Rev:

Digitimer

Constant Current Stimulator model DS7A (including DS7AH)

OPERATOR'S MANUAL

CE
0120

The DS7A/DS7AH has been Listed for human use
in Europe, USA, Canada and other Countries.

Caution: Federal law restricts this device to sale by or on the order of a physician.

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File Ref: N:\Docs\Company\Manuals\DS7A\Issue-11 \ DS7A-iss11.lwp
First Issued: June 19, 1996

Released: February 7, 2013
Printed: 08 February 2013

Product Registration

Please take time out to register your new product. Details are after the "Contents" page, following.

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The **Digitimer** DS7A Constant Current Stimulator

(The DS7AH looks the same, but the decimal point on the Output Control is one position to the right)

NOTE: Where "DS7A" is written is this manual, details apply to the DS7A and DS7AH unless noted otherwise.

This page is left intentionally blank to provide an insertion place of any changes subsequent to the printing of this document.

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WARNING & CAUTION

WARNING

For Patient and Operator safety, this manual should be fully read and understood before use of this product.

CAUTION

Please note that where
"Percutaneous Stimulation"
is referred to in this document, it means
"Electrical Stimulation Through the Skin"
and NOT the use of Needle electrodes.

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PURCHASE INFORMATION

A record of salient information, on this page, will aid the Operator should this information become necessary in the future.

Date of Purchase: _____

Dealer: _____

Dealers Tel. Number: _____

Dealers Fax Number: _____

Dealers e-mail address: _____

Contact name at Dealer: _____

Serial Number of Unit: _____

Other Notes: _____

PRODUCT REGISTRATION

For a speedy response to all your questions now and in the future, please take time out to register your new **DS7A Stimulator** at **www.digitimer.com/register** now!

Product registration permits us to quickly advise you of any safety matters or new product information.

A point of contact for all questions regarding the DS7A is **www.digitimer.com/support**.

The site's contents are now growing rapidly, so please bookmark it so that you visit it regularly to check out the new items.

Why Register your purchase?

Digitimer Limited periodically offers enhancements and updates to our products. Without product registration, users of our products may miss out on announcements of important enhancements to the products that they are using.

Digitimer Limited does not make our customer list available to anyone else. Any information that you provide to us is strictly confidential.

How to Register your purchase

Product registration can be accomplished in two ways. You may fill out and mail in the product registration/warranty card supplied with each Digitimer Limited product. You may also register on-line at our **www.digitimer.com/register** web page.

Product announcement mailing list

Digitimer Limited has e-mailing lists which we use as our primary outlet for announcements of new products, product enhancements and product updates. We strongly recommend that all users of our products sign up for the list that is most appropriate to their area of interest. E-mail is kept to a minimum and list membership is kept in the strictest confidence. Only Digitimer Limited can send mail to members of our e-mailing lists.

You may join the DS7A mailing list through our **www.digitimer.com/register** web page.

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Please send any comments regarding this product or manual (omissions, amendments, deletions, problems, adverse events, etc.) by fax or e-mail, to ***Digitimer*** *at address in this manual.*

Thank you

EU - DECLARATION OF CONFORMITY

DECLARATION OF CONFORMITY

Digitimer Limited

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We declare that the product detailed below as described in the DS7A/AH Technical File is in conformity with EU Directive 93/42/EEC as a **Class IIa medical device** and is subject to the procedure set out in Annex II of Directive 93/42/EEC under the supervision of Notified Body Number 0120, SGS UK Ltd, Weston-super-Mare.

DS7A and DS7AH Constant Current High Voltage Stimulators

Date of Issue: *29th August 2012*

J R Smale
Managing Director
Digitimer Ltd

CE
0120

File N:\Docs\Company\Quality\Technical Files\DS7\DS7-TechFile-Al2-DS7-Dec-Conf \ DS7 D o/ C-Iss002.lwp
Last Updated - January 17, 2012
Printed - August 29, 2012

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FDA - INDICATIONS FOR USE

Indications for Use

510(k) Number: **K051357**

Device Name: **DIGITIMER DS7A and DS7AH CONSTANT CURRENT HIGH VOLTAGE STIMULATORS**

Indications for use:

The DS7A and DS7AH are stimulators intended for use during neurological monitoring and assessment in a clinical environment.
They are intended for use by trained personnel either competent to apply appropriate stimuli or under the supervision and instruction of one who is.

Prescription Use __✓___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buehler

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K051357

Page 1 of 1

EQUIPMENT DESCRIPTION

This manual is to be used as a reference for operators of the **Digitimer** DS7A Stimulator.

The Digitimer Stimulator model DS7A provides constant current high voltage pulses of brief duration for percutaneous stimulation during investigation of the electrical activity of nerve and muscle tissue. The output current is continuously variable over the range 0 to 100 milliamps, from a source voltage continuously variable from less than 100 volts to 400 volts, to meet the requirements of human pathological cases. Short pulse durations have been made available to minimise any discomfort to the subject. The pulse duration range can be varied from 50 microseconds to 2 milliseconds in six steps. A specially designed isolated output stage maintains a square (current) pulse shape while minimising stimulus artefacts.

The DS7A is mounted in a non-conductive, flame retardant, free standing case and is mains powered.

For higher voltages the Digitimer Stimulator model D185 is suggested.

The stimulator accepts an external electrical trigger pulse input and triggers on the factory set edge at approximately +2.6 Volts. Alternatively a foot switch may be connected to a socket on the rear panel or the front panel push button pressed. A TTL compatible Trigger output is provided at a BNC socket at the rear panel - this can be factory set to have a positive or negative active state.

REGULATORY STATEMENTS

EN 60601:2006 Classifications

This equipment is CLASS I with TYPE BF Applied Parts.

This equipment is NOT sealed against any ingress of water and is therefore IPX0.

This equipment is NOT intended to be used sterile. If it is necessary to remove contamination from the surface of the equipment, an alcohol moistened cloth may be used. Sterilisation of any electrodes should be performed according to the recommendations from their manufacturer.

This equipment must NOT be used in the presence of flammable anaesthetic gases.

This equipment is rated for CONTINUOUS operation.

Environmental

This unit does not produce any waste.

As with all electronic devices, at the end of its life it should be disposed of by a registered waste contractor who is made aware of its nature.

CLEANING, MAINTENANCE & SERVICING

If the stimulator requires cleaning, it should be unplugged from the mains power supply and wiped with a damp cloth.

This equipment does not require any regular maintenance but Digitimer recommends that the DS7A is returned to the factory for inspection and re-testing every 2 years. Please contact us for a reference number and instructions before despatching the unit.

For on-site testing, a guide to recurrent testing procedures is given in Appendix 4 of this document.

Before each use - The case and all leads should be inspected for any damage. The equipment (or the lead) should be sent for repair if any damage is found.

For all servicing requirements please contact **Digitimer**, who can advice on best course of action. **Digitimer** also offer to supply a service manual (chargeable) to fully qualified, and certified, service repair centres.

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UNPACKING YOUR DS7A STIMULATOR

Your DS7A Stimulator was delivered in a carton which was carefully designed to protect the DS7A case against damage in shipment. It would be advisable to keep the carton in case you need to relocate or return your DS7A some time in the future.

ACCESSORIES

The following items should have been packed with you DS7A Stimulator:

1 x Power Cord, 110 V or 230 V type, depending on your location;

1 x DS7A Stimulator Operator's Manual.

1 x Safety Certificate for the unit.

If any of these are missing, please contact your Distributor, or Digitimer Limited, immediately.

The following items are optional purchases:

Headboxes (patient connection, extension leads):

D185-HB1	Electrode Connection Headbox with a 5 pairs of DIN 42 802-1 1.5 mm "TouchProof" sockets that are colour coded to the original sockets- 4.5m
D185-HB4	Electrode Connection Headbox with a pair (2) of DIN 42 802-1 1.5 mm "TouchProof" sockets that are colour coded to the original sockets - 4.5m

Trigger Cables:

D185-TC1	Trigger Cable (BNC - 3.5mm) - 1.5m
D185-TC2	Trigger Cable (BNC - SMB) - 1.5m
D185-TC3	Trigger Cable (BNC - BNC) - 1m

Foot switches:

D185-FS1	Foot switch to IP68

Fuller details and usage is contained in the Accessories section later in this manual.

PRECAUTIONS AND WARNINGS

a) - Read Manual
Carefully study this Operator's Manual before using the DS7A Stimulator.

b) - Explosion and Fire
The DS7A must not be used in an explosive atmosphere or in the presence of flammable anaesthetic gases.

c) - High voltages
Dangerous voltages are present within this unit. Do not remove covers, and refer servicing to qualified personnel.

d) - Damage
The DS7A and/or any accessories must not be used if there are any signs of external damage.

e) - Moisture
The DS7A and/or any accessories must not be used if any parts are damp or wet.

f) - Input Connectors
Only equipment that complies with EN 60601 (IEC 601) should be connected to the trigger or foot switch inputs.

g) - Output Connectors
Only equipment that complies with EN 60601 (IEC 601) should be connected to the trigger or Current Monitor outputs.

h) - Electrical Interference
This unit has been fully tested for EMC conformity of Medical Devices. This unit should NOT be used near radio transmitters. If any "strange" behaviour of the unit is noted, discontinue use immediately and refer to qualified EMC engineer. Refer to Appendix 5 for further information.

i) - Electrical Stimulation Safety
The safety considerations involved in electrical stimulation for motor evoked potentials have been reviewed by Agnew and McCreery (1987) and by Barker et al (1988). These papers are listed in the appendices of this manual and should be fully read.

j) - Electronic Implants
Understand that this unit may not be appropriate for use on patients with cardiac pacemakers or electronic implants.

k) - Do NOT use transthoracically
Only use this Stimulator on one limb at a time. Do NOT use transthoracically. Doing so could influence the rhythm of the heart.

l) - Needle Electrodes
Please note that where "Percutaneous Stimulation" is referred to in this document, it means "Electrical Stimulation Through the Skin" and NOT the use of Needle electrodes.

The use of Needle Electrodes is NOT recommended, due to the possibility of high current densities at stimulation sites.

Continued ...

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m) - Electrode Isolation

The following generally applies to the use of nerve and muscle stimulators, and especially those designed for percutaneous use. See, for example, the section on Safety of Apparatus in Guld et al, 1970[1].

It is essential for safety that the connections from the stimulator to the subject are isolated from earth/ground, and this means that a earth/ground connection must not be made to either terminal on the stimulator or to either stimulating electrode. Similarly, it is undesirable to place an earth/ground electrode on the patient close to one of the stimulating electrodes. It is also important that an unintentional path to earth/ground should not be introduced by attempts to monitor the stimulating current (see below), or in any other way.

As an instance of such dangers, it is likely that when using the DS7A Stimulator with recording apparatus, it will be necessary to have an earth/ground electrode on the subject somewhere in the vicinity of the recording electrodes. If a second earth/ground connection was to be made to one of the stimulating electrodes, current could flow between the other stimulating electrode and the recording earth/ground electrode. Since the recording site would be some distance from the stimulating site, structures other than those between the stimulating electrodes, e.g. the heart, might be reached by the unintended spread of current via the recording earth/ground electrode. **It is important, therefore, that the output terminals of the DS7A Stimulator should be connected only to the stimulating electrodes and to nothing else.**

Attempts to measure the stimulus current, by inserting a resistor into one stimulating lead and using an oscilloscope to measure the voltage drop across the resistor, are likely to violate the rule of not connecting a path to earth/ground to either side of the stimulator output.

The safe way to monitor the stimulating current (should this be necessary) is by means of a suitable (Medical grade) current transformer, preferably of the clip on type, which can be clipped over one of the stimulator output leads.

n) - "Output Enable"

An operational protocol should be established whereby the "Output Enable" switch of the **DS7A** is only switched to "ON / enabled" when delivery of a stimulus is specifically required.

o) - Simultaneous Connection of Equipment

Simultaneous connection of a patient to the DS7A and high frequency surgical equipment may result in burns at the site of stimulation and possible damage to the stimulator.

p) - DS7A and Therapy Equipment

Operation of the DS7A in close proximity (e.g. 1m) to a shortwave or microwave therapy equipment may produce instability in the stimulator output.

q) - DS7A and MRI scanners

The DS7A is not suitable for use in close proximity to extreme magnetic fields, such as those generated by MRI scanners.

r) - DS7A and Defribrillators

The DS7A is not classified as being defribrillator proof.

s) - Modification

WARNING - Do NOT modify this equipment without authorization of the manufacturer.

[1] **Guld, C., Rosenfalk, A., and Willison, R. G.** (1970), Technical factors in recording electrical activity of muscle and nerve in man. *Electroenceph. Clin. Neurophysiol*., **28**:399-413

PRODUCT INTENDED USAGE

The Digitimer DS7A Stimulator is intended for use as shown in the "Indications for Use" section that follows. It is intended to be used by persons trained in its use. Users are expected to be able to properly operate the DS7A Stimulator and associated instruments.

The DS7A Stimulator is not intended for use in life support situations, or in situations where improper operation or failure of the DS7A Stimulator can result in personal injury to user or patient.

Digitimer Limited makes no representation that the design, implementation, testing or manufacture of the DS7A Stimulator meet more than reasonable standards for use as a medical product.

As stated in the Digitimer Limited Warranty Statement, supplied with each product, "Digitimer Limited Expressly disclaims all warranties to buyer except the limited warranty set forth therein, including without limitation to any and all implied warranties of merchantability and fitness for a particular purpose."

INDICATIONS FOR USE

The Digitimer DS7A and DS7AH are stimulators intended for use during neurological monitoring and assessment in a clinical environment

They are intended for use by trained personnel either competent to apply appropriate stimuli or under the supervision and instruction of one who is.

This is from our FDA application for registration of the product.

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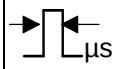
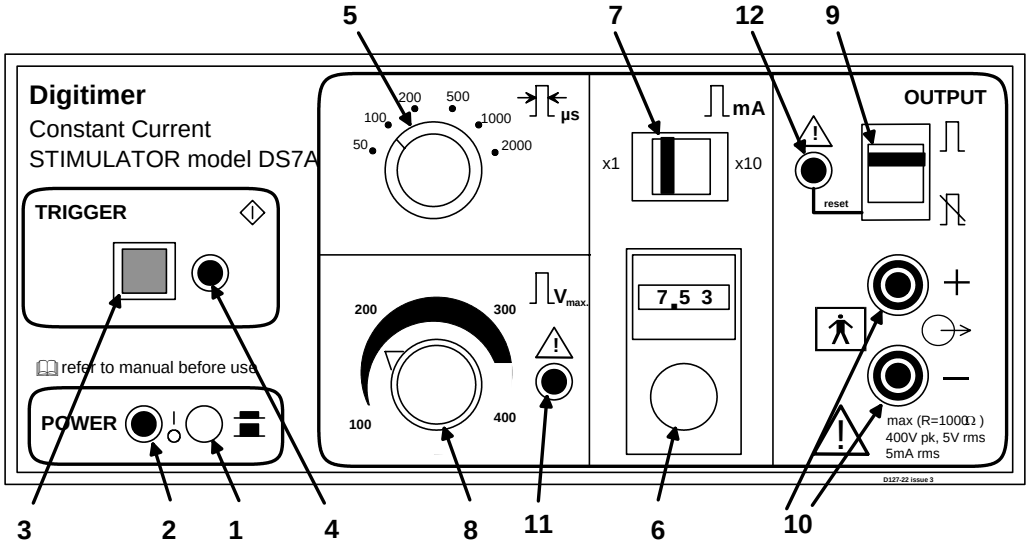
EXPLANATION OF SYMBOLS USED ON DS7A

The majority of these symbols comply with and are documented in BS 7139 : 1989 (IEC 878 : 1988).

Front Panel			
	Output Enabled with switch in this position		Plus; positive connection of connection to patient (Anode)
	Output Disabled with switch in this position		Minus; negative connection of connection to patient (Cathode)
	Attention, consult accompanying documents		Type BF applied part
	Output (stimulus connection to patient)		"Start Process" Manual Trigger Button
	Output Stimulus. Adjustment for Stimulus strength in mA.		Output Stimulus. Adjustment for maximum Voltage of stimulus.
	Consult operator documentation (this manual) before use of this equipment.		Output Stimulus. Adjustment for Pulse Duration of Stimulus, in µs.
	Off (power) - Indicates OFF position of Mains Power switch		On (power) - Indicates ON position of Mains Power switch
	Off (power) - Indicates OFF position of Mains Power switch		On (power) - Indicates ON position of Mains Power switch

Rear Panel			
	Equipotentiality Connector	CE **0120**	Digitimer have declared that this equipment complies with the Medical Device Directive under the supervision of Notified Body 0120 (SGS UK Ltd.)
	Attention, consult accompanying documents.		Input - signal input connector. Note: Only connect to other Medical Equipment.
	Positive going pulse required		Output - signal output connector. Note: Only connect to other Medical Equipment.
	Active "high" square wave pulse produced		Foot switch connector. Note: Only connect to other Medical Equipment.

FRONT PANEL CONTROLS



1. Mains Power ON/OFF switch (push ON, push OFF). When in the unit is on.
2. POWER ON is indicated by a green LED. When lit, indicates that the unit is on.
3. Manual trigger switch. Upon pressing this switch, a single output is produced.
4. A valid TRIGGER signal is indicated by a amber LED. A flash indicates a valid trigger signal - either from an external source or the manual push button.
5. Pulse Duration switch that sets the duration between 50 µs and 2 ms (2000 µs) in 6 steps.
6. Current Amplitude control of output pulses. This gives a continuously variable between 0 - 10 mA (or 0 - 100 mA if the x10 range is selected).
7. x1 and x10 RANGE selection switch. This gives either an output range of 0 - 10 mA, as indicated in the window of the Current Amplitude Control or 0 - 100 mA by multiplying Current Amplitude Control display by a factor of ten.
8. Voltage Amplitude Control of output pulses (maximum). This sets the maximum voltage that can occur on the electrodes and is continuously variable between 100 - 400 V.
9. * Output Enable Switch. In the ON position, the unit is able to generate output pulses. In the OFF position the patient is isolated from the electronics of the unit. Switching to the OFF position also resets the FAULT indicator latch.
   NB: This is not the primary power supply switch.
10. Isolated Output Sockets to patient stimulating electrodes. The RED (upper) socket will go positive with respect to the BLACK socket. The RED socket will be the ANODE.
11. OUT OF COMPLIANCE is indicated by an amber LED. When lit, indicates that the unit was <u>unable</u> to supply the current of the requested stimulus strength.
12. * A FAULT is indicated by a red LED. When lit this indicates that the unit has detected a possible internal fault and <u>should not be used</u>. NB: As a test, this indicator will illuminate at power-on for a few seconds. If the Output Enable Switch (9) is ON, it **must** be switched into the OFF position to reset the circuitry before use of the unit.

* See notes over the page ...

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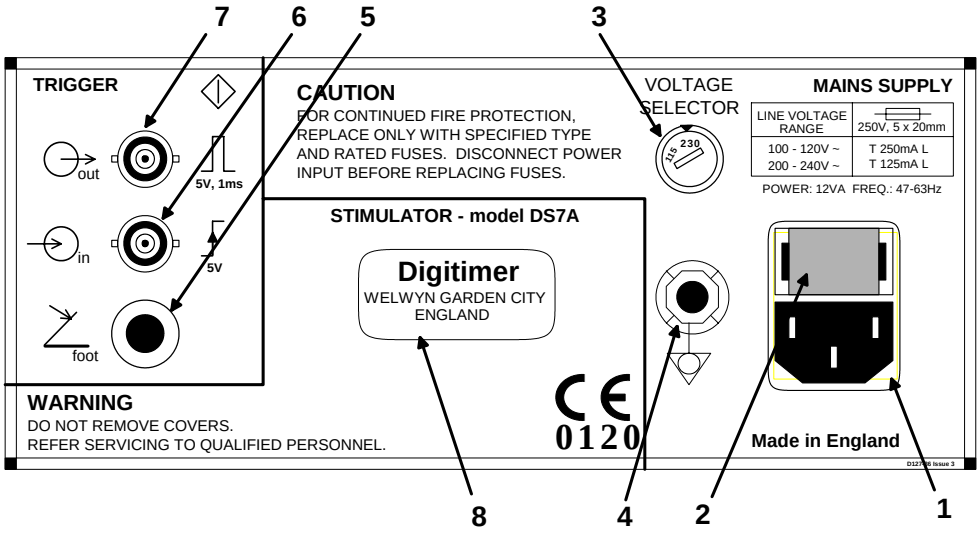
Notes on Front Panel Controls

1. With the Output Enable switch [9] in the "ON" (upward) position:
   i. The FAULT lamp [12] will be on at POWER-ON;
   ii. The FAULT lamp [12] will come on if a Fault is detected;
   iii. The FAULT lamp [12] will NOT go off;
   iv. The Output Enable switch [9] must be placed in the "OFF/reset" (downward) position until it does go off;
2. With the Output Enable switch [9] in "OFF/reset" (downward) position:
   i. The FAULT lamp [12] will be on for ~5 seconds at POWER-ON;
   ii. The FAULT lamp [12] will be on for ~1 second if a transient FAULT is detected;
   iii. The FAULT lamp [12] will stay on if a PERMANENT fault is detected.
3. When the FAULT lamp [12] is on, no stimuli will be presented to the subject;
4. As a precaution against inadvertent triggering of stimuli to the subject, the Output Enable switch [9] should be placed in the "OFF/reset" (downward) position when stimuli are not required.

   It is a good habit to place the Output Enable switch [9] in the "OFF/reset" (downward) position before Power-off, so that it is in the "OFF/reset" (downward) position at Power-on. The FAULT lamp [12] will then automatically extinguish after about 5 seconds. (unless there is an internal fault detected);

REAR PANEL CONTROLS



1. Mains inlet. Connect only to correct mains supply using supplied lead with moulded mains plug. THIS UNIT MUST BE EARTHED. The mains lead must contain the PROTECTIVE EARTH CONDUCTOR.
2. Mains fusing. Remove mains lead before opening. For continued electrical and fire safety, the correct fuses must be fitted before use of the unit.
3. Voltage selector allowing selection of local mains supply (115 or 230V). This must be correctly set before application of mains power to the unit.
4. Protective Earth Terminal (PET). This is an extra Earthing terminal to the PROTECTIVE EARTH CONDUCTOR that is the third wire in the mains cable. It is fitted to allow an earth reference for the unit and bonding point for connection to a POTENTIAL EQUALISATION CONDUCTOR.
5. Footswitch input allowing a footswitch to be used to trigger the unit.
6. TRIGGER IN socket that allows an external voltage change to trigger the unit (Logic signal (+3 to +15V) +ve edge, TTL compatible).
7. TRIGGER OUT socket that provides a trigger output pulse whenever the unit receives a valid TRIGGER IN.
8. Position of Serial Number label that contains the MOD. RECORD status.

A blank serial number label showing the MOD RECORD STATUS area.

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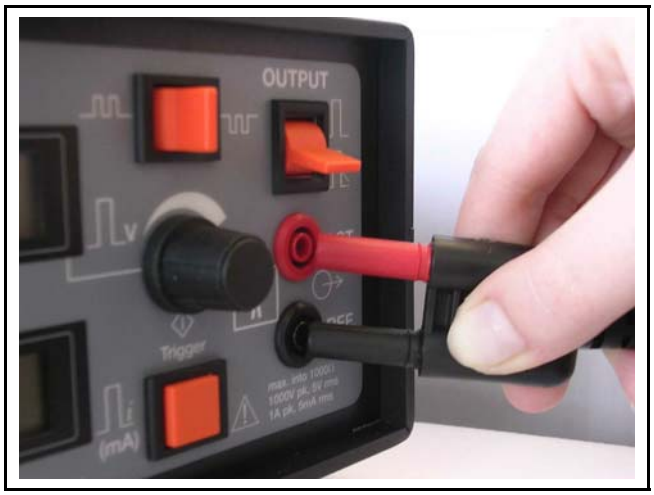
INSERTION OF DS7A STIMULUS OUTPUT CONNECTOR

Please note that there are two levels of force needed to insert the Stimulus Output connector into the Stimulus Output Sockets on the DS7A. Note, the pictures show a D185 which has the same sockets.



This photograph shows the correct orientation.

Red Plug to Red Socket.

To get to this point, very little force is required.

This photograph shows the connector **partially** inserted.

At this point increased resistance will be felt.

More force is required to fully insert the connector.

This zoomed photograph shows the connector **fully** inserted.

INSTALLATION & INITIAL CHECK

Before installation and use of the DS7A, ensure that this manual has been read and understood.

Before use with a patient, the DS7A should be tested in its operational location using a simulated situation.

If required, due to the associated EMG-system, the Trigger parameter selection switches may need adjustment, as described in this manual.

The DS7A should be situated near and within easy reach of the Recordist using the EMG-system to which the DS7A will be attached.

The DS7A should be stood on a sturdy flat surface where the front panel can easily be viewed.

Check that the Mains Voltage Selection and Fuses are correct for the local supply.

With the power switched off, connect the power cord between the DS7A and an appropriate outlet.

Connect a Trigger Cable between the DS7A and the EMG-system in the manner you have chosen, as described in this manual.

With the Output Enable switch (top RH corner) downward [disabled], switch on the power to the DS7A.

Check that the POWER indicator is illuminated, and the FAULT indicator illuminates for approximately 2 second.

Check that the TRIGGER indicator illuminates, for less than a second, each time the Trigger button is pressed.

If the Triggering is set for the DS7A to trigger the EMG-system - check that when the Trigger button is pressed the EMG-system acquires a sweep of data.

- or - *If the Triggering is set for the DS7A to be triggered by the EMG-system* - check that when the EMG-System sends a trigger pulse the DS7A TRIGGER indicator flashes.

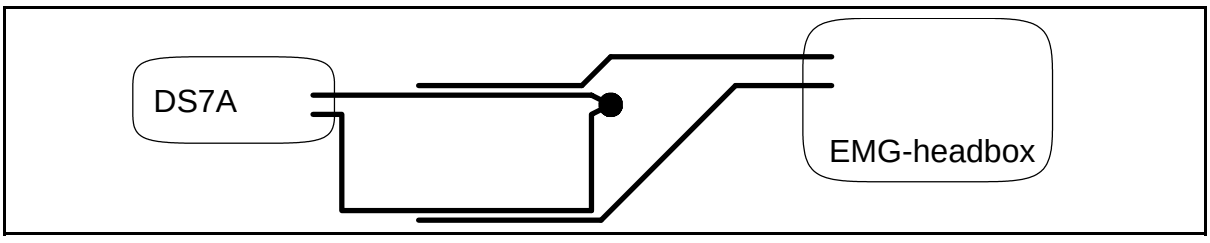
To check that the DS7A and EMG-system are synchronised using the stimulus artefact -

- connect two patient stimulating electrode leads into the DS7A Output sockets and lay them on some insulating material. Connected together the "electrodes" to form a "short-circuit" and arrange the leads NOT to run parallel to each other.

- connect two recording leads into the Input of one channel of an EMG-system and lay them on the same insulating material. Do NOT connect these together, or allow them to touch the "Stimulating Electrodes";

- arrange the "Recording Electrode" leads so that they each run parallel to one of the "Stimulating Electrode" leads;

- with the DS7A Output Enabled, a suitable stimulus intensity (start low at 5mA, and increase if necessary) and EMG-system settings, the recorder should be able to record the artefact from the stimulator operating. Check that this is at the time expected, which will usually be at the very start of the recording sweep.



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STIMULUS CONTROL

There are three parameters on the unit that determine the strength of the stimulus given to the patient.

These are:-

stimulus duration set by 'Pulse Duration' control

the current set by 'Current max.' control and 'x1 / x10' Range Switch

maximum voltage set by 'Volts max.' control
(only has an effect if output is out-of-compliance.)

The rate at which the unit is triggered will also determine the strength of the stimulus given to the patient.

'Pulse Duration' control

This six position switch selects the duration of the stimulation pulse presented to the patient. The settings between 50 and 500 microseconds are more appropriate for percutaneous stimulation.

'Current max.' control and 'x1/x10' Range switch

These two controls set the amount of constant current stimulation given to the patient. The 10-turn rotary dial goes from '0.00' (zero stimulation) to '9.99' which is either 9.99 milliamps or 99.9 milliamps dependent on the 'x1/x10' switch. This current is only possible if the voltage available is sufficient to generate the required current. This is set by:-

'Volts max.' control

This control sets the maximum voltage, available from which the stimulation current is generated. The User may wish to limit the maximum voltage that could appear on the electrode terminals by setting this control less than the maximum of 400 Volts. If the 'Volts max.' control is not set high enough, this is indicated by:

'Out of Compliance' indicator

This indicator shows that the Current selected was not supplied for all or some of the pulse duration, because the Voltage selected was too low for the impedance of the patient electrode circuit.

This can indicate one of two things. Firstly that the electrode is not in proper contact with, or has a high impedance contact with, the patient OR the Voltage selected is too low for the Current required.

Remember that this is governed by Ohm's Law, that is:-

Current = Voltage / Resistance. [in Amps, Volts and Ohms]

Therefore if 100 Volts is selected and the electrode impedance is 2000 ohms the maximum current that can be supplied is 0.05 Amps (50 mA).

MAXIMUM STIMULUS REPETITION RATES

The DS7A has internal fuses that limit the amount of power that is supplied to the patient. This results in a restriction on the stimulus Repetition Rate - vs - Pulse Duration - vs - Stimulus Intensity which is shown on the graph on the following page .

This graph shows that, for instance, with 2 ms pulse duration any stimulation current up to the maximum of 100 mA can be delivered for a repetition rate less than approximately 25 per second.

The Maximum frequency at which the unit can be triggered for a given output current and pulse duration can be calculated using the following equation.

$$\text{Freq.} < 5{,}000{,}000 / (PW \times I_{max})$$

where	Freq.	is the trigger frequency, in pulses per second (Hz)
	PW	is the Pulse Duration set on the unit, in microseconds (µs)
	I_{max}	is the stimulus current, in milliamps (mA)

In most cases of patient stimulation this graph will not be of concern but when the DS7A is used with certain preparations it may have to be referred to.

Trigger Out Pulse Duration

The Trigger Output Pulse Duration is 1 ms (900-1000µs). This limits the minimum interval between any two stimuli pulses to 1 ms (equivalent to a 1 kHz repetition rate). See section on Trigger Polarity.

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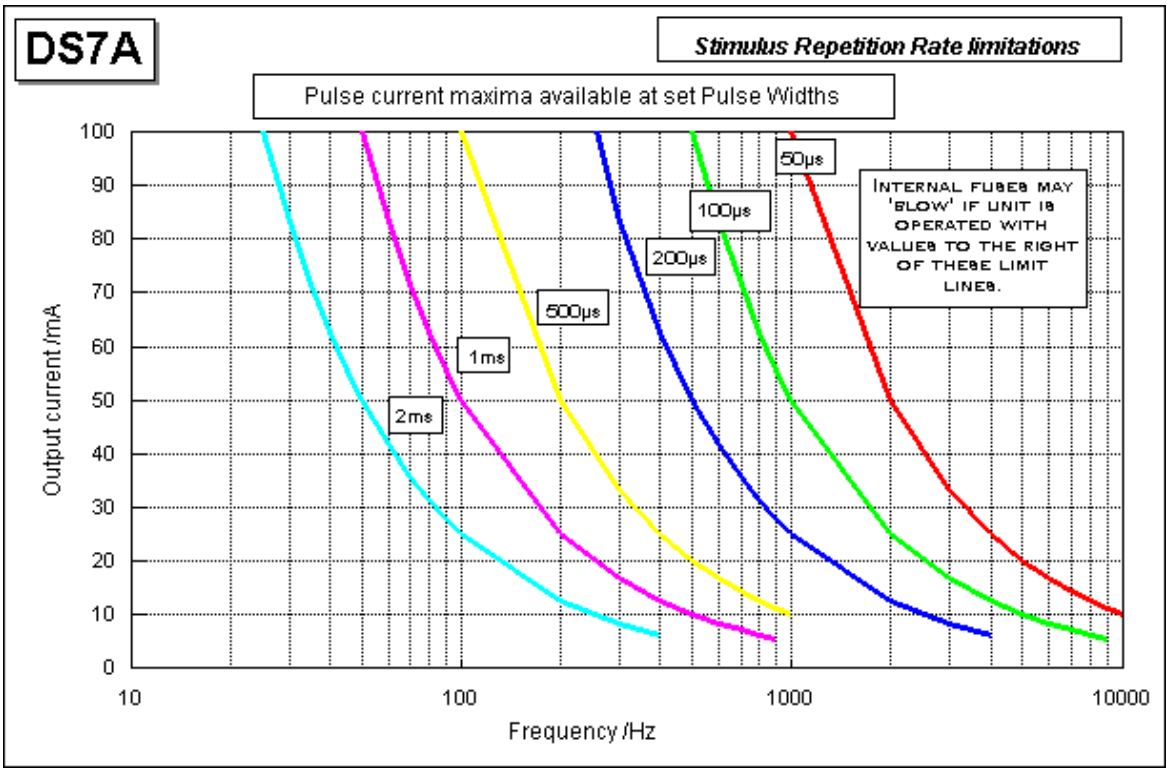
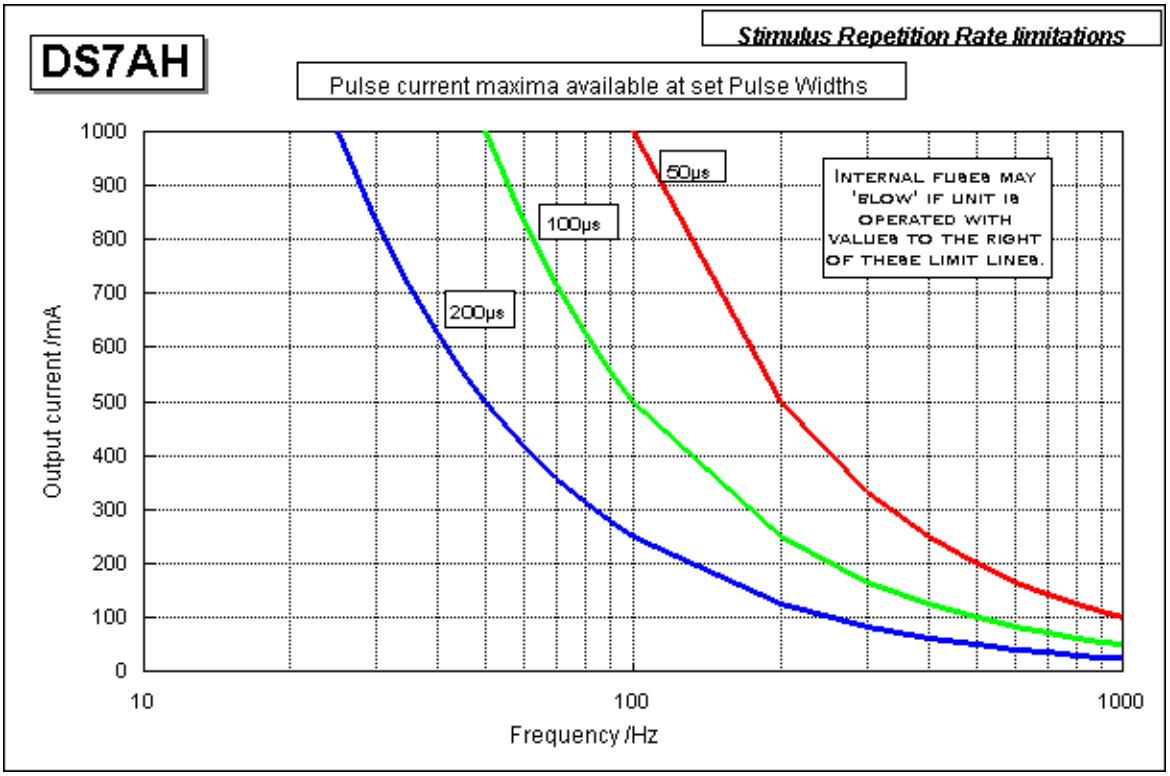
GRAPHS OF MAXIMUM REPETITION RATES



NOTE: Frequencies above 1000 Hz are not permitted with the DS7A.



SPECIFICATIONS

Stimulus Output

CURRENT	Selected by 10 turn dial and x1/x10 switch
	Dial reading 0.00 to 9.99 - DS7A giving 0 to 10 mA (9.99 mA) for x1 setting - DS7A and 0 to 100 mA (99.9 mA) for x10 setting - DS7A
	Dial reading 0.00 to 99.9 - DS7AH giving 0 to 100 mA (99.9 mA) for x1 setting - DS7AH and 0 to 1000 mA (999 mA) for x10 setting - DS7AH
PULSE DURATION	50, 100, 200, 500, 1000, 2000 microseconds (µs) - DS7A 50, 100, 200 microseconds (µs) - DS7AH
COMPLIANCE	Continuously variable from 100V to 400V
ON/OFF	On is up Off disables output and open circuits terminals
CONNECTIONS	4 mm shrouded sockets (red and black) on 3/4" centres
	Red socket goes positive with reference to black socket

Trigger

	The Maximum trigger rate is 1,000 pps (1 kHz).
INPUT	Electrical via Rear Panel BNC socket: Triggers : Logic signal (+3 to 15V) +ve edge, TTL compatible (-ve edge by factory change). Minimum Pulse Duration is 5 microseconds
	Front panel: Push button
	Rear panel: 1/4" mono jack socket for foot switch. (contact closure)
OUTPUT	Rear panel BNC, positive TTL pulse, 1 ms (950 ±50µs) wide (can be factory set for a negative pulse)

Indicators

TRIGGER	LED - Amber, flashes for each trigger received
OUT OF COMPLIANCE	LED - Amber, lit when selected current not delivered
FAULT	LED - Red, illuminated on sensed over-current internally or to the patient. The unit is latched in this condition until reset by the Output On/Off switch being placed in the OFF position.
POWER ON	LED - Green, illuminated for power on

Continued ...

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External Fuses

Note these should ONLY be changed by qualified persons

100 - 120 V mains	T 250 mA L	5 x 20 mm, 250 V
200 - 240 V mains	T 125 mA L	5 x 20 mm, 250 V

Internal Fuses

Note these should NOT be changed by non-qualified persons

Fuse Reference	F3 and F4 - T 315 mA L - 5 x 20 mm, 250 V.

Dimensions

Size:	255 x 100 x 225 mm (d x h x w) 270 x 110 x 225 mm (d x h x w) - over controls and feet
Weight:	2.1 kg (approx.)

Temperature

Operating Range	10°C to 40°C	30 to 75%, non-condensing
Storage Range	-40°C to 70°C	10 to 100%, non-condensing
Transport Range	-40°C to 70°C	10 to 100%, non-condensing

Other

Power:	100 - 120V or 200 - 240V @ 47-63 Hz
Rating:	<30 VA
Case Material	UL94 V-0 Flame Retardant

STIMULATING ELECTRODES

The choice of electrodes to use with the DS7A is dependant upon the specific application and should be determined by the clinician in charge of the procedure. A wide variety of proprietary electrodes are available, ranging from small saline soaked felt pads (ideal for stimulating the ulnar nerve on the patients wrist) through to large self-adhesive electrodes (needed to obtain the low electrode impedance necessary when stimulating large muscles such as the quadriceps).

Due to the possibility of generating high current densities, the use of needle electrodes is NOT recommended.

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MAINS CONNECTION

The DS7A is shipped complete with a safety tested mains lead (fitted with a suitable moulded mains plug) to most countries.

If the mains plug supplied is not suitable please advise Digitimer Ltd of the correct plug for your country.

As it is not possible to obtain certain moulded mains plugs in the UK we will supply a mains lead with a British plug in these cases.

Mains Plug connections

If you have to remove the fitted plug to connect your own plug, the connections are:-

Line or Hot	- Brown
Neutral	- Blue
Ground or Earth	- Green/Yellow

A mains plug should be used which is so constructed that if the lead is pulled the ground wire cannot come into contact with the line or neutral pins.

This Instrument MUST be Earthed.

Mains Plug fuse

If it is possible to fit a fuse into the mains plug, this should be of the correct style and be rated at 5 Amps.

Mains Voltage Selector

Check that the voltage selector on the back panel of the instrument is set correctly for your supply voltage. The factory setting is 230 volts and the alternative is 115V.

The 230V setting allows use on supplies from 200 to 240V

The 115V setting allows use on supplies from 100 to 120V

TRIGGER POLARITY

These can be modified be moving jumpers mounted on the printed circuit board and MUST ONLY BE DONE BY QUALIFIED PERSONNEL as high voltages exist internally.

The unit should be returned to the factory (or a qualified distributor) if Qualified Personnel are not available. Instructions are available from the company to Qualified Personnel only.

Input trigger

The DS7A is factory set to trigger from the positive going edge of an applied external signal which should be between TTL (+5V) and +15V in amplitude and of at least 5 µs duration.

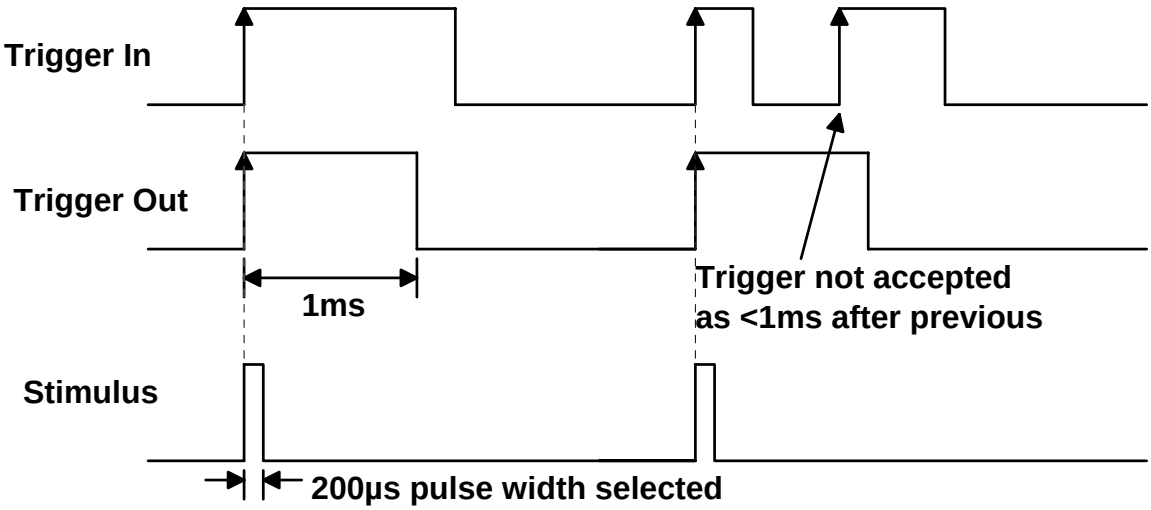
It can be changed so that the DS7A triggers from a negative going (from a positive voltage greater that +3V, to zero volts) input.

The minimum voltage that is applied to this socket is -0.5V
The maximum voltage that is applied to this socket is +17V

Output trigger

A pulse of 1 ms (nominally) is produced in synchronism with the start of each stimulation pulse from the rear panel BNC socket. It is factory set to be positive going TTL (+5V) which is normally at zero volts.

It can be changed to be normally at +5V going to zero volts for the duration of the pulse.



This shows the factory set Positive Trigger In & Trigger Out and 1 ms Trigger Out.

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EXPLANATION OF SYMBOLS USED ON ACCESSORIES

The majority of these symbols comply with and are documented in BS 7139 : 1989 (IEC 878 : 1988).

Accessories			
+	Plus; positive connection of connection to patient (Anode)	—	Minus; negative connection of connection to patient (Cathode)
	Output - signal output connector. Note: Only connect to other Medical Equipment.		Type BF applied part
CE **0120**	Digitimer have declared that this equipment complies with the Medical Device Directive under the supervision of Notified Body 0120 (SGS UK Ltd.)		Consult operator documentation (this manual) before use of this equipment.

D185-HB1

This provides a 4.5 m extension of the patient output sockets terminating in a small box that can be positioned near the patient's head. The box has five (5) 1.5 mm DIN 42 802-1 style "TouchProof" sockets for both connections for those who wish to use protocols with linked cathodes and/or anodes.

The moulded twin shrouded 4 mm connector (not shown) should be inserted into the pair of DS7A Stimulus Output sockets with a Red-to-Red and Black-to-Black mating.

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D185-HB4

This provides a 4.5m extension of the patient output sockets (4 mm shrouded) terminating in a pair (2) of DIN 42 802-1 style "TouchProof" sockets that are colour coded to the original sockets.

The moulded twin shrouded 4 mm connector (shown above, centre) should be inserted into the pair of DS7A Stimulus Output sockets with a Red-to-Red and Black-to-Black mating.

D185-TCX - TRIGGER CABLES

All DS7A - EMG-system will require one Trigger cable.

Trigger cables with different connectors are offered to synchronously link the DS7A with a recording system. The recording system **must** conform to the EN 60601 (IEC 601) standard.

The correct operation of the trigger link should be confirmed before the "system" is used in practice.

A number of Trigger cables are offered. These will be increased as and when necessary. Please refer to the EXTERNAL CONNECTION section of this manual for more details of the cable required and connection details.

D185-TC1 Trigger Cable (BNC - 3.5 mm) 1.5 m (5 ft)

Use: To trigger Nicolet Viking III or IV from DS7A.

D185-TC2 Trigger Cable (BNC - SMB) 1.5 m (5 ft)

Use: To trigger DS7A from Nicolet Viking III or IV.

D185-TC3 Trigger Cable (BNC - BNC) 1 m (3 ft)

Use: Standard BNC-BNC connector used for triggering with most other monitoring systems.

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D185-FS1

This medical grade foot switch is sealed to IP68 so as to meet all the requirements of EN 60601 (IEC 601), including for use within operating theatres.

The lead is fitted with a mono 3.5 mm jack plug. A 3.5 mm to ¼" jack plug adapter to allow the foot switch to be plugged into the **DS7A** is supplied.

Note that it is the pressing of the foot switch which initiates a stimulus to the patient. The releasing of the foot switch or continued pressing of it does not produce any extra stimuli.

The foot switch should only be inserted into the **DS7A** "Foot Switch" socket (rear panel) when the DS7A Output Enable switch is in the Disabled (down) position.

CONNECTION OF DS7A TO AN EMG SYSTEM

The following section shows the leads necessary to connect the DS7A to the some EMG Systems.

If your system is not shown please advise us and we will aim to add it to the document.

Introduction

To record responses evoked by the stimulation produced by the DS7A Stimulator, a EMG recording system is required.

This EMG recording system must be synchronised to the DS7A so that the recording starts at the same time of the stimulus.

This is done by the trigger connection cable.

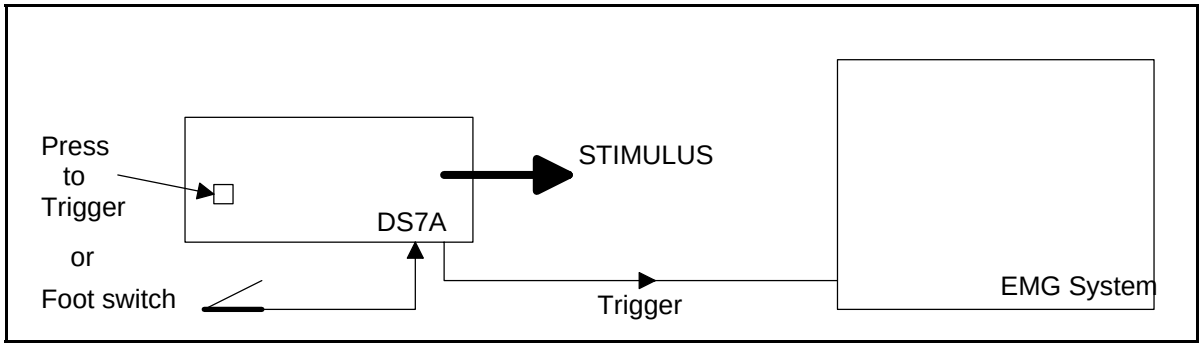
Modes

There are two basic modes of trigger synchronisation -

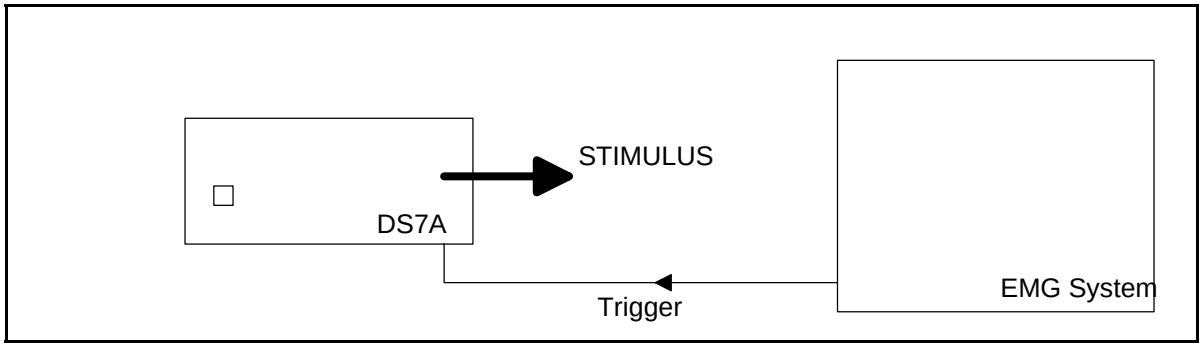
a) - DS7A triggers the EMG system.
Uses the DS7A Trigger-Out socket to transmit the trigger signal to the EMG system.

b) - The EMG system triggers the DS7A.
Uses the DS7A Trigger-In socket to receive a trigger signal from the EMG system.

DS7A - Trigger-Out



DS7A - Trigger-In



NOTE - If the DS7A front panel Trigger button or foot switch is pressed, a stimulus will be presented without triggering the EP system.

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Setting up the EMG system

All EMG systems are different but some settings will be good starting places.

Amplifier sensitivity	~50 μV / division
No. of Sweeps	1
Artefact rejection	OFF
Stimulus Repetition Rate	0.5 Hz (every 2 sec.) or EXTERNAL

Artefact Rejection

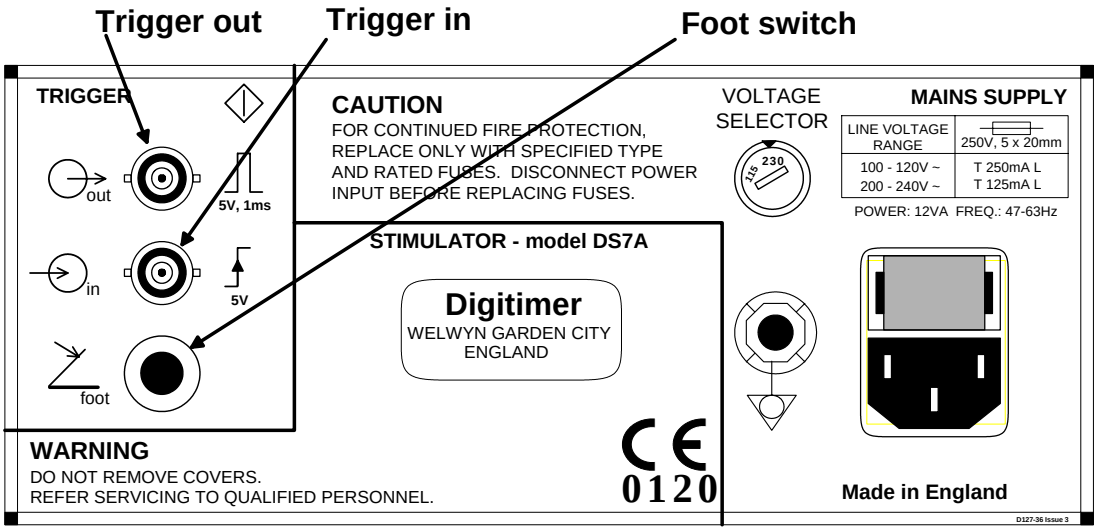
Most EMG systems have a method to disable or enable different levels of Artefact rejection. Precise methods will vary with manufacturer and model.

Depending on the particular set-up used, the DS7A can often produce large amplitude stimulus artefacts. These can produce a "reject" of the recorded sweep.

If this is the case the Artefact Rejection should either be turned-off (disabled) or set to ignore the large transients (stimulus artefacts) in the first part of the sweep.

Making Trigger Connections to the DS7A

All Trigger connections to the DS7A will be made to the rear panel, shown below.



Symbols used in connection with the Trigger.

	Output - signal output connector. Note: Only connect to other Medical Equipment.		Active "high" square wave pulse produced
	Input - signal input connector. Note: Only connect to other Medical Equipment.		Active "low" square wave pulse produced
	Positive going pulse required		Negative going pulse required
	Foot switch connector. Note: Only connect to other Medical Equipment.		

Description of socket function

TRIGGER-OUT socket - provides a trigger output pulse whenever the unit receives a valid TRIGGER-IN signal.

TRIGGER-IN socket - allows an external voltage change to trigger the unit (Logic signal (+3 to +15 V) +ve edge, TTL compatible).

Foot switch input - allows a foot switch to be used to trigger the unit.

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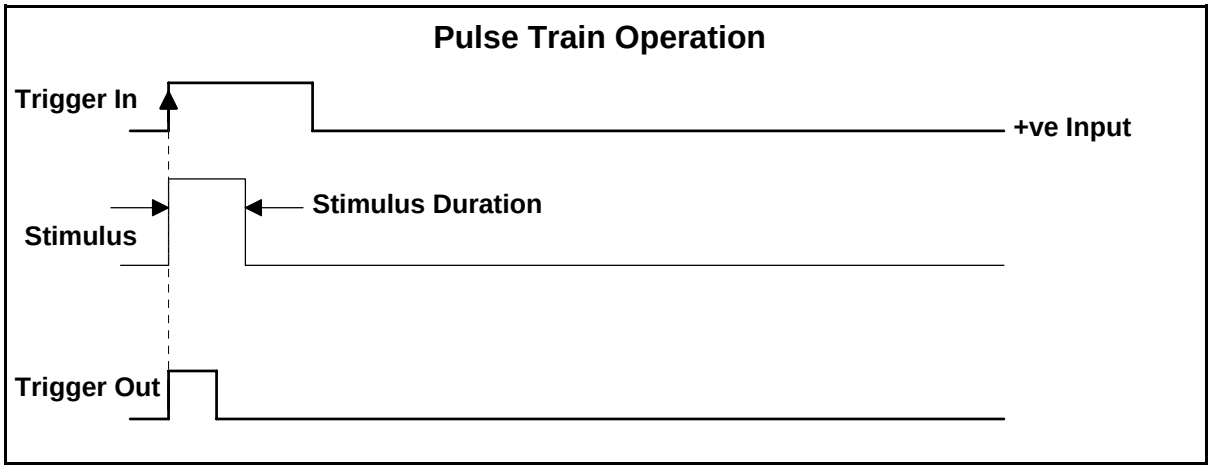
Electrical characteristics of Triggers

Input options	Manual front panel mounted push button.
	Foot switch via rear panel socket. Note that only Medical grade switches should be used, such as the D185-FS1.
	Logic signal (+3 to +15 V) +ve edge, TTL compatible (-ve edge by internal change).
Output	Positive TTL compatible signal 1 ms duration for recorder synchronisation. (100 µs and/or active low by internal change).

Trigger pulse to output stimulus relationship



An external Trigger-In, or front panel button or foot switch, will initiate a stimulus pulse, as indicated above, without any delay.

The Trigger-Out signal will also be produced in synchrony with this signal.

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Numerous papers, abstracts and booklets are available from **Digitimer** - please see the website ***www.digitimer.com*** for the current list and request form.

APPENDIX 1 .. DS7A MODIFICATION RECORD STATUS

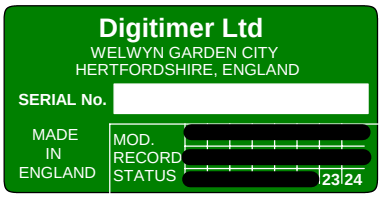
The DS7A has a "MOD RECORD" label fixed to its rear panel.

This indicates which modifications have been performed to that unit and all numbers may NOT be struck through.

New Instruments

Currently, all new units (at time of first delivery) have had all numbers struck through and this implies a 'Mod. State' that is the highest number that has been struck through.

i.e. If all number 1 through 22 have been struck through - the MOD STATUS is "22".



Units that have been modified after first delivery

Units may have had some modifications done subsequent to manufacture and all numbers may NOT be struck through.

The Modifications made

The recent changes that have occurred indicating a rise in 'Mod. State' are:-

Mod. State	Change from previous 'Mod. State'
10	a) The FAULT indicator (and output inhibit circuit) is now latched. The OFF position of the Output Enable Switch is used to 'reset' this latch. b) The 100 µs Trigger Out and 10 kHz repetition rate has been removed. (Trigger Out is 1 ms, max. Rep. is 1000 Hz)
11	Front & Rear panels labelling changed to include more symbols and conformance with the MDD requirements. Trigger LED now amber not Green.
12	Internal modifications including larger Output Capacitor.
13	Output Current dial changed from 4 to 3 digit due to failures of 4-digit dial mechanisms.
14	Internal changes to reduce errors due to leakage on PCB due to contamination.
15	PCB up-issued to incorporate numerous, previous, changes (CN.1749)
16	Front Panel Pulse Duration switch now has keyed component and knob. (CN.1819)
17	Internal changes to add diode to discharge capacitor. (CN.1879)
18	More ESD material added to enable full compliance the 60601-1-2:2001. (CN.1964)
19	Minor internal electronic changes for increased ESD and EMC (CN.1987)
20	Case changed to UL94 V-0 Flame Retardant material in Ivory with Brown trim. Handle assembly is removed. (CN.1982/1992)
21	Internal circuitry added to inhibit excessive pulses due to o.c. Pulse Duration switch (CN.2002)
22	Changed the two internal fuse holders from "clips", which are prone to weakening over time to a "board mounted" type. This reduces the risk of either fuse going open circuit which can result in overloading and failure of the remaining fuse.

The MOD RECORD STATUS is part of the Serial Number label fitted to the rear panel - see REAR PANEL CONTROLS section.

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APPENDIX 2 .. DS7AH - HIGH OUTPUT CURRENT

The following information details a factory modification of the basic design of peripheral nerve stimulator to the higher maximum current at reduced pulse duration provided by the DS7AH. This option is offered to overcome the difficulty of stimulating deep peripheral nerves with large area electrode pads.

In this situation the capacity associated with the electrodes limits the rate of increase of stimulating voltage when the stimulating machine is of constant current type as the DS7A design. There are two possible solutions, increase the stimulus time or increase the stimulus current. The latter alternative has been favoured on the basis of reduced patient discomfort since the human pain receptors are relatively slow acting in comparison to the motor nerves.

Since the stimulus energy and charge available are limited in the DS7A design any increase in stimulus current will be achieved by reduction of stimulus time. The DS7AH option will provide a maximum stimulus current of 1 amp at up to 400 volts compliance at pulse durations up to 200 µs maximum compared to the standard DS7A specification of 100 mA at pulse durations up to 2 ms.

Performance Differences over standard DS7A

As described above the DS7AH has an increased stimulus current pulse output providing maximum currents of 100 mA on the x1 range and 1000 mA on the x10 range compared to 10 mA and 100 mA for the standard DS7A. The current output of the DS7AH can be checked on a resistance load of maximum value 3.5k ohms for the x1 range and 350 ohms for the x10 range. By comparison the maximum values of load resistance on the DS7A are 35 k ohms and 3.5 k ohms.

Safety Considerations

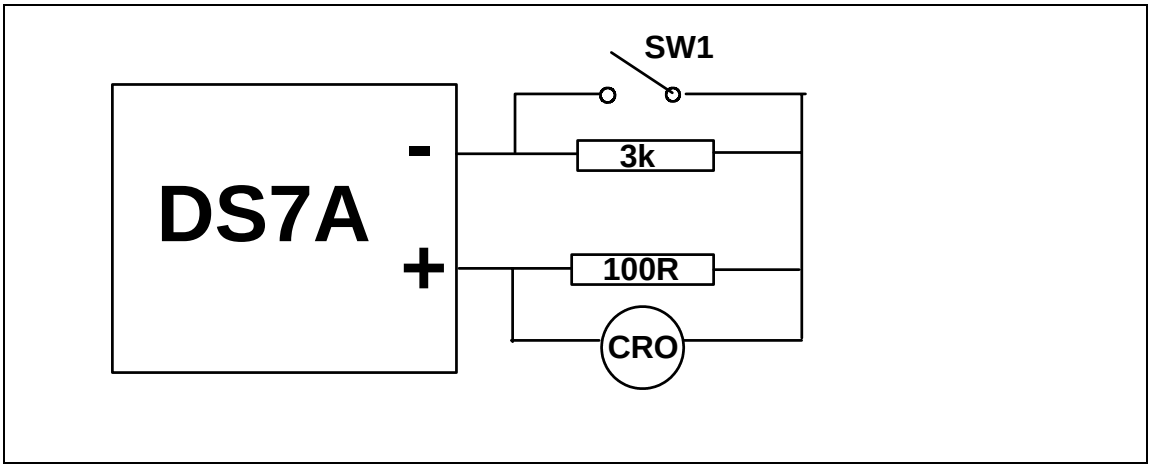
Since there are no changes to the isolation components and clearances nor is there any increase in maximum output voltage, the safety features of the DS7A are maintained in the DS7AH. In operation although the DS7AH can provide higher stimulus current, this is dependent on achieving a low electrode impedance by the use of large area electrodes.

There is no increase in the maximum available stimulus charge and energy with the DS7AH option. These two parameters dictate the stimulus operating conditions relative to patient safety and are unchanged from the DS7A to the DS7AH. The DS7AH option is accordingly used for short stimulus pulse time investigations with large area electrode pads to reduce patient discomfort.

APPENDIX 3 .. OPERATIONAL TESTS

These tests are to be **performed only by qualified personnel**.

Connect a 100R resistor (1/2W) in series with a power resistor in the range 2000 to 3000 ohms (5 watts or greater) across the output terminals. Monitor the potential across the 100R resistor. Note the 100R should be connected to the positive terminal which is the common terminal of the oscilloscope monitor. See circuit below.



Using a repetitive trigger (except for test 5) :

1. With SW1 open set voltage control to 400V, pulse duration 1000 microseconds and current control to 100 mA (maximum CW, x10 range). Trigger DS7A and record stimulus output potential generated across the 100R resistor - should be 10 volts peak, 1 ms wide. Check that the amber "Trigger" indicator is turned on.
2. Now close SW1 and check that potential across 100R resistor has not changed appreciably.
3. With SW1 reopened reduce voltage control until potential across 100R resistor reduces. Check then that the amber "out of compliance" indicator is turned on.
4. Now switch the current range from x10 to x1 and check that potential across 100R resistor falls from 10 volts peak to 1 volt peak.
5. Check that all three methods of triggering operate correctly.
   a) Manual front panel switch
   b) Foot switch through rear panel jack socket
   c) Electrical pulse trigger through rear panel Trigger-In BNC socket.
6. Check that there is a Trigger Output pulse coincident with the stimulus pulse.

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APPENDIX 4 .. RECURRENT TESTING OF THE DS7A

Recurrent testing of medical electrical equipment is often required as part of the equipment management policy of hospitals or other responsible organisation. These tests may be required before the equipment is put into service, or after fixed time intervals.

The international standard, IEC 62353 (Recurrent test and test after repair of medical electrical equipment), suggests testing intervals. For equipment that applies electrical energy, to directly influence the function of nerves or muscles, as the DS7A can, the suggested test intervals should be no more than 24 months.

Every DS7A supplied is extensively tested by Digitimer before delivery.

These instructions are meant as a guide to suitably qualified test personnel, with authority to perform these tests on behalf of the responsible organisation for the equipment involved. They provide guidance to allow the tests to be accomplished without causing damage to the equipment or exposing the test personnel to risk. They cannot and must not replace the training and experience required for testing medical electrical equipment.

Test Procedure

Before commencing the test procedure it is important to fully understand the operation of the DS7A by reading the Operator's Manual.

The DS7A is a Class 1 device with Type BF applied parts.

There is no requirement, in any of these tests, to open the case of the DS7A. All repair procedures should be referred to Digitimer or a local distributor.

Visual Inspection

Visually check for any damage to the enclosure of the DS7A. Also carefully check for damage to the supply lead and any input or output cables.

Check that the voltage selector on the rear panel is set to suit the local supply voltage.

Check that the 2 mains fuses, housed within the appliance coupler, are of the correct rating and type for the local supply voltage.

Check for signs of contamination or fluid spill. If fluid has entered the enclosure refer the repair to Digitimer or it's local distributor.

Check that the tamper-evident seals on the rear of the DS7A are unbroken and un-disturbed. Evidence that the enclosure has been opened may indicate the need for more extensive testing.

Continues over ...

Electrical Tests

The electrical tests may be most easily accomplished using combination test equipment such as the Rigel 277 Electrical Medical Safety Analyser.

Earth Resistance - Accessible conductive parts are required to show a low impedance connection to protective earth. The DS7A may be tested at currents up to 25A but the only accessible conductive parts are the Potential Equalisation Terminal on the rear panel and the shell of the BNC connectors.

Leakage Currents - Connect the DS7A to the test equipment according to the instructions for a Class 1 device with Type BF applied parts. The applied parts of the DS7A are the red and black output terminals on the front panel. As they are Type BF they may be tested as one part.

Leakage current measurements should be taken with the unit switched on and the output enabled.

All of the leakage current measurements, in both normal condition and single fault condition, may be taken with the DS7A connected as described.

Insulation Resistance - Insulation resistance may be measured using test voltages of up to 350V.

Functional Test

Refer to section "Appendix 3 .. Operational Tests".

CAUTION: The DS7A can generate high output voltages; care should be taken to insulate all connections and avoid coming into contact with the output voltages. Special care should be taken to avoid contact with both output terminals simultaneously.

Evaluation, Documentation and Preparation for Normal Use

The test results obtained should be analysed for possible non-conformance to standards and the results recorded in line with the policy of the responsible organisation involved. Should the records show a deterioration in test results the frequency of testing may need to be revised.

Assuming satisfactory test completion the DS7A may be returned to normal use. Check that the supply voltage selector and the supply fuses are correct for the intended site of operation.

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APPENDIX 5 .. GUIDANCE & DECLARATIONS ON ELECTROMAGNETIC COMPATIBILITY

Electromagnetic Emissions (Table 1)

<table>
<tr><td colspan="3">The Digitimer DS7A is intended for use in the electromagnetic environment specified below. The customer or the user of the Digitimer DS7A should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The Digitimer DS7A 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.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class A</td><td rowspan="3">The Digitimer DS7A is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Not applicable</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions
IEC 61000-3-3</td><td>Not applicable</td></tr>
</table>

Electromagnetic Immunity (Table 2)

The Digitimer DS7A is intended for use in the electromagnetic environment specified below. The customer or the user of the Digitimer DS7A 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 ±8 kV	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 ±1 kV for input/output lines	±2 kV ±1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV line(s) to earth	±1 kV ±2 kV	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 5 sec	COMPLIANT COMPLIANT COMPLIANT COMPLIANT	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Digitimer DS7A requires continued operation during power mains interruptions, it is recommended that the Digitimer DS7A 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 $\boldsymbol{U_T}$ is the a.c. mains voltage prior to application of the test level.			

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Electromagnetic Immunity (Table 4)

The Digitimer DS7A is intended for use in the electromagnetic environment specified below. The customer or the user of the Digitimer DS7A should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Digitimer DS7A, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Recommended separation distance $d = [3,5/3] \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = [3,5/3] \sqrt{P}$ 80MHz to 800Mhz $d = [7/3] \sqrt{P}$ 800MHz to 2.5GHz 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 metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] 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 electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If measured field strength in the location in which the Digitimer DS7A is used exceeds the applicable compliance level above, the Digitimer DS7A should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Digitimer DS7A.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable & mobile RF communications equipment & the Digitimer DS7A (Table 6)

The Digitimer DS7A is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Digitimer DS7A can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Digitimer DS7A as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = [3,5/3]\sqrt{P}$	**80 MHz to 800 MHz** $d = [3,5/3]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = [7/3]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.12	1.12	2.33
10	2.88	2.88	5.76
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance ***d*** in metres (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.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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APPENDIX 6 .. GUIDANCE ON SYSTEM INTEGRATION

Potentially, the DS7A stimulator relies for its action upon the simultaneous use of other pieces of equipment, as it is incapable of producing repetitive stimulation without a trigger input. For example, when used for muscle or nerve physiology studies it may be employed alongside an EMG recorder, a personal computer and/or other TTL compatible trigger device. The computer would be used to analyse the signal from the EMG recorder and possibly produce the stimulation trigger protocol from a fitted data acquisition/control interface card. So, the DS7A and the EMG recorder are equipment designed as Medical Electrical Equipment, while the computer and trigger source are not specifically designed as medical equipment.

Using a combination of Medical Electrical Equipment (M.E.E.) and "non-M.E.E." can introduce hazards; careful consideration is required of equipment choice and how it is connected together.

The use of a combination of equipment creates a "system" The international collateral standard IEC /(EN) 60601-1-1 "Safety Requirements for Medical Electrical Systems" contains the requirements for continued safety and guidance on integration. This is also now covered in IEC60601-1:2005 at Clause 16. Users should familarise themselves with these requirements.

Connection of non-medical equipment into a medical system can introduce leakage (or touch) currents in excess of that allowed for medical equipment into the patient environment. For Users of the DS7A involved studies like those above there are two methods by which this hazard can be eliminated.

I. Power the non-medical devices via a separation or isolation transformer. This removes the leakage currents from the circuits.

II. Keep all equipment outside the Patient Environment. The Patient Environment is generally considered to be the patients bed or couch and the space surrounding it, to a distance of 1.5 metres. For the DS7A this is easily achieved using the 2m or 4m Output Extension Lead, part number D185-HB4-2m and D185-HB4 respectively. However separate measures would be required to move the EMG recorder outside the Patient Environment.

With either solution some other factors should also be remembered.

Never touch the patient whilst simultaneously touching the "non-medical" parts of the system. With the DS7A this would extend to the BNC connectors on the rear panel.

Using portable multiple socket outlets can introduce new risks. They are easily damaged and a fault in the multiple socket outlet can mean that the leakage currents of all the connected equipment appear in the patient connected equipment.

If a portable multiple socket outlet must be used keep it off the floor (where it is most easily damaged). It is better to use permanent wall mounted socket outlets.

Never use multiple socket outlets plugged into one another (a "daisy chain" or from an extension lead.

Should you be in any doubt over the correct steps to take when connecting the DS7A into a system, obtain advice from your orginisations Bio-engineering / Medical Physics / E.B.M.E. department. Advice may also be obtained from Digitimer Ltd.

WARRANTY INFORMATION

Limited Warranty

Digitimer Limited warrants to the first purchaser, for a period of one year from the date of purchase, that this Digitimer Instrument (hereafter referred to as the "Product") will be free from defective workmanship and materials, and agrees that it will, at its option, either repair the defect or replace the defective Product or part thereof at no charge to the purchaser for parts and labour. The Product must be returned to Digitimer Limited, carriage paid and insured. Digitimer Limited will return the Product, carriage paid and insured, in the most appropriate method as determined by Digitimer Limited. If a faster shipping service is desired by the customer, any additional special delivery expenses must be paid by the customer.

This warranty does not apply to shipping damage. Digitimer Limited fully insures all shipments. Any claims of damage upon receipt must be filed with the carrier and Digitimer Limited immediately.

This warranty does not apply to any exterior appearance item of the Product which has been damaged or defaced, which has been subjected to misuse and abuse, abnormal service or handling, or which has been altered or modified in design or construction.

This warranty does not apply to any interconnection cables supplied with the Product.

This warranty does not apply if any unauthorised repairs, modifications or alterations have been made to the Product.

This warranty applies to software products only to the extent of maintenance release software to correct improper operation of the Product. Software updates to increase the capabilities of the present product are not to be provided under the terms of this warranty. Updates will be sent at no cost to the customer by normal common carrier routes. If faster delivery is desired, the customer must assume any additional expenses for special delivery service.

No sales organisations, other than Digitimer Limited itself, are authorised to make any warranties other than those described above, or to extend the duration of any warranties beyond the time period described above on the behalf of Digitimer Limited. If Digitimer Limited agrees to such a modification of this warranty, Digitimer will furnish a modified copy of this agreement, which must be presented if a claim is being made under these modified terms.

Obtaining Warranty Service

Warranty service of this Product can be obtained by returning the Product, carriage paid and insured, to Digitimer Limited, or the Distributor from whom the equipment was purchased. Prior authorisation before shipping the product is advised for the most expedient service.

Product change or discontinuation

Digitimer reserve the right to discontinue any instrument or to change its specification without notice, and without responsibility for incorporating changes in instruments already sold.

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Digitimer

Constant Current Stimulator model DS7A (including DS7AH)

OPERATOR'S MANUAL

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