



ML1101 Stimulus Isolator

Owner's Guide





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Product: ML1101 Stimulus Isolator

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ADInstruments Pty Ltd. ISO 9001:2008 Certified Quality Management System

Reg. No. 1053

- | | |
|--|--|
|  DANGER | • This alerts the user to imminent death or serious injury arising from misuse of the stimulator. |
|  WARNING | • This alerts the user to possible death or serious injury arising from misuse of the stimulator. |
|  CAUTION | • This alerts the user to possible injury or damage to property arising from misuse of the stimulator. |

Notes are also provided in this manual to alert the user to specific instructions or recommendations.

 WARNING

This device is designed for experimental and research applications and must not be used for therapeutic purposes.

 CAUTION

Connect this device only to recommended stimulators and be sure to observe all provided instructions.

 CAUTION

Turn off this device before connecting the stimulator lead cables to the output terminals on this device to prevent electric shock.

 CAUTION

Do not touch the connector pins. Discharge electrostatic energy by touching a grounded metal part before connecting. The instrument may be damaged by electrostatic energy.

 CAUTION

Before making connections to disconnections from this device, turn off both devices and unplug them from the AC outlet. Connecting and disconnecting devices that are on and plugged in may expose you to electric shock.

 CAUTION

Any device other than our electronic stimulator should be grounded before connecting it to this device.

 CAUTION

When maintaining (cleaning, sterilizing, etc.) the stimulator, be sure to turn the power off and unplug the power cable from the power outlet first. Failure to do so may result in an electric shock or malfunction.

GENERAL HANDLING PRECAUTIONS

This device is intended for use only by qualified medical personnel.

Use only our approved products with this device. Use of non-approved products or in a non-approved manner may affect the performance specifications of the device. This includes, but is not limited to, batteries, recording paper, pens, extension cables, electrode leads, input boxes and AC power.

Please read these precautions thoroughly before attempting to operate the instrument.

1. To safely and effectively use the instrument, its operation must be fully understood.

2. When installing or storing the instrument, take the following precautions:

- (1) Avoid moisture or contact with water, extreme atmospheric pressure, excessive humidity and temperatures, poorly ventilated areas, and saline or sulphuric air.
- (2) Place the instrument on an even, level floor. Avoid vibration and mechanical shock, even during transport.
- (3) Avoid placing in an area where chemicals are stored or where there is danger of gas leakage.
- (4) The power line source to be applied to the instrument must correspond in frequency and voltage to product specifications, and have sufficient current capacity.
- (5) Choose a room where a proper grounding facility is available.

3. Before Operation

- (1) Check that the instrument is in perfect operating order.
- (2) Check that the instrument is grounded properly.
- (3) Check that all cords are connected properly.
- (4) Pay extra attention when the instrument is combined with other instruments to avoid misdiagnosis or other problems.

4. During Operation

- (1) The instrument must receive continual, careful attention.
- (2) Turn power off or remove electrodes and/or transducers when necessary to assure the safety.

5. To Shutdown After Use

- (1) Turn power off with all controls returned to their original positions.
- (2) Remove the cords gently; do not use force to remove them.
- (3) Remove the power cord from the AC SOURCE socket to isolate the instrument from the AC supply mains.
- (4) Clean the instrument together with all accessories for their next use.

6. The instrument must receive expert, professional attention for maintenance and repairs. When the instrument is not functioning properly, it should be clearly marked to avoid operation while it is out of order.

7. The instrument must not be altered or modified in any way.

8. Maintenance and Inspection:

- (1) The instrument and parts must undergo regular maintenance inspection at least every 6 months.
- (2) If stored for extended periods without being used, make sure prior to operation that the instrument is in perfect operating condition.
- (3) Technical information such as parts list, descriptions, calibration instructions or other information is available for qualified user technical personnel upon request from your distributor.

CAUTION

United States law restricts this device to sale by or on the order of a physician.

EMC RELATED CAUTION

This equipment and/or system complies with the International Standard IEC 60601-2 for electromagnetic compatibility for medical electrical equipment and/or system. However, an electromagnetic environment that exceeds the limits or levels stipulated in IEC 60601-1-2, can cause harmful interference to the equipment and/or system or cause the equipment and/or system to fail to perform its intended function or degrade its intended performance. Therefore, during the operation of the equipment and/or system, if there is any undesired deviation from its intended operational performance, you must avoid, identify and resolve the adverse electromagnetic effect before continuing to use the equipment and/or system.

The following describes some common interference sources and remedial actions:

1. **Strong electromagnetic interference from a nearby emitter source such as an authorized radio station or cellular phone:**
Install the equipment and/or system at another location. Keep the emitter source such as cellular phone away from the equipment and/or system, or turn off the cellular phone.
2. **Radio-frequency interference from other equipment through the AC power supply of the equipment and/or system:**
Identify the cause of this interference and if possible remove this interference source. If this is not possible, use a different power supply.
3. **Effect of direct or indirect electrostatic discharge:**
Make sure all users and patients in contact with the equipment and/or system are free from direct or indirect electrostatic energy before using it. A humid room can help lessen this problem.
4. **Electromagnetic interference with any radio wave receiver such as radio or television:**
If the equipment and/or system interferes with any radio wave receiver, locate the equipment and/or system as far as possible from the radio wave receiver.
5. **Interference of lightning:**
When lightning occurs near the location where the equipment and/or system is installed, it may induce an excessive voltage in the equipment and/or system. In such a case, use an uninterruptible power supply.
6. **Use with other equipment:**
When the equipment and/or system is adjacent to or stacked with other equipment, the equipment and/or system may affect the other equipment. Before use, check that the equipment and/or system operates normally with the other equipment.
7. **Use of unspecified accessory, transducer and/or cable:**
When an unspecified accessory, transducer and/or cable is connected to this equipment and/or system, it may cause increased electromagnetic emission or decreased electromagnetic immunity. The specified configuration of this equipment and/or system complies with the electromagnetic requirements with the specified configuration. Only use this equipment and/or system with the specified configuration.

Caution - continued

8. Use of unspecified configuration:

When the equipment and/or system is used with the unspecified system configuration different than the configuration of EMC testing, it may cause increased electromagnetic emission or decreased electromagnetic immunity. Only use this equipment and/or system with the specified configuration.

9. Measurement with excessive sensitivity:

The equipment and/or system is designed to measure bioelectrical signals with a specified sensitivity. If the equipment and/or system is used with excessive sensitivity, artifact may appear by electromagnetic interference and this may cause mis-diagnosis. When unexpected artifact appears, inspect the surrounding electromagnetic conditions and remove this artifact source.

If the above suggested remedial actions do not solve the problem, consult your distributor for additional suggestions.

NOTE about Waste Electrical and Electronic Equipment (WEEE) directive 2002/96/EEC

For the member states of the European Union only:

The purpose of WEEE directive 2002/96/EEC is, as a first priority, the prevention of waste electrical and electronic equipment (WEEE), and in addition, the reuse, recycling and other forms of recovery of such waste so as to reduce the disposal of waste.

Contact your representative for disposal at the end of its working life.

Symbol	Description
	The products marked with this symbol apply to the European WEEE directive 2002/96/EEG and require separate waste collection. For the products labeled with this symbol, contact your representative for disposal at the end of its working life.

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Device Overview

Introduction

This isolator is designed to be used together with an electronic stimulator (1001) for electric stimulation.

This device insulates the output from ground. This minimizes the area of stimulation to produce stimulation with greater precision while reducing stimulation artifacts, facilitating observation of evoked action potential.

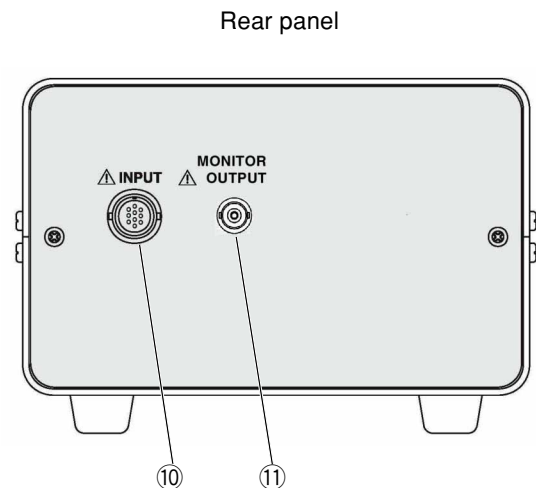
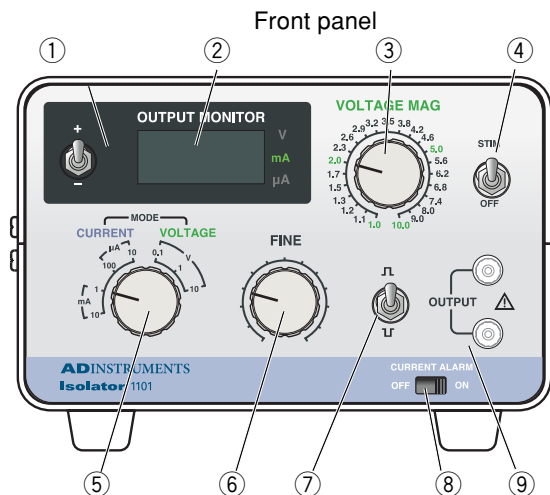
WARNING

This device is designed for experimental and research applications and must not be used for therapeutic purposes.

Features

1. **Numeric power indication**
Indicates the amount of power that goes through the device.
2. **Constant-voltage/current output of both positive and negative polarity**
The device can output the biphasic wave constant voltage that is essential for evoked action potential induction during experiments with cells and other samples.
3. **Excellent input and output linearity**
The output changes linearly with respect to the amplitude of the input signal.
4. **Built-in over current alarm**
An alarm is generated when the electrode resistance of the load is too large for the set current to pass.

Parts and Functions



No.	Part	Description
①	+/-: Stimulator output display polarity switch	Selects the polarity of the stimulator output to display on the OUTPUT MONITOR ②. This setting is not related to ⑦. +: Displays the positive pulse of the stimulator output on the OUTPUT MONITOR ②. -: Displays the negative pulse of the stimulator output on the OUTPUT MONITOR ②.
②	OUTPUT MONITOR: Output panel meter	Displays output settings as well as output voltage and current during stimulation.
③	VOLTAGE MAG: Voltage magnifier knob	When ⑤ is set to "VOLTAGE", use this knob to select how many times the voltage selected with knob ⑥ will be multiplied during output.
④	STIM/OFF: Output switch	STIM : Outputs stimulation voltage or current. OFF : Turns off stimulation voltage and current. Also use this setting to preset a stimulation voltage or current.
⑤	MODE: CURRENT/VOLTAGE Current/Voltage selector	Select current or voltage output.
⑥	FINE: Output adjuster	Adjusts output voltage and current.
⑦	⏏/⏚: Output polarity switch	Selects the polarity of output from this device. ⏏ : Red terminal becomes +. ⏚ : Red terminal becomes -.
⑧	CURRENT ALARM: ON/OFF Constant-current alarm switch	ON : Outputs an alarm when the load electrode resistance during constant-current output is too large to output current. OFF : No alarm is output.
⑨	OUTPUT: Output terminals	Connect an electrode lead to output stimulation voltage or current to human subjects.
⑩	INPUT: Input connector	Use the supplied connecting cable to connect this connector to the output connector (to ISO) on an electronic stimulator.
⑪	MONITOR OUTPUT: Output connector	Use this connector to connect to a monitoring device to monitor OUTPUT waveforms.

Operation

Connections

⚠ CAUTION

Connect this device only to recommended stimulators and be sure to observe all provided instructions.

⚠ CAUTION

Do not touch the connector pins. Discharge electrostatic energy by touching a grounded metal part before connecting. The instrument may be damaged by electrostatic energy.

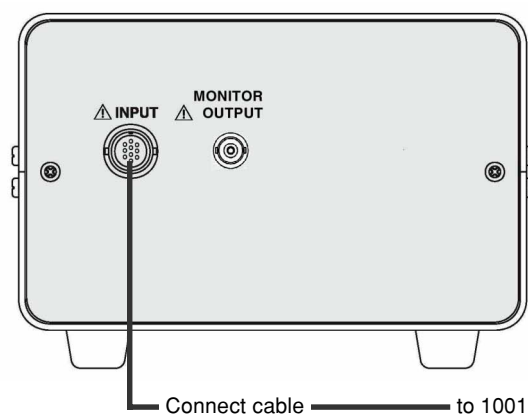
⚠ CAUTION

Any device other than our electronic stimulator should be grounded before connecting it to this device.

Connect this device to our electronic stimulator (1001).

1. Connect the power cable of the electronic stimulator.

Note: For information on how to connect the power cable of the electronic stimulator and how to connect it to ground, refer to the Operator's Manual supplied with the electronic stimulator.

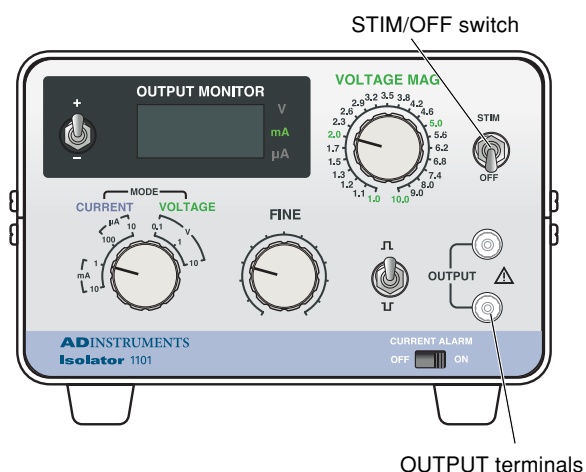


2. Turn off the electronic stimulator before connecting the isolator output connector (to ISO connector) on the electronic stimulator to the INPUT connector on this device using the supplied connecting cable.

Note: Be sure to securely lock the connectors to prevent accidental disconnection.

⚠ CAUTION

Before making connections to or disconnections from this device, turn off both devices and unplug them from the AC outlet. Connecting and disconnecting devices that are on and plugged in may expose you to electric shock.

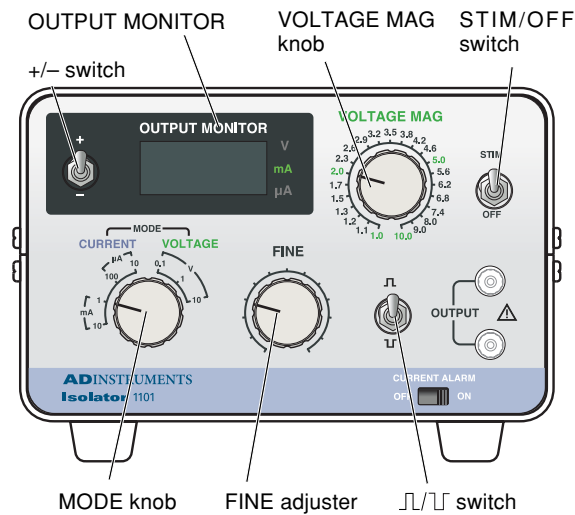


3. Set the STIM/OFF switch on this device to "OFF".
4. Turn on the electronic stimulator.
5. Connect the stimulation electrode leads to the OUTPUT terminals on this device.

⚠ CAUTION

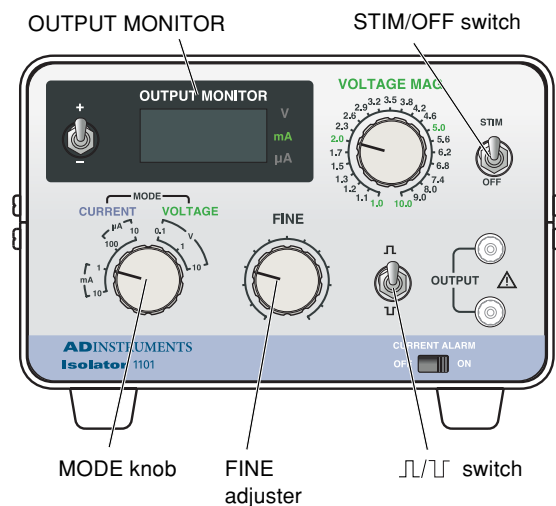
Turn off this device before connecting the stimulator lead cables to the output terminals on this device to prevent electric shock.

Output setup for constant-voltage stimulation



1. Set the electronic stimulator in operating mode and set the output voltage to maximum.
2. Use the +/- switch (Stimulator output display polarity switch) to select the output polarity to be displayed on the OUTPUT MONITOR.
+ : Displays the positive pulse of stimulator output
- : Displays the negative pulse of stimulator output
* This setting is not related to the setting in step 5.
3. Set the MODE knob to the required VOLTAGE range.
4. While observing the OUTPUT MONITOR, turn the FINE adjuster to adjust the output voltage.
5. Use the $\square/\square$ switch (output polarity switch) to select the output polarity from this device.
 $\square$: Red terminal becomes +
 $\square$: Red terminal becomes -
6. Set the STIM/OFF switch to "STIM" to start stimulation output.
7. To multiply the set voltage, turn the VOLTAGE MAG knob to the target voltage multiplier.

Output setup for constant-current stimulation



1. Set the electronic stimulator in operating mode and set the output voltage to maximum.
2. Set the MODE knob to the required CURRENT range.
3. While observing the OUTPUT MONITOR, turn the FINE adjuster to adjust the output current.
4. Use the $\square/\square$ switch (output polarity switch) to select the output polarity.
 $\square$: Red terminal becomes +
 $\square$: Red terminal becomes -
5. Set the STIM/OFF switch to "STIM" to start stimulation output.

Precautions

1. Make sure that the electronic stimulator is turned off before connecting this isolator.
2. Never leave the device in an overload condition (output terminals short-circuited) for five minutes or more.
3. When the CURRENT ALARM switch is on, the constant-current range over alarm indicates that the isolator output dynamic range is not sufficient with regard to the load electrode resistance and cannot let through the current at the set value. Should this happen, lower the current one step or lower the load electrode resistance.
4. When the CURRENT ALARM switch is on and no connection has been made to the OUTPUT terminals, pay attention to the following.
 - The alarm may occur even when the FINE adjuster is turned fully counterclockwise.
 - When the pulse width is set to 1 ms or lower, the alarm trigger level changes between 0 to about 100 μ A.
5. Switching the STIM/OFF switch from OFF to STIM may lower the set voltage. This is because the voltage in the OFF setting is not exposed to a load while the STIM setting is and thus the voltage drops due to the internal impedance.
6. Direct current places a load on the isolator. Turn off the DC switch on the electronic stimulator when it is not used for stimulation.
7. Connect a short, unshielded, single wire lead electrode to the OUTPUT terminals. Other cable types may degrade pulse characteristics and make accurate stimulation impossible.
8. While the electronic stimulator makes it possible to set the pulse width (DURATION) down to 10 μ s, note that the output response of the isolator is shorter than the output pulse characteristics of the stimulator when making short pulse width stimulation settings.
9. When CURRENT MODE is set to 10 μ A and the pulse width is 100 μ s or less, the displayed value at the OUTPUT MONITOR and the signal from the MONITOR OUT connector are lower than the actual stimulation output.

Maintenance

CAUTION

When maintaining (cleaning, sterilizing, etc.) the stimulator, be sure to turn the power off and unplug the power cable from the power outlet first. Failure to do so may result in an electric shock or malfunction.

After Use Inspection

Be sure to conduct the following after-use inspections after finishing stimulator use. These inspections should be performed to ensure smooth and normal operation next time.

After-Use Inspection tasks

Item	Description
Operating condition	Check if the device is in normal working order.
	Check for dirt, scratches and damages on the exterior.
State and storage	Check if the electrodes are clean.
	Wipe off any moisture and dry the device thoroughly.
	Check to see if the device was turned off.
	Check if any chemicals, water or other remain on the device.
	Check if the device is properly stored.

Cleaning

Device Exterior

Note: Turn off the power and unplug the device before maintenance (cleaning, disinfection, etc.) to prevent malfunction and electric shock.

Use a soft cloth moistened in a solution of neutral detergent to wipe away any dirt. Then remove moisture with a dry soft cloth.

Note: Never use thinner, acetone, benzene or other organic solvents as they may damage the paint or resin parts.

After using water (cleanser) for cleaning, remove any remaining moisture with a thoroughly wrung out cloth making sure that no liquid enters the interior of the device.

Electrodes

Cationic soap and water will be enough for normal cleaning.

Dry all metal parts thoroughly before storing to prevent rust.

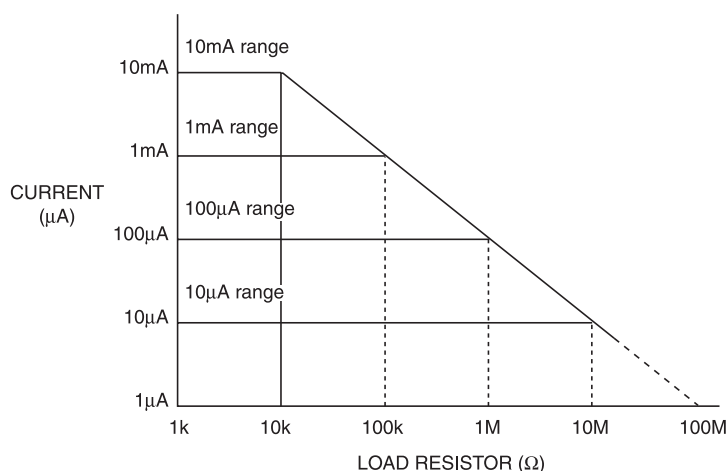
Do not use alcohol to clean electrode leads (or extension cables) as it may cause the vinyl coating to harden.

Technical Data

Standard

Performance and Specifications

Input specifications	Maximum input amplitude: ± 10 V or less Input connector: 10-pin connector
Isolation method	Analog signal transmission through hot coupler
Constant-voltage section	Rough adjustment: 0.1, 1, 10 V (3-step adjustment) Fine adjustment: Control for continuous adjustment of all ranges Magnification meter: $\times 1$ to $\times 10$ (23-step control) Output maximum current: 10 mA Output impedance: 200 Ω or less (2 k Ω or less in the 1 V range) Pulse response: 10 μ s or less rising for all ranges Excessive deviation: 5% or less for all ranges
Constant-current section	Rough adjustment: 10 μ , 100 μ , 1 m, 10 mA (4-step adjustment) Fine adjustment: Control for continuous adjustment of all ranges Pulse response: 10 μ s or less ($R_L = 10$ k Ω) rising for all ranges Excessive deviation: 5% or less for all ranges
Output current characteristics	Guaranteed stimulation current range (see diagram below)



Output insulation: Between output terminals and cabinet 100 M Ω or more (500 DC V)

Stray capacitance: Between output terminals and cabinet 150 pF or less

Display Indication: 3-digit LED indication + unit
Accuracy: 5% or less

Output polarity switch Provided

Output OFF function STIM ON/OFF switch Provided

OVERLOAD detection function Provided

An alarm is generated when the guaranteed range of stimulation current is exceeded.

Environmental Conditions

- Usage environment conditions

Operating temperature range: 10 to 40°C

Operating humidity range: 30 to 90%

Atmospheric pressure: 70 to 106 kPa

- Storage environmental conditions:

Storage temperature range: -20 to 65°C

Storage humidity range: 10 to 90%

Atmospheric pressure: 70 to 106 kPa

Usable Life

6 years (based on self-certification of company data)

Safety Classification

Degree of protection against harmful ingress of liquids: IPX0 (devices without special protection)

Degree of protection against flammable anesthetic gas Not protected (unsuitable)

Mode of operation: Continuous operation

Dimensions and Mass

Dimensions: 160 (W) x 100 (H) x 250 (D) mm

Mass: 2 kg

Electromagnetic compatibility

IEC60601-1-2 :2001 (when connected to 1001)

Guidance and manufacture's declaration - electromagnetic emissions

This Model 1101 is intended for use in the electromagnetic environment specified below.

The customer or the user of the 1101 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Group 1	The 1101 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The 1101 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-3	Complies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacture's declaration - electromagnetic immunity

This Model 1101 is intended for use in the electromagnetic environment specified below.

The customer or the user of the 1101 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment -Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	$<5\% U_t$ ($>95\%$ dip in U_t) for 0.5 cycle $40\% U_t$ (60% dip in U_t) for 5 cycles $70\% U_t$ (30% dip in U_t) for 25 cycles $<5\% U_t$ ($>95\%$ dip in U_t) for 5s	$<5\% U_t$ ($>95\%$ dip in U_t) for 0.5 cycle $40\% U_t$ (60% dip in U_t) for 5 cycles $70\% U_t$ (30% dip in U_t) for 25 cycles $<5\% U_t$ ($>95\%$ dip in U_t) for 5s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the 1101 requires continued operation during power mains interruptions, it is recommended that the 1101 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_t is the AC mains voltage prior to application of the test level.			

Guidance and manufacture's declaration - electromagnetic immunity

This Model 1101 is intended for use in the electromagnetic environment specified below.

The customer or the user of the 1101 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the 1101, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^{*1}, should be less than the compliance level in each frequency range^{*2}. Interference may occur in the vicinity of equipment 
NOTE1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
^{*1} Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the 1101 is used exceeds the applicable RF compliance level above, the 1101 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the 1101. ^{*2} Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the 1101

This Model 1101 is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the 1101 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 1101 as recommended below, according to the maximum output power of the communications.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.72
1	1.2	1.2	2.3
10	3.8	3.8	7.2
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

System Composition for EMC test

This 1101 is tested to comply with IEC 60601-1-2 :2001 with the following composition. If any part which is not specified by our company is used, the EMC specifications might not be satisfied.

Units	Cable length
1101 Isolator	_____
1001 Electronic stimulator	_____
Connecing cable	2.5 m

Accessories

Name	Quantity	Code number
Connecting cable	1 pc	699512A