Leak Current Measurement - Essential to Electrical Safety

Compliance with IEC 60601-1:2005 (3rd Edition) is now mandatory.
(*Starting on June 1, 2012, medical electrical equipment sold in the EU must comply with IEC 60601-1:2005 (3rd Edition).)

The ST5540 also complies with JIS T0601-1:2012.

The ST5540 series features an improved measuring method and dramatically faster cycle times thanks to its uninterrupted polarity switching capability. The new devices support rated currents of up to 20A, making it more than ideal for use with products built to new standards.
Complies with all standards (suitable for use with all networks)

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.

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.

(Medical) JIS standards
JIS T0601-1:2012, 1999

(Medical) IEC standards
IEC 60601-1:2005 (3rd Edition)

Comparison of ST5540/ST5541 Functionality

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<th>Category</th>
<th>Standard compliance</th>
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<tr>
<td>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 3rd edition</td>
</tr>
<tr>
<td>Patient leak current (external SIP/SOP voltage)</td>
<td>Medical device manufacturers and dealers</td>
<td>IEC60990</td>
</tr>
<tr>
<td>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>Patient leak current (current resulting from external voltage at parts of device that come into contact with patients)</td>
<td>Hospitals</td>
<td></td>
</tr>
<tr>
<td>Patient measurement current</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total patient leak current (between parts of device that come into contact with patient and ground)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total patient leak current (external SIP/SOP voltage)</td>
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<td></td>
</tr>
<tr>
<td>Total patient leak current (external voltage at specific F-type applied part)</td>
<td>Public agencies</td>
<td>Electrical vehicle standards UL 2231-1 and UL 2231-2</td>
</tr>
<tr>
<td>Total patient leak current (current resulting from external voltage at parts of device that come into contact with patients)</td>
<td>Electric vehicle manufacturers</td>
<td></td>
</tr>
<tr>
<td>Contact current (between device enclosure and lines)</td>
<td>Manufacturers of general electrical devices</td>
<td></td>
</tr>
<tr>
<td>Contact current (between device enclosure and ground)</td>
<td>Household appliance industry</td>
<td></td>
</tr>
<tr>
<td>Contact current (between device enclosure and device enclosure)</td>
<td>Information device industry</td>
<td></td>
</tr>
<tr>
<td>Ground leak current</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Free current measurement</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*The ST5540 also complies with old standards.
There are various standards in place concerning networks (body simulated resistance), and a standard-compliant network is required in order to make measurements.

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

ST5540 compliance

For Standard- and Regulation-compliance

Measurement of General-use Electrical Devices

ST5541

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.

**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.

**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.

**Improved test reliability**

Blown fuse check function

When measurement starts, the instrument checks for unintentional probe misalignment using a preconfigured lower limit setting.

**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.

**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.

**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.

**Peak value display**

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

**Allowable value**

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

**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 T0601-1, eliminating the need for the user to provide external switches.

Connection terminals

- **S10 terminal**: Switch for connecting a functional 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 the 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 similar installations.

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).

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 changes.

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.

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.

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.

### EXT I/O description

<table>
<thead>
<tr>
<th>Output</th>
<th>Description</th>
<th>Input</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>TEST</td>
<td>Outputs low continuously during automatic measurement.</td>
<td>START</td>
<td>Starts automatic measurement at low.</td>
</tr>
<tr>
<td>MEAS</td>
<td>Outputs the measurement count automatic measurement and measurement of multiple items.</td>
<td>STOP</td>
<td>Forcibly terminates measurement at low.</td>
</tr>
<tr>
<td>PASS</td>
<td>Outputs the PASS judgment result for each measurement item.</td>
<td>LOAD (0 to 4)</td>
<td>Accepts external power supply input from 5 VDC to 24 VDC.</td>
</tr>
<tr>
<td>FAIL</td>
<td>Outputs the FAIL judgment result for each measurement item.</td>
<td>EXT.DCV</td>
<td>Accepts external power supply input from 5 VDC to 24 VDC.</td>
</tr>
<tr>
<td>LOW</td>
<td>Generates continuous output once a low signal is encountered during automatic testing.</td>
<td>INT.DCV</td>
<td>Generates internal 5 VDC output (not isolated from internal circuitry).</td>
</tr>
<tr>
<td>T-FAIL</td>
<td>Generates continuous output once a FAIL result is encountered during automatic testing.</td>
<td>INT.GND</td>
<td>Generates internal GND output (same as the case ground level).</td>
</tr>
<tr>
<td>INT.DCV</td>
<td>Generates internal 5 VDC output (not isolated from internal circuitry).</td>
<td>KEYLOCK</td>
<td>Disables switches other than the start switch.</td>
</tr>
</tbody>
</table>

Inlet

Outlet

- Connectivity not supported for USB memory. Data communications only.
- Cannot be used while an RS-232C connection is active.

- Cannot be used while an RS-232C connection is active.
## General specifications

**Display**
- 320 × 240 dot matrix LCD (with backlight)
- 6 x 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

**Instrument power supply**
- 100/200/240 VAC, as specified by customer
- Rated power supply frequency: 50/60 Hz
- Rated power: 30 VA

**Line power supply for device being measured and outlet**
- Rated supply voltage: 100 to 250 VAC
- Rated supply power frequency: 50/60 Hz
- Rated current: Input, terminal block: 20 A
- Output, terminal block: 20 A

**Outlet max. allowable leak current**
- 50 mA

**Measurements**

### Measurement current
- DC / AC / DC+AC / AC peak

**Allowable measurement current**
- Max. 50 mA (DC/AC peak mode)
- Max. 75 mA (AC peak mode)

**Measurement ranges**
- DC / AC / DC+AC mode: 50 μA / 500 μA / 5 mA / 50 mA
- AC peak mode: 500 μA / 1 mA / 10 mA / 75 mA

**Range switching**
- AUTO/HOLD

**Trigger method**
- Manual: Generates trigger automatically internally, free-run measurement
- Automatic: Starts measurement based on external start signal

**Measurement terminals**
- T1 terminal, T2 terminal (with built-in fuse holder), T3 terminal (110% voltage application terminal: ST5540 only)
- (Step-up isolation transformer required for 110V application)

**Measurement methods**
- Measurement of voltage drop across body simulated resistance points Calculation and display of current values
- True rms measurement
- Measurement unit floats relative to instrument ground.

**A/D conversion method**
- ΔΣ method (20-bit)

**Input resistance**
- 1 MΩ±1 ± (single-ended input)
- Not including voltage measurement unit, body simulated resistance (current detection circuit)

**Dielectric strength**
- Between power supply terminals and protective ground: 1.38 kV AC (50 Hz), 15 sec
- Between measurement terminals and power supply terminals: 2.40 kV AC (60 Hz), 60 sec
- Between measurement terminals and control circuit: 2.90 kV AC (100 Hz), 15 sec

**Standard compliance**
- EMC: EN 61326
- EN 61000-3-2
- EN 61000-3-3
- Safety: EN 61010

**Conductive RF**
- 3% f.s. or less of 3 V

**Magnetic field effects**
- (Representative value when conducting measurements in the AC 500 μA range)

**Input capacitance**
- 150 pF or less (between T1 and T2 terminals)
- 60 dB or greater at 60 Hz / 40 dB or greater at 10 kHz
- 40 dB or greater at 100 kHz / 40 dB or greater at 1 MHz
- (Isolated from network circuit with fuse shortened)

**Network (body simulated resistance)**
- **Medical-use electrical devices:**
  - Network B (ST5540 only)
  - Basic measurement element: 1 kΩ
  - Filter: 10 kΩ ± 15%
- **Electrical Appliances and Materials Safety Act: Network A**
  - Basic measurement element: 1 kΩ
  - Filter: 10 kΩ ± 11.22 Ω / 579 Ω
- **IEC 60990: Network C**
  - Basic measurement element: 1.5 kΩ / 500 Ω
  - Filter 1: 10 kΩ ± 22 nF
  - Filter 2: 10 kΩ ± 20 Q / 6.22 nF / 0.91 nF
- **UL: Network D**
  - Basic measurement element: 1.5 kΩ ± 0.15 Ω
  - Basic measurement element: 1 kΩ
  - Basic measurement element: 2 kΩ
  - Basic measurement element: 5 kΩ / 500 Ω
  - Filter 375 Q / 0.22 µF / 500 Q
  - Safety conductor current: Basic measurement element (35 Q)

**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 x basic accuracy x (T-23) for operating temperature T (°C)
- **Signal leakage range:**
  - DC ≤ f ≤ 100 kHz 100 kHz < f ≤ 1 MHz
  - ±4.0 f.s. ±2.0 f.s. ±2.0 f.s.
  - ±(2.0%rdg.+7dgt.) ±5.0 f.s. ±25.0 f.s.

**Measurement mode: AC**

### AC peak

**Range Guaranteed accuracy Resolution Accuracy**

- **75.0 mA**
  - From 8 mA: 100 µA ±(2.0% rdg.+6dgt.)
  - ±5.0% f.s.
  - ±15.0% f.s.

- **10.00 mA**
  - From 0.8 mA: 10 µA ±(2.0% rdg.+6dgt.)
  - ±2.5% f.s.

- **1.000 mA**
  - From 100 µA: 1 µA ±(2.0% rdg.+6dgt.)
  - ±2.0% f.s.

- **500.0 µA**
  - From 40 µA: 0.1 µA ±(2.0% rdg.+6dgt.)
  - ±2.0% f.s.

**Measurement mode: AC + DC**

### AC peak

**Range Guaranteed accuracy Resolution Accuracy**

- **75.0 mA**
  - From 2.80 mA to 75.00 mA: 100 µA ±(2.0% rdg.+6dgt.)
  - ±5.0% f.s.

- **10.00 mA**
  - From 2.80 mA to 13.00 mA: 10 µA ±(2.0% rdg.+6dgt.)
  - ±5.0% f.s.

**Measurement mode: DC**

### AC / DC **+ DC**

**Range Guaranteed accuracy Resolution Accuracy**

- **50.0 mA**
  - From 2.80 mA to 50.00 mA: 10 µA ±(2.0% rdg.+6dgt.)
  - ±5.0% f.s.

- **10.00 mA**
  - From 2.80 mA to 13.00 mA: 10 µA ±(2.0% rdg.+6dgt.)
  - ±5.0% f.s.

**Accessories**
- ST5540: One set of L2200 test leads (one red, one black) + one red L2200 test lead
- ST5541: One set of L2200 test lead (one red, one black)
- ENCLOSURE PROBE 9195 × 1
- CD-ROM × 1 (USB Driver)
- Spare fuse × 1 (250 V 30 mA, measurement use)
- Approx. 320 (W) × 110 (H) × 253 (D) mm
- Approx. 4.5 kg

**Dimensions**
- Width: 190 (D) mm

**Weight**
- Approx. 4.5 kg

**Enclosure probe**
- 9195 × 1

**Temperature coefficient**
- Add 0.1 x basic accuracy x (T-23) for operating temperature T (°C)

**Voltage monitor accuracy**
- Error (Representative value when conducting measurements in the AC 500 μA range)
- ±5.0% f.s.
- ±2.5% f.s.
- ±15.0% f.s.

**Current monitor accuracy**
- Error (Representative value when conducting measurements in the AC 500 μA range)
- ±15.0% f.s.
AC GROUNDING HiTESTER 3157

An essential safety conductor measuring instrument for standards testing

3157 (power supply: 100 to 120 VAC)
3157-01 (power supply: switchable 100 to 120 VAC/200 to 240 VAC)

Options

SAFETY TEST DATA MANAGEMENT SOFTWARE 9267
REMOTE CONTROL BOX 9613 (single) (start/stop control use)
REMOTE CONTROL BOX 9614 (dual) (start/stop control use)
GP-IB INTERFACE 9518-02
GP-IB CONNECTOR CABLE 9151-02 (2 m)
RS-232C INTERFACE 9593-02 (Not CE marked)

*The 9442 printer can be used with the 9593-02 and CONNECTION CABLE 9446.
When using the RS-232C CABLE 9638, the 3157's handshake functionality is not available.

Instrument alone cannot perform measurements. Purchase either two CURRENT PROBE 9296 units or one each CURRENT PROBE 9296 and CURRENT APPLY PROBE 9297.

Standard compliance (examples)

- IEC 60065
- IEC 60335-1
- IEC 60601-1
- IEC 60950-1
- IEC 61010-1
- JIS-C1010-1
- UL (various applicable standards)
- IEC 60065
- IEC 60335-1
- IEC 60601-1
- IEC 60950-1
- IEC 61010-1

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.

Safety Standard for Hospital Electrical Equipment
JIS T 1022:2006 Measurement

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.

Simple safety conductor testing in compliance with various domestic and overseas safety standards and laws
Safety conductor resistance measurement of medical-use electrical devices and general-use electrical devices
Ground connection testing when installing electrical machine tools and power distribution panels
Testing of safety grounding and isoelectric grounding work for medical equipment
Evaluation of contact state under high current application

Featuring feedback control capable of applying a stable constant current even under fluctuating load conditions
Featuring a soft start function for applying current after verifying the connection to the device under test.

Main ground line
Medical ground center
Ground branch line
Ground branch line
Medical outlet
Medical ground terminal

—
Grounding electrode

Medical outlet
Medical ground terminal

■ 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.
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

**Options**

- RS-232C CABLE 9637 (9-pin to 9-pin, cross, 1.8 m)
- RS-232C CABLE 9638 (9-pin to 25-pin, cross, 1.8 m)
- PRINTER 9442
- AC ADAPTER 9443-01 (for printer, Japanese version)
- AC ADAPTER 9443-02 (for printer, EU version)
- CONNECTION CABLE 9444 (for printer)
- RECORDING PAPER 1196 (25 m, 10 rolls)
- ELECTRIC SAFETY TESTING SOFTWARE 9267

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