET switch to the NORMAL position and turning on the DUT, the meter display will continue to read MAINS (line) voltage, but under the load of the device being tested. Depending on the device's operating current and the electrical supply wiring, the voltage differential may be significant. The value under load should be checked against the device's ratings to be sure that the actual value remains within prescribed limits. Excessive drop also suggest that a dedicated line of increases capability should be run to the instrument.

Measuring the Device's Current

Switch the FUNCTION switch to CURRENT. The meter will display the device's current to 19.99 Amperes. The OUTLET switch should be in NORMAL, L2 in CLOSED and the device turned on and placed in its maximum load condition to obtain the proper reading. Logging this data may help in spotting problems early by noting changes in values.

Measuring the Earth Resistance

This test is only applicable to devices utilizing three-wire (grounded) power cords. Connect the black coil cord cable to the CHASSIS connector on the rear panel of the analyzer. Clamp the clip of the cable to the DUT's exposed chassis or the enclosure if conductive. Care should be taken to assure that bare metal is reached and that both jaws of the clip are in contact with the chassis. Metal labels or incidental conductive hardware should not be used for this test.

Once connection is made, rotate the FUNCTION switch to EARTH RESISTANCE and read its value directly in ohms to 19.99 ohms. This test is best made with the OUTLET switch in the OFF position.

Measuring the Leakage Current

EARTH CURRENT. The Earth Leakage Current is that current that flows normally in the ground wire of the device and thus only applicable to devices utilizing three-wire (grounded) power cords. See section on "What is Being Measured" for additional discussion on earth leakage current.

The current is measured by switching the FUNCTION switch to EARTH LEAKAGE. The leakage current will display to 1999 µA (microamperes). Measurement should be made under all combination of the OUTLET switch, Normal and Reverse, the L2 (NEUTRAL) switch in Closed and Open, and the device power turned on and off.

NOTE: BE SURE TO PAUSE IN THE OFF (MIDDLE) POSITION WHEN SWITCHING FROM NORMAL TO REVERSE.

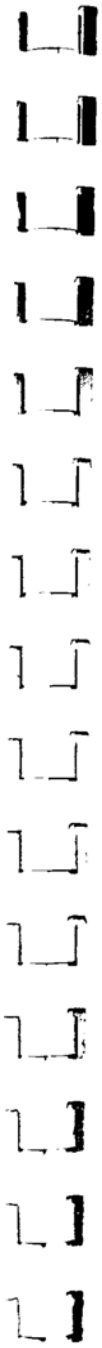
ENCLOSURE (CHASSIS) LEAKAGE CURRENT. The enclosure (chassis) leakage current is that current that flows between the conductive chassis or enclosure and earth (ground) measured through 1,000-ohm impedance. Be sure to select the appropriate test load on the top panel of the analyzer (see Fig. 2). The test load selection is made, using a small slide switch that selects either the AAMI or the IEC601 test load. The user will decide which is the more appropriate test load for the particular application.

Connect the black coil cord cable to the CHASSIS connector on the rear (top) of the analyzer. Clamp the clip on the cable in turn to accessible conductive sections of the chassis and the enclosure, Metal labels or incidental conductive hardware are not applicable for this test.

To make the measurement, place the FUNCTION switch in the ENCLOSURE LEAKAGE position and read the display directly in microamperes. Measurement should be made under all combinations of the OUTLET switch, Normal and Reverse, the L2 (NEUTRAL) switch in Closed and Open, and the device power turned on and off.

NOTE: BE SURE TO PAUSE IN THE OFF (MIDDLE) POSITION WHEN SWITCHING FROM NORMAL TO REVERSE.

PATIENT LEAD LEAKAGE Patient lead to ground leakage current is that current that would flow through individual patient leads and all the patient leads connected together, if the patient was to come into contact with earth ground.



Connect the patient leads to the corresponding universal ECG connectors on top of the analyzer. Select PATIENT LEAD LEAKAGE with the FUNCTION switch and read leakage current in micro amps for any combination of the OUTLET switch, L2 switch, the ground intact or lifted, and the DUT power on or off for the lead selected by the LEADS switch. Rotate the LEADS switch to each lead to test individually and the to the all position for testing with all leads connected together.

Patient Aux Current

The patient auxiliary (lead-to-lead) current is the current that flows from any patient lead to any other patient lead and to all other leads connected together. Under normal conditions, the current is primarily input bias current, measuring current or leadoff sensing current. The worse case condition will be measured from the individual lead to all other connected together. This is the measurement made by the DALE601/601E Electrical Safety Analyzers.

Measurement is made with the patient leads connected to the universal connectors on top of the analyzer and the FUNCTION switch placed in the PATIENT AUX CURRENT position. Selection by the LEADS switch will test the individual leads.

M.A.P. (Lead Isolation sink current)

WARNING

HIGH VOLTAGE, 120/240 VOLTS WITH RESPECT TO EARTH GROUND IS ACCESSIBLE AT THE PATIENT CONNECTIONS DURING PART OF THIS TEST. TAKE CARE WHEN HANDLING THE PATIENT LEADS.

The Patient Lead Isolation Current is that current that would flow in individual leads or all leads connected together, if line volts, 120 or 240 volts with respect to earth ground were to come into contact with the patient.

Measurement is made with the patient leads attached to the universal lead connectors on the top of the analyzer, the FUNCTION switch placed in M.A.P. mode and the individual lead to be tested selected by the LEADS switch. To apply the high voltage to the leads safely, press the ISO TEST switch. The voltage is only applied when pressed. While the ISO TEST is energized, read isolation current in microamperes (μA). Test should be performed in all combination of the OUTLET switch, L2 (neutral) switch and with the device under test ON and OFF.

External Measurements

The DALE601/601E provides the capability of making leakage current and isolation current measurements between selected points. For leakage current measurements, connect the black coil cord cable to the CHASSIS connector and the red cable to the EXTERNAL connector on the back of the analyzer. With the FUNCTION switch in the EXTERNAL position, clip the two cables to the two points for which leakage current is to be measured. The meter will display the leakage current between the two points to 1999 μA. The number displayed is also the voltage gradient in millivolts between the two points, based on a voltmeter with an input impedance of 1000 ohms.

To measure the electrical isolation of a probe or transducer, electrical connection must be made to each sides of the isolation barrier by a red and black cable as described above. Set the FUNCTION switch to EXTERNAL and press the ISO TEST switch. This will apply isolated line voltage between the two sides, and the meter will display the isolation current that flows. Actual method for making connection to either side of the isolation barrier will vary with the device to be tested and thus full details cannot be provided here. Dale has developed a full line of adapters for specific applications. Please refer to the Accessory section of this manual.

In addition, the DALE601/601E can take resistance measurements between selected points. If electrical devices are involved, it is desirable that they be turned off. Connect the two black chassis cables to the CHASSIS and EXTERNAL connectors and clip onto the two points to be measured. Set the FUNCTION switch to EARTH RESISTANCE and the display will read the resistance between the two points.

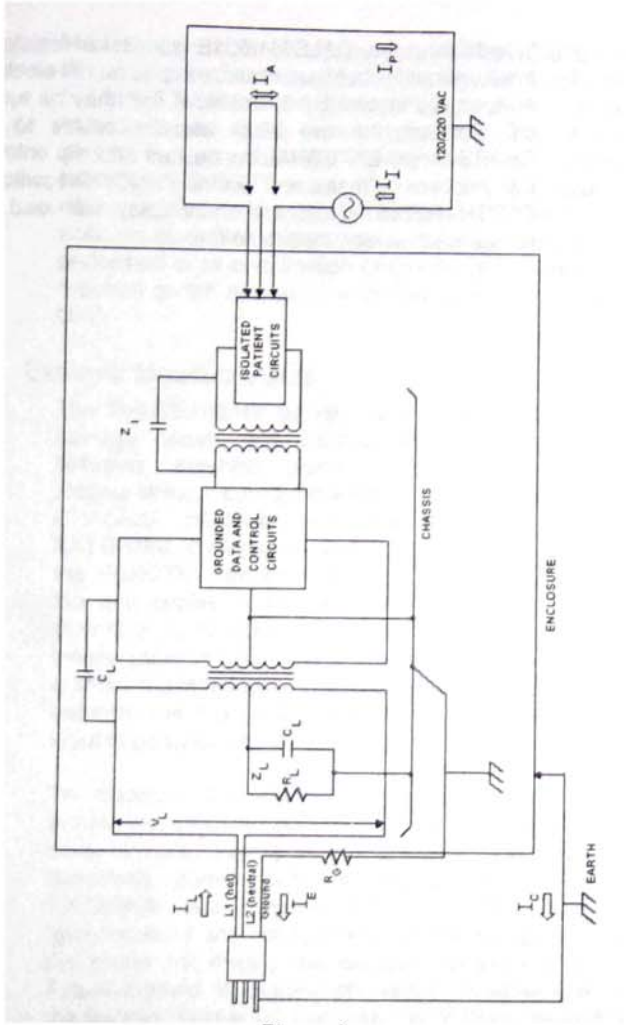


Figure 3
Block schematic of a line-operated instrument with isolated patient circuits to evaluate measurements made with the DALE601/601E

What is being measured

This section reviews the parameters measured by the DALE601/601E Electrical Analyzers, how they occur, and typical values found.

FIGURE 3 above is a rough block diagram of a typical line operated instrument with patient connections. All measured parameters are labeled for discussion. Understanding the mechanism that creates these parameters should be helpful in investigating and resolving problems that may arise and thus ensuring a safer environment. It should be recognized that these voltages and currents are a natural phenomena, and their presence within reasonable limits does not constitute a hazard. A significant change from previous measurements or from the device specification should be carefully reviewed with suspicion.

MAINS VOLTAGE [V_L] is the mains power supplied by the electrical distribution system of the hospital. It is shown as a three-wire system of HOT, NEUTRAL (L2) and GROUND with NEUTRAL like GROUND returned to true earth at their entry into the building. The voltage measured will depend upon:

- The power utility company's output and distribution to the hospital
- The distribution system within the hospital, primarily a function of age where older systems have marginal capacity for the electrical needs of today's equipment
- The load on the line being measured, not only that of the device under test, but of other devices on the same line.

The DALE601/601E measurement is made between the HOT and NEUTRAL wires via transformer coupling to isolate the measuring circuits from the line. As recommended, measurement of the line voltage with the

device under test **OFF** and then **ON** will provide indication if the line is adequate for the device. A large drop may suggest that a dedicated line of higher ampacity should be run in for the device.

INSTRUMENT CURRENT [I_L] is the current used by the device under test. When turned on, the device should be operated in its various modes to determine the worst condition to track. Verify that the device under test current is within the current rating of the DALE601/601E being used.

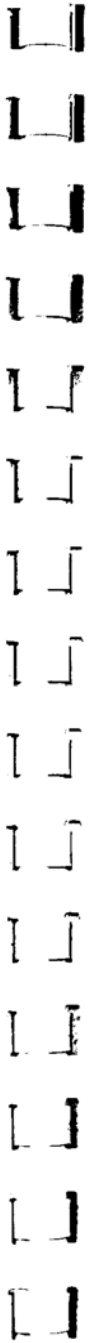
Measurement is made in the HOT wire via transformer coupling to ensure that the total current is measured, as it is possible that the NEUTRAL and GROUND wire could share the return path.

EARTH RESISTANCE [RG], (grounding resistance) is the resistance from the device's conductive "grounded" chassis to the grounding terminal on the receptacle in which it is plugged. The resistance is largely made up of the GROUND wire in the power cable and is directly proportional to its length. See Table 1 for typical values for a 10-foot cable. The resistance measurement also includes the junction resistance in connecting the wire at both ends, and the bulk resistance of the chassis from the grounding point to the point of measurement.

GROUND RESISTANCE OF 10-FOOT POWER CABLE

WIRE SIZE AWG	RESISTANCE MILLIOHMS
18	64
16	41
14	25

Underwriters Laboratory (UL) limits the ground resistance to 100 milliohms (0.1 ohms) for new products



and National Fire Protection Association (NFPA) to 150 milliohms, or 500 milliohms for devices in the field. Maintaining a low resistance is important to protect against the chassis becoming "hot" as a result of an internal fault causing current to flow to the chassis. The resulting voltage drop across the ground wire will raise the potential of the chassis with respect to the local ground and thus create a potential hazard.

Because of the low values of resistance being measured, the DALE601/601E utilizes a four wire Kelvin bridge to make the measurement. This avoids the introduction of errors due to contact resistance of the cable connectors and to the length of the test cable. Resistance is measured between the clip on the black chassis cable and the grounding pin receptacle of the DALE601/601E.

EARTH LEAKAGE CURRENT [I_E] (internal chassis current) is the current that flows in the GROUND wire of the power cable to return the chassis leakage current to true earth ground. This current does not constitute a hazard as long as the ground wire remains intact and the current does not become excessive. This could occur by a major fault, resulting in the ground wire sharing the load current with the neutral wire or supplying the total return. In addition to the rise of the chassis potential with respect to the local ground reference, the local ground reference can rise with respect to true earth as established by the cold water pipes. It should be pointed out that this current becomes the chassis leakage current for conductive enclosure when tested under open ground condition as discussed below.

Leakage current is due to the proximity of the hot wire or line potential components to the chassis represented by **ZL**, a combination of capacitance, **CL**, and resistance, **RL**, components. Particular sources of this current are as follows:

1. Power transformers and motors with large winding masses in close proximity to large conductive masses, which are physically mounted to the chassis. Such leakage can be both capacitive, across a dielectric, and resistive through conductive flux residue or poor insulation.

2. Line filters installed to protect against conductive EMI, particular in newer computerized devices. These components include real capacitance from both the hot and neutral wires to ground. Typical leakage currents are in the 100 to 500-µA ranges although special low leakage units, down to 50 µA, are available, specifically targeted for the medical device industry.

3. Switching power supplies with significant electronics directly connected to the power line, and complicated by the introduction of the higher switching frequencies used in the supply.

4. Power cable with the parallel run of the hot wire in intimate contact with the ground wire. Leakage current is dependent upon wire gauge, insulation dielectric, and length. Typical values for a ten-foot cable can range from 10 to 15 µA. A special low leakage cable is available with comparative leakage of 3 to 4 µA.

The measurement is made using the 1000-ohm AAMI load placed directly in series with the ground wire. Open neutral will usually represent the worst case.

ENCLOSURE LEAKAGE CURRENT [Ic], also referred to as dual leakage current, is the current that flows between the accessible conductive chassis or enclosure and earth ground. As stated above, this current under the condition of an open ground is the same as the earth current. With ground intact, the current should be very low, reflecting the milliohm impedance of the ground wire paralleling the 1000-ohm AAMI load.

Differentiation between the earth and enclosure (chassis) currents is made due to the wide use of insulated enclosures today. Therefore, there is no accessibility to a conductive chassis. Under these conditions the earth current represents total leakage.

The DALE601/601E measures chassis leakage from the exposed metal part on the DUT, through the black cable and the AAMI load, back to the ground. Measurement should be made under all conditions, particularly with ground lifted and open neutral, which usually represents the worst case.

PATIENT LEAD LEAKAGE [I_P] (source) current is the current that flows between an individual patient lead and ground. It represents the condition of a patient with leads attached touching ground such as an electric bed. If the patient connections are not isolated, then this current will reflect the earth current when tested under the open ground condition, as this is its only path back to true earth.

For devices incorporating isolated patient connections, this current is reduced by the patient isolating impedance Zi, a combination of resistive and capacitive leakage. Although originally required only for devices incorporating intra-cardiac electrodes or conductive pathways directly to the heart, it has found its way into standards for all devices having any patient applied parts.

Measurement is made to the lead selected by the lead selector switch, with the other side of the AAMI load connected to system ground. Current measured should be the same for all leads, including the **ALL** position, as the current represents the isolation impedance to the patient circuit.

PATIENT AUXILIARY CURRENT [I_A] (lead-to-lead) is the current that flows from one lead to another lead and includes the following:

- ❑ Bias current of the input amplifier
- ❑ Reverse leakage current of input protection diodes,
- ❑ Lead-off sensing current
- ❑ Impedance measurement current such as for respiration

The currents can be DC or AC or a combination of both, and thus needs to be measured utilizing true RMS technique. This avoids the waveform introducing errors in converting to an RMS value since each wave form (DC, AC sine or square) has its own conversion factor. The measurements are made with a true RMS converter to provide the common base necessary for accurate readout with a variety of common waveforms.

Measurement is made with a completely floating circuit to avoid extraneous leakage currents to ground introducing errors. Measurement is made from the selected lead to all other leads connected together thus reducing the permutations required to cover all possibilities. The single lead carrying the most current will generally be the reference lead, R_L, as this acts as the return for the other leads. Therefore, the leads can be taken in groups of four with the common reference lead, R_L, and then summed.

M.A.P. (MAINS ON APPLIED PARTS) [I_i] (patient sink) current is the current that would flow into the device under test if the patient were to come into contact with full line voltage. This could occur with an electric bed, which has become ungrounded and has a short to the frame. While measurement is made in each individual lead, a common value will be found for all leads as well as for the **ALL** position, as this is the measurement for the isolation of the patient circuit. To assure proper reading, the test should be run with ground intact.

For this test, the DALE601/601E provides a specially shielded line voltage secondary on its power transformer that minimizes internal leakage currents from the measuring circuit. This avoids the necessity of measuring the current and subtracting it from all readings. The current is limited with a 120 KΩ resistor for user protection. For additional safety, the current is only applied to the patient leads when the **ISO TEST** is pressed.

EXTERNAL capability is provided to extend the use of the DALE601/601E to that of a:

- ❑ **Ohmmeter** capable of making resistance measurements in the milliohm range for chassis bonding measurements.
- ❑ **Low impedance (1,000 Ω) voltmeter** as specified by the NFPA, with a range to 1,999 mV.
- ❑ **1,000 µA ammeter** to measure the leakage current between two devices or between the DUT (device under test) and a local ground reference. Range is to 1,999 µa.
- ❑ **Isolation tester** for ultrasound probes and other transducers independently from the device in which it is used.

RESISTANCE MEASUREMENTS between two points are made to verify the integrity of permanently installed equipment whose ground cannot be broken to measure the chassis leakage current. These devices are usually high power devices, which can have high leakage currents and depend on the bonding of all chassis to a common point for safety.

The resistance between two points is measured in the **RESISTANCE** mode of the **FUNCTION** switch, utilizing two black chassis cables for input leads through the **CHASSIS** and **DUAL** connectors. Care needs to be exercised to

insure that ground connections do not provide parallel measurement circuits causing erroneous results. This is accomplished by not connecting any device to the DALE601/601E instrument receptacle.

Measurement is made with 10 mA DC current and is highly resistant to AC currents flowing between the measurement points, as a result of chassis leakage current from either or both devices. However, such leakage current may have a DC component from rectification within the instrument. This DC current adds and subtracts from the measurement current resulting in some error. Reversing the connections and averaging the two readings can correct this.

LEAKAGE CURRENT AND VOLTAGE GRADIENTS between two points is also measured for permanently installed equipment as additional verification of the integrity of the installation. These measurements are equivalent, as the relationship between volts and current across 1,000 Ω is one (1) mV per μA.

Measurement is made from the **DUAL** position of the **FUNCTION** switch with one black cable in the **CHASSIS** connector and a red cable in the **DUAL** connector as meter inputs.

The measurement circuit is isolated from ground and, to be maintained, must avoid having a device plugged into the analyzer's receptacle. These should be removed during any dual measurements.

Connection of the two cables to the surface of choice will result in direct display of the leakage current or gradient. Measurement is made to 1999 μA or 1999 mV respectfully.

ISOLATION TESTING of probes and transducers making internal contact to a patient is provided to assure the reliability of the isolation barrier. These devices incorporate electrical circuits, which can introduce or

sink hazardous currents to the patient if he comes into contact with line potential, or becomes grounded as previously described. Additional difficulty is generated with these devices, as they generally require sterilization before use. Thus, testing before sterilization is recommended.