Leak Current Measurement - Essential to Electrical Safety

- Uninterrupted polarity switching function dramatically reduces cycle time
- Support for rated currents up to 20 A gives the instrument more than adequate capability for testing products designed to comply with new standards

For medical-use electrical devices and essential to electrical safety

Compliance with IEC 60601-1:2005 Ed 3.0, JIS T 0601-1:2012

(*Starting on June 1, 2012, medical electrical equipment sold in the EU must comply). Model ST5540 comply with IEC 60601-1:2005 +A1:2012 (Ed 3.1), and IEC 62353 of 2017

Compliance with Electrical Appliances and Materials Safety Act, JIS, IEC, and UL standards for general-use electrical devices
Leak current parameters as defined for medical-use electrical devices include ground leak current, contact current, patient leak current, and patient measurement current. The ST5540 provides a single solution for measuring all of these leak current variants.

Complies with IEC 60601-1:2005 +A1:2012 (Ed 3.1)

In order to prevent the danger of electric shock, electrical devices use power supplies that are isolated from parts of the device that may come into contact with the body. However, it is impossible to achieve infinite insulation resistance. Some leak current always exists, and its magnitude changes as the insulation degrades over time. The LEAK CURRENT HiTESTER ST5540/ST5541 provides an easy-to-operate solution for measuring leak current in electrical devices, making it eminently suitable for use in an extensive array of applications, ranging from production lines to equipment maintenance and inspections.

ST5540 compliance

*Compliance with medical IEC standards became mandatory in June 2012.
*Medical JIS standards were revised in June 2012.

Comparison of ST5540 Functionality

<table>
<thead>
<tr>
<th>Measurement mode</th>
<th>Category</th>
<th>Standard compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient leak current (between parts of device that come into contact with patient and ground)</td>
<td>• Public agencies</td>
<td>• Electrical vehicle standards UL 2231-1 and UL 2231-2</td>
</tr>
<tr>
<td>Patient leak current (external SIP/SOP voltage)</td>
<td>• Electric vehicle manufacturers</td>
<td>• Electrical Appliances and Materials Safety Act</td>
</tr>
<tr>
<td>Patient leak current (external voltage at specific F-type applied part)</td>
<td>• Manufacturers of general electrical devices</td>
<td>• IEC, JIS, and UL standards</td>
</tr>
<tr>
<td>Patient leak current (current resulting from external voltage at parts of device that come into contact with patients)</td>
<td>• Medical device repair and maintenance businesses</td>
<td>• IEC60990</td>
</tr>
<tr>
<td>Patient measurement current</td>
<td>• Hospitals</td>
<td>• IEC62353</td>
</tr>
<tr>
<td>Total patient leak current (between parts of device that come into contact with patient and ground)</td>
<td>• Medical industry (Japan Association for Clinical Engineering Technologists, etc.)</td>
<td>• IEC60601-1 (Ed 3.1)</td>
</tr>
<tr>
<td>Total patient leak current (external SIP/SOP voltage)</td>
<td>• Medical device manufacturers and dealers</td>
<td></td>
</tr>
<tr>
<td>Total patient leak current (external voltage at specific F-type applied part)</td>
<td>• Medical device repair and maintenance businesses</td>
<td></td>
</tr>
<tr>
<td>Total patient leak current (current resulting from external voltage at parts of device that come into contact with patient)</td>
<td>• Hospitals</td>
<td></td>
</tr>
<tr>
<td>Contact current (between device enclosure and lines)</td>
<td>• Household appliance industry</td>
<td></td>
</tr>
<tr>
<td>Contact current (between device enclosure and ground)</td>
<td>• Information device industry</td>
<td></td>
</tr>
<tr>
<td>Contact current (between device enclosure and device enclosure)</td>
<td>• Public agencies</td>
<td></td>
</tr>
<tr>
<td>Ground leak current</td>
<td>• Electric vehicle manufacturers</td>
<td></td>
</tr>
<tr>
<td>Free current measurement</td>
<td>• Manufacturers of general electrical devices</td>
<td></td>
</tr>
</tbody>
</table>

*The ST5540 also complies with old standards.
### Measurement of General-use Electrical Devices

ST5541 provides standard support for standard-compliant networks (excluding medical-use electrical devices).

#### ST5541 compliance

<table>
<thead>
<tr>
<th>Electrical Appliances and Materials Safety Act</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ministerial ordinance defining technical standards for electrical devices</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>JIS standards</th>
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</thead>
</table>

<table>
<thead>
<tr>
<th>IEC standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>IEC60990: 2016</td>
</tr>
<tr>
<td>IEC60065: 2014</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>UL standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>UL2231-1: 2002, UL2231-1: 2012 (revision 2016)</td>
</tr>
<tr>
<td>UL1492: 1996 (revision 2013)</td>
</tr>
<tr>
<td>UL492: 1996, etc.</td>
</tr>
</tbody>
</table>

There are various standards in place concerning networks (body simulated resistance), and a standard-compliant network is required in order to make measurements.

#### Comparison of ST5541 Functionality

<table>
<thead>
<tr>
<th>Measurement mode</th>
<th>Category</th>
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</tr>
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<tbody>
<tr>
<td>• Contact current (between device enclosure and lines)</td>
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<tr>
<td>• Ground leak current</td>
<td>• Household appliance industry</td>
<td></td>
</tr>
<tr>
<td>• Free current measurement</td>
<td>• Information device industry</td>
<td></td>
</tr>
</tbody>
</table>

### A single, robust solution for leak current measurement
The ST5540/ST5541 can switch polarity without stopping the supply of power to the device under measurement. Old models require that the device under measurement be turned off and then back on again when switching polarity, but the ST5540 and ST5541 let you progress smoothly to the next testing process.

- **Uninterrupted polarity switching function**
  The ability to conduct tests without turning off the power when switching the power supply polarity dramatically reduces cycle times. The ST5540/ST5541 can switch polarity without stopping the supply of power to the device under measurement. Old models require that the device under measurement be turned off and then back on again when switching polarity, but the ST5540 and ST5541 let you progress smoothly to the next testing process.

- **Safety conductor current measurement function**
  The ST5540/ST5541 can perform safety conductor current measurement as defined in standards such as IEC 60990 and IEC 60950-1.

- **Automatic measurement functionality**
  Simple operation allows you to switch power supply polarity and automatically make measurements with the target device in the normal and single-fault states, displaying the peak values. You can also set the measurement time and wait time. These capabilities help reduce operation time.

- **Circuit breaker for device under measurement**
  The instrument’s workbench-type design features a terminal block and a circuit breaker on the front panel, making it deal for embedding in test lines and simplifying connectivity with the device being measured, even while rack-mounted.

- **110% voltage application jack**
  The instrument’s 110% voltage application jack, which is used during testing of medical devices, outputs the target device line power supply voltage as-is. The polarity can be switched (ST5540 only).

- **Simple, interactive operation**
  The ST5540/ST5541 uses a touch panel that lets you configure settings by touching selections in response to information displayed on the panel, keeping operation simple.

- **Ability to store up to 30 sets of measurement conditions**
  The instrument can save and load up to 30 sets of measurement conditions, allowing you to immediately switch between conditions.

- **Improved test reliability**
  Blown fuse check function
  When measurement starts, the instrument checks for unintentional probe misalignment using a preconfigured lower limit setting.

- **Save measurement data for 100 devices**
  Measurement data (peak values) can be stored in the instrument’s built-in memory. Saved data can be checked on the stored data reference screen after measurement is complete. Data can be stored for up to 100 test targets, with each target being identified by a registered device name and control number. Additionally, the instrument can store a maximum of 2,000 peak value data points. Together, these capabilities eliminate the need to jot down measured values at the measurement site.

- **Allowable value**
  The maximum allowable value under the standard in question is automatically set. Settings can also be changed as desired by the user.

- **Peak value display**
  Displays the type of power supply fault and the peak value for the leak current, which varies with target device operation.

- **Data storage**
  Measurement data:
  For up to 100 target devices
  Measurement conditions:
  Up to 30 sets
**Expandability for the Future**

- **All the switch terminals needed for standard-compliant measurement**
  
  The ST5540/ST5541 provides the terminals needed to perform leak current measurement in compliance with IEC 60601-1 and JIS T6061-1, eliminating the need for the user to provide external switches.

  **Connection terminals**

  - **S10 terminal**: Switch for connecting a function ground terminal to the measurement power supply system's ground point. Allows connectivity to ground to be configured during leak current measurement.
  - **S12 terminal**: Switch for connecting the parts of device that come into contact with the patient to the measurement power supply circuit's ground point. Allows connectivity to ground to be configured during leak current measurement.
  - **S13 terminal**: Switch for connecting contactable metallic parts that are not protectively grounded to the ground line. Allows connectivity to ground to be configured during leak current measurement.
  - **E terminal**: Connected to the E (earth) LINE IN terminal. This terminal is always connected and cannot be configured.

  *S10, S12, S13, and E are available on the ST5540 only.

- **Standard USB interface**

  The ST5540/ST5541’s standard USB interface simplifies automatic testing on manufacturing lines and in similar installations.

- **Separation of the instrument’s power supply and target device lines**

  The instrument's power supply and target device line power supply are separated, helping prevent damage due to the inadvertent input of an incorrect supply voltage. There's no need to change the ST5540/ST5541's supply voltage, even if the target device's supply voltages change.

- **External control via EXT I/O**

  Start of measurement and loading of measurement conditions can be controlled from an external source. Additionally, judgment results, test signals, and other data can be output, making it possible to use the instrument to develop an automated line.

  **Input signals**
  - Active-low input
  - EXT-DCV terminal input voltage
  - EXT-DCV terminal input voltage or open
  - 0.3 VDC or less

  **Output signals**
  - Open collector output
  - 24 VDC (when not using the EXT-DCV terminal)
  - 60 mA DC per signal (low level)

  In addition to outputting judgment results for each measurement item, the instrument also provides T-FAIL output, which is generated continuously once a FAIL result is encountered during automatic testing.

- **Standard RS-232C port**

  The ST5540/ST5541’s standard RS-232C port can be used to control the instrument from a computer and to print data using the 9442 printer (option).

- **Support for rated currents of up to 20 A**

  The ST5540/ST5541 supports currents of up to 20 A and voltages of up to 250 V. Its ability to accommodate large currents allows it to be used with a more extensive range of target products, including devices from new fields such as electric vehicles and household appliances.

  (Line power supply terminal block for device under test)
**General specifications**

- **Display**: 320 × 240 dot matrix LCD (with backlight)
- **Control**: 6 × 6 matrix touch panel
- **Operating temperature and humidity range**: 0°C to 40°C, 80% RH or less (non-condensing)
- **Storage temperature and humidity range**: -10°C to 50°C, 80% RH or less (non-condensing)
- **Temperature and humidity range within which accuracy is guaranteed**: 23°C ±5°C, 80% RH or less (non-condensing)
- **Guaranteed accuracy period**: 1 year
- **Operating location**: Indoor use at an elevation not exceeding 2,000 m
- **Input capacitance**: 150 pF or less (between T1 and T2 terminals)
- **Transmission line power supply for device**: 100/120/220/240 V AC, as specified by customer
- **Input resistance**: 1 MΩ ±1% (single-end input)
- **A/D conversion method**: ΔΣ method (20-bit)
- **Measurement terminals**: T1 terminal, T2 terminal (with built-in fuse holder), T3 terminal (110% voltage application terminal: ST5540 only)
- **Input resistance**: 1 MΩ ±1% (single-end input)
- **Calculation and display of current values**: Measurement unit floats relative to instrument ground.
- **True rms measurement**: Calculated value when the voltage is detected across both ends of a network consisting of non-inductive resistance with a theoretical value of 1 kΩ
- **Automatic measurement**: A/D conversion method: ΔΣ method (20-bit)
- **Stabilization time**: 20 min
- **Temperature and humidity range within which accuracy is guaranteed**: 23°C ±5°C, 80% RH or less, non-condensing
- **Warm-up time**: 20 min
- **Temperature and humidity range**: -10°C to 50°C, 80% RH or less (non-condensing)
- **Dimensions**: Approx. 320 (W) × 110 (H) × 253 (D) mm
- **Mass**: Approx. 4.5 kg
- **Line power supply for device being measured and outlet**: Rated power supply: 100 to 250 VAC
- **Rated power supply frequency**: 50/60 Hz
- **Rated power**: 30 VA
- **Output, terminal block**: 20 A

**Leak current measurement unit**

- **Measurement current**: DC/AC/AC+DC/A peak
- **Allowable measurement current**: Max. 50 mA (DC / AC / AC+DC mode)
- **Measurement current**: 60 × 6 matrix touch panel
- **Accuracy (current measurement unit)**: ±2.0%rdg.+6dgt. ±5.0%f.s. ±25.0%f.s.

**Accuracy (current measurement unit)**

- **Temperature and humidity range within which accuracy is guaranteed**: 23°C ±5°C, 80% RH or less, non-condensing
- **Temperature coefficient**: Add 0.1 × basic accuracy x (T-23) for operating temperature T (°C)
- **Warm-up time**: 20 min
- **Range Guaranteed accuracy**: Range Guaranteed accuracy
- **Resolution**: Resolution
- **Accuracy**: Accuracy

**Measurement mode: AC’1 / AC+DC**

<table>
<thead>
<tr>
<th>Range</th>
<th>Guaranteed accuracy range</th>
<th>Resolution</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>50.00 mA</td>
<td>0.01 μA to 13.00 mA</td>
<td>±0.1 μA</td>
<td>±(2.0%rdg.+6dgt.)</td>
</tr>
<tr>
<td>5.000 μA</td>
<td>0.01 μA to 1.30 mA</td>
<td>±0.01 μA</td>
<td>±(2.0%rdg.+6dgt.)</td>
</tr>
<tr>
<td>500.0 μA</td>
<td>0.01 μA to 1.30 mA</td>
<td>±0.01 μA</td>
<td>±(2.0%rdg.+6dgt.)</td>
</tr>
<tr>
<td>50.000 μA</td>
<td>0.01 μA to 10.00 mA</td>
<td>±0.01 μA</td>
<td>±(2.0%rdg.+6dgt.)</td>
</tr>
</tbody>
</table>

**Measurements**: The following accuracy values also apply when using voltmeter mode.

- **DC, 15 Hz ≤ f ≤ 100 kHz**: 100 kHz < f ≤ 1 MHz
- **1 kHz < f ≤ 100 kHz**: 100 kHz < f ≤ 1 MHz

**Measurement mode: AC peak**

- **Range**: 75.0 μA to 50.00 mA
- **Accuracy**: ±5.0%f.s.

**Voltage monitor accuracy**

- **Range**: 300 V
- **Accuracy**: ±5.0%rdg.+10dgt.

**Current monitor accuracy**

- **Range**: 300 V
- **Accuracy**: ±5.0%rdg.+10dgt.
- **Measurement methods**: Average value, True rms value
- **Current monitor accuracy**: ±5.0%f.s.

**Safety conductor current accuracy**

- **Range**: DC / AC’4 / AC+DC

**Measurement mode: DC / AC’4 / AC+DC**

<table>
<thead>
<tr>
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</tr>
<tr>
<td>10.00 mA</td>
<td>0.01 μA to 13.00 mA</td>
<td>±0.01 μA</td>
<td>±(2.0%rdg.+6dgt.)</td>
</tr>
</tbody>
</table>

**Measurement mode: AC peak**

- **Range**: 75.0 μA to 50.00 mA
- **Accuracy**: ±5.0%f.s.
### For JIS T 1022:2006 Measurement at Hospitals Electrical Devices

#### Combination of Instruments for Leak Current Testing and Safety Conductor Testing

The following are key parts of any safety inspection of electrical equipment:
- **Leak current test**: Measure with the ST5540 and ST5541.
- **Safety conductor test** (also known as a ground line resistance test or ground conductor test): Measure with the 3157.

The 3157 can also be used for conducting measurements under the JIS T 1022:2006 safety standard for hospital electrical equipment.

#### AC GROUNDING HiTESTER 3157

**Protective Ground Tester Indispensable for Standards Certification**

- **IEC 60065**
- **IEC 60335-1**
- **IEC 60601-1**
- **IEC 60950-1**
- **IEC 61010-1**
- **JIS-C1010-1** (Electrical Appliances and Materials Safety Act)
- **UL (various applicable standards)**

**Model : AC GROUNDING HiTESTER 3157**

**Model No.** (Order Code)  | (Note)
--- | ---
3157-01  | (100-120 / 200-240 VAC switching)

Note: This instrument is not capable of performing measurement by itself. Please purchase two Current probe units or one Current probe and one Current apply probe, depending on your measurement application.

- **Standard compliance (examples)**
- **IEC 60065**
- **IEC 60335-1**
- **IEC 60601-1**
- **IEC 60950-1**
- **UL (various applicable standards)**
- **JIS-C1010-1**

*When using the Printer 9442, also purchase the RS-232C Interface 9593-02.*

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**Measuring between the grounding center and grounding terminal**

Verify that the electrical resistance between the medical outlet’s grounding electrode connector or medical ground terminal and medical ground center is less than or equal to 0.1 Ω by applying a current of approximately 25 A with an AC current with a no-load voltage of 6 V or less and measuring the resistance using the voltage droop method.

* This measurement requires an extension cable (available separately). The extension cable is a special-order item; please contact your HIOKI distributor for more information.

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- **Easily perform protective continuity testing in compliance with international safety standards and laws**
  - 1) Protective continuity resistance measurement for medical devices and general electrical devices
  - 2) Ground connectivity testing when installing electrical machine tools and distribution panels
  - 3) Testing of protective grounding and isopotential grounding work for medical equipment
  - 4) Evaluation of contact status using large currents
- **Feedback control system that is capable of applying a stable current even with a fluctuating load**
- **Soft-start function that checks the connection to the device under test before applying the current**

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The optional PRINTER 9442 can be used to print data via the instrument’s RS-232C interface, providing a convenient way to attach a hard copy of test data.

### Printing saved data

Saved measurement data is displayed (pressing the print key within the same data unit causes all data in the data unit to be printed).

### Isolation transformer

Standards require use of an isolation transformer when measuring medical-use electrical devices. Please purchase a transformer with the necessary rated capacity.

### Leak current tester supplies

*Some standards require use of an isolation transformer. Product inquiries should be directed to:

**Isolation transformer model numbers**
- 100 to 110 V (Japan): HSW-2KSP
- 240 to 264 V (overseas): HSW-5KSP

For more information: Tokyo Rikosha Co., Ltd.
Phone: +81-48-856-3851 (reception)
http://www.tokyorikosha.co.jp

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**Example printout**

<table>
<thead>
<tr>
<th>Date</th>
<th>Instrument name</th>
<th>Control number</th>
<th>Connection class and applied part</th>
<th>Network</th>
<th>Measurement mode</th>
<th>Filter</th>
<th>Allowable value (upper limit)</th>
<th>Allowable value (lower limit)</th>
<th>Maximum value</th>
<th>Judgment result</th>
<th>Polarity</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010-09-10</td>
<td>ELECTRIC-123</td>
<td></td>
<td>E2</td>
<td>TOUCH1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Print method:** Thermal serial dot

Paper width/print speed: 112 mm/53.5 cps

Power supply: AC ADAPTER 9443 or included nickel-metal-hydride battery (good for approx. 3,000 lines of print when fully charged with the 9443 adapter)

Dimensions: Approx. 160 (W) × 66.5 (H) × 170 (D) mm

Mass: Approx. 580 g

*CONNECTION CABLE 9444 and AC ADAPTER 9443 are required in order to connect the 9442 printer.

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**ST5540, ST5541 shared options**

**TEST LEAD L2200**
- 70 cm (2.30 ft) length, detachable large alligator clips or needle tips are bundled, CAT IV 600V, CAT III 1000V

**ENCLOSURE PROBE 9195**
- For the ST5540 series, 3156/3155

**PRINTER 9442**
- For printing numerical values, 112 mm (4.41 in) paper width

**AC ADAPTER 9443-02**
- For the Primeter 9442, 220 V

**CONNECTION CABLE 9444**
- For the Primeter 9442, 112 mm (4.41 in) × 25 m (82.03 ft), 10-wire, 2-pin

**RECORDING PAPER 1196**
- For the Printer 9442, 112 mm (4.41 in) × 25 m (82.03 ft), 10-wire, 2-pin

**RS-232C CABLE 9637**
- For the PC, 15-pin, cross, 1.8 m (5.91 ft) length

**RS-22C CABLE 9638**
- For the PC, 15-pin, cross, 1.8 m (5.91 ft) length

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**Model : LEAK CURRENT HiTESTER ST5540**

Model No. (Order Code) (Note)
ST5540 (For medical-use and electrical devices)

**Model : LEAK CURRENT HiTESTER ST5541**

Model No. (Order Code) (Note)
ST5541 (For electrical devices)