Introducing a leak current measuring instrument that complies with the IEC 60601-1 standard (3rd edition, with the ST5540), the ST5540 series feature an improved measuring method and dramatically faster cycle times, thanks to its uninterrupted polarity switching. The new devices support rated currents of up to 20A, making it more than ideal for use with products built to new standards.
Medical Electrical Devices

IEC 60601-1: (2005) 3rd Edition-compliant ST5540

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.

Some examples of the standards with which the instrument complies are listed below. The ST5540 can be used with all standards that apply to the networks in which it is used.

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**

(Medical) JIS standards

JIS T0601-1 : (1999)

(Medical) IEC standards

IEC60601-1 : (2005) 3rd

### Comparison of ST5540/ST5541 Functionality

#### Measurement mode

- Patient leak current (between parts of device that come into contact with patient and ground)
- Patient leak current (external SP/SSP voltage)
- Patient leak current (external voltage at specific F-type applied part)
- Patient leak current (current resulting from external voltage at parts of device that come into contact with patients)
- Patient measurement current
- Total patient leak current (between parts of device that come into contact with patient and ground)
- Total patient leak current (external SP/SSP voltage)
- Total patient leak current (external voltage at specific F-type applied part)
- Total patient leak current (current resulting from external voltage at parts of device that come into contact with patient)
- Contact current (between device enclosure and lines)
- Contact current (between device enclosure and ground)
- Contact current (between device enclosure and device enclosure)
- Ground leak current
- Free current measurement

#### Category

- Medical industry (Japan Association for Clinical Engineering Technologists, etc.)
- Medical device manufacturers and dealers
- Medical device repair and maintenance businesses
- Hospitals
- Public agencies
- Electric vehicle manufacturers
- Manufacturers of general electrical devices
- Household appliance industry
- Information device industry

#### Standard compliance

- IEC 60601-1 3rd edition
- IEC60990
- IEC60601-1 3rd edition
- UL 2231-1 and UL 2231-2
- Electrical Appliances and Materials Safety Act
- IEC, JIS, and UL standards

*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).

Electrical Appliances and Materials Safety Act
Ministerial ordinance defining technical standards for electrical devices

ST5540 compliance

JIS standards

IEC standards

UL standards

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 (patent pending). 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 ideal for embedding in test lines and simplifying connectivity with the device being measured, even while rack-mounted.

### 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.

### Data storage
Measurement data: For up to 100 target devices Measurement conditions: Up to 30 sets

### 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.
**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, 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. (*Connectivity not supported for USB memory. Data communications only.)*

- 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.

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

- 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.

<table>
<thead>
<tr>
<th>Input signals</th>
<th>Active-low input</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max. applied voltage</td>
<td>EXT.DCV terminal input voltage</td>
</tr>
<tr>
<td>High level</td>
<td>EXT.DCV terminal input voltage or open</td>
</tr>
<tr>
<td>Low level</td>
<td>0.3 VDC or less</td>
</tr>
<tr>
<td>Output signal</td>
<td>Open collector output</td>
</tr>
<tr>
<td>Max. load voltage</td>
<td>24 VDC (when not using the EXT.DCV terminal)</td>
</tr>
<tr>
<td>Max. output current</td>
<td>60 mA DC per signal (low level)</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Output</th>
<th>TEST : Outputs low continuously during automatic measurement.</th>
</tr>
</thead>
<tbody>
<tr>
<td>MEAS : Outputs the measurement count automatic measurement and measurement of multiple items.</td>
<td></td>
</tr>
<tr>
<td>PASS : Outputs the PASS judgment result for each measurement item.</td>
<td></td>
</tr>
<tr>
<td>FAIL : Outputs the FAIL judgment result for each measurement item.</td>
<td></td>
</tr>
<tr>
<td>LOW : Generates continuous output once a low signal is encountered during automatic testing.</td>
<td></td>
</tr>
<tr>
<td>T-FAIL : Generates continuous output once a FAIL result is encountered during automatic testing.</td>
<td></td>
</tr>
<tr>
<td>INT.DCV : Generates internal 5 VDC output (not isolated from internal circuitry).</td>
<td></td>
</tr>
<tr>
<td>INT.GND : Generates internal GND output (same as the case ground level).</td>
<td></td>
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<tr>
<th>Input</th>
<th>START : Starts automatic measurement at low.</th>
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<tr>
<td>STOP : Forcibly terminates measurement at low.</td>
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<tr>
<td>LOAD (0 to 4) : Accepts external power supply input from 5 VDC to 24 VDC.</td>
<td></td>
</tr>
<tr>
<td>EXT.DCV : Accepts external COM input.</td>
<td></td>
</tr>
<tr>
<td>EXT.COM : Enables switches other than the start switch.</td>
<td></td>
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</table>
ST5540/ST5541 Specifications

**General specifications**

- **Display**: 320 x 240 dot matrix LCD (with backlight)
- **Control**: 6 x 6 multi-touch panel
- **Operating temperature and humidity range**: 0°C to 40°C, 85% 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
- **Line power supply**: 100/200/240 VAC, as specified by customer
- **Rated power**: 30 VA
- **Line power supply for device being measured and outlet**: Rated supply voltage: 100 to 240 VAC
- **Rated power supply frequency**: 50/60 Hz
- **Measurement methods**: DC / AC / AC+DC
- **Maximum current measurement unit**

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**Measurement mode: AC**

- **Frequency**: Maximum: 1 MHz
- **Phase**: Maximum: 180°
- **Input capacitance**: Maximum: 1000 pF
- **Magnetic field effects**: Maximum: 3 mTesla or less at 1 V
- **Magnetic field effects**: (Representative value when conducting measurements in the AC 500 mA range)

**Conductive RF**

- **EMC**: EN 61326
- **Safety conductor current accuracy**: Rated: 100 µA
- **Input capacitance**: 150 pF or less (between T1 and T2 terminals)

**Measurement mode: DC**

- **Frequency**: Maximum: 1 MHz
- **Phase**: Maximum: 180°
- **Input capacitance**: Maximum: 1000 pF
- **Magnetic field effects**: Maximum: 3 mTesla or less at 1 V

**Input capacitance**: 150 pF or less (between T1 and T2 terminals)

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**Voltage monitor accuracy**

- **Frequency**: Maximum: 1 MHz
- **Phase**: Maximum: 180°
- **Input capacitance**: Maximum: 1000 pF
- **Magnetic field effects**: Maximum: 3 mTesla or less at 1 V

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**Safety conductor current accuracy**

- **Frequency**: Maximum: 1 MHz
- **Phase**: Maximum: 180°
- **Input capacitance**: Maximum: 1000 pF
- **Magnetic field effects**: Maximum: 3 mTesla or less at 1 V

**Range Guaranteed accuracy**

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**Measurement mode: DC**

- **Frequency**: Maximum: 1 MHz
- **Phase**: Maximum: 180°
- **Input capacitance**: Maximum: 1000 pF
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**Measurement mode: AC**

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- **Phase**: Maximum: 180°
- **Input capacitance**: Maximum: 1000 pF
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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) (stop/stop control use)
- GP-IB INTERFACE 9518-02
- GP-IB CONNECTOR CABLE 9151-02 (2 m)
- RS-232C INTERFACE 9593-02

*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.

Standard compliance (examples)

- 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)

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 3157

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

**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)**

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