Digitimer DS5

Isolated Bipolar
Constant Current Stimulator

OPERATOR'S MANUAL

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Product Registration

Please take time out to register your new product.

Details are included in the General Information Chapter

You can even do it online at:-

www.digitimer.com/register

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CHAPTER 1
GENERAL INFORMATION

Product Description & Intended Usage

The DS5 is an isolated bipolar constant current electrical stimulator that has been developed for the new and increasingly important field of clinical nerve excitability testing. These studies, including electrotonus and threshold electrotonus, are giving us added understanding of human nerve excitability and the pathophysiology of diseases such as diabetic neuropathy, carpal tunnel syndrome (CTS), amyotrophic lateral sclerosis (ALS), multifocal motor neuropathy (MMN), motor neurone disease (MND) taxolcisplatin neuropathy and neuromyotonia.

Unlike many electrical stimulators, the DS5 is not a traditional "square wave pulse stimulator", instead, it produces an isolated constant current stimulus proportional to a voltage applied at its input, with the shape of the input waveform describing the shape of the stimulus. As a result, when driven by a compatible computer based digital to analogue interface, the DS5 is capable of generating a stimulus consisting of multiple components including sine waves, ramps, square waves or totally arbitrary waveforms. Patient safety is assured at all times by the implementation of safety features which, amongst other things, limit the amount of energy passed to the subject.

The DS5 stimulator has four input voltage ranges (±1V, ± 2.5V, ±5V, ±10V) making it widely compatible with signal generating hardware. The input voltage range and the output current range (±10mA, ±25mA or ±50mA) are selected via the controls on the front of the stimulator. On the rear of the device are three BNC sockets, one accepting the voltage input waveform, the other two providing current and voltage output monitors, allowing the stimulus waveform parameters to be fed into a data acquisition system so they can be recorded alongside your EMG data. Although the DS5 has been primarily designed for clinical studies of peripheral nerves using threshold tracking techniques, because the unit provides a current output proportional to the voltage input and can deliver up to ±50mA (from a source of greater than ±100V), it should appeal to any researchers wishing to safely apply a computer controlled constant current stimulus to a patient or research volunteer.

The DS5 meets all the requirements of the Medical Device Directive (MDD) by implementing the EN 60601 Standard. The Digitimer DS5 stimulator is intended to be used by persons trained in its use, who are expected to be familiar with the principles and safety issues of electrical stimulation. Users should be able to operate the DS5 stimulator, the controlling software, and any associated instruments correctly before carrying out any patient or human volunteer studies. The DS5 stimulator is not intended for use in life support situations, or in situations where improper operation or failure of the DS5 stimulator can result in personal injury to user or patient.

Digitimer Limited makes no representation that the design, implementation, testing or manufacture of the DS5 stimulator meets 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."

Precautions & Warnings

WARNING
For Patient and Operator Safety, this manual should be FULLY read and understood before use of this product

Operator's Manual

Carefully study this Operator's Manual before using the DS5 Bipolar Constant Current Stimulator.

Risks to Patient Safety

- Stimulating electrodes should not be placed thoracically or trans-thoracically as this may increase the risk of cardiac fibrillation. A warning to this effect is given on the outside of the DS5.

- Care should be taken when selecting appropriate stimulating electrodes. If the current density of the chosen electrode is greater than 2mA rms/cm^2 then the operator should pay extra attention to stimulus parameters to ensure that the patient does not suffer burns at the stimulation site.

- Simultaneous connection of a patient to the DS5 and high frequency surgical equipment may result in burns at the site of stimulation and possible damage to the stimulator.

- Operation of the DS5 in close proximity (e.g. 1m) to a shortware or microwave therapy equipment may produce instability in the stimulator output.

- The DS5 is not suitable for use in close proximity to extreme magnetic fields, such as those generated by MRI scanners.

Patient Exclusion Criteria

Patients fitted with an implanted electronic device such as a cardiac pacemaker should NOT be subjected to stimulation unless specialist medical opinion has been obtained.

Explosion and Fire

The DS5 must not be used in an explosive atmosphere or in the presence of flammable anaesthetic gasses.

High Voltages

Dangerous voltages are present within this unit. Do not remove covers, and refer servicing a Digitimer representative.

Damage

The DS5 and/or any accessories must not be used if there are any signs of external damage.

Moisture

The DS5 and/or any accessories must not be used if any parts are wet or damp.

Input/Output Connectors

Only equipment that complies with EN(IEC) 60601 (Medical Equipment), EN(IEC) 60950 (IT Equipment) or EN(IEC) 61010 (Laboratory Equipment) should be connected to the DS5 input/output connectors. See Chapter 4, Annex 4 for guidance on choice of equipment and system integration.

Electrical Interference

This unit has been fully tested for EMC conformity of Medical Devices, however, special precautions need to be taken in relation to Electromagnetic Compatibility (EMC) when installing medical electrical equipment. (see Guidance on Electromagnetic Compatibility (Chapter 4, Annex 3) for further technical information).

   ◆   This unit should NOT be used near radio transmitters as RF equipment can affect medical electrical equipment. If any 'strange' behaviour of the unit is noted, discontinue use immediately and refer to a qualified EMC engineer.

   ◆   The DS5 stimulator should not be used adjacent to or stacked with other equipment. If such use is required, then the behaviour of the stimulator should be monitored to confirm normal operation in this configuration.

   ◆   All cables (except patient leads) connected to the DS5 should be no longer than 3 metres in length.

Regulatory Statements

EU Declaration of Conformity

DECLARATION OF CONFORMITY

Digitimer Limited

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We declare that the product detailed below as described in the DS5 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.

DS5 Isolated Bipolar Constant Current Stimulator

Date of Issue: *13th March 2007*

J R Smale
Managing Director
Digitimer Ltd

CE 0120

File: N:\Docs\Company\Technical File\DS5\DS5 Tech File A\ DS5 D of C-Iss02.lwp
Last Updated - March 12, 2007
Printed - March 12, 2007

EN 60601 (IEC 60601):1990 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 DS5 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 Chapter 4, Annex 1.

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.

Modification Status

The green and white serial number label affixed to the rear of each DS5 contains the unique serial number of that unit. This serial number should be quoted whenever technical support is requested from Digitimer or one of our representatives.

The DS5 stimulator has serial numbers of the following format: DS5-72-2006. The last 4 digits of the serial number denote the year of manufacture.

The lower section of the label contains the "MOD. RECORD STATUS" (Modification Record Status) which indicates the build status of the unit and any modifications that have been subsequently performed to the unit.

At the time of writing, no changes to the DS5 have caused a rise in the MOD RECORD STATUS, hence no numbers are crossed out.

Unpacking

After unpacking the DS5 stimulator from the shipping carton, please inspect each piece for any sign of shipping damage. Please contact the carrier and your distributor, or Digitimer Limited, immediately if there is any damage. Do not dispose of the shipping carton, as the carrier will want to examine it in order to process a damage claim. Digitimer Limited and their distributors insure all shipments to cover shipping damage.

It is also advisable to keep the shipping carton in the event that the instrument needs to be returned for service.

Supplied Accessories

The following items should have been packed with your DS5 stimulator:-

- ◆ Mains (Power) Lead (Cord).
- ◆ USB Connection Cable (Please refer to Chapter 4, Annex 2 before connecting).
- ◆ Operator's Manual (this document).
- ◆ Test Record Sheet

Please note that the USB cable supplied is specifically for use with the DS5. USB cables from other suppliers are NOT suitable for use with this stimulator and may result in increased EMC emissions or decreased EMC immunity.

Optional Accessories

In order to facilitate electrode connection we offer the **D185-HB4 Electrode Extension Cable**. This provides a 4.5m (14.5ft) extension of the patient output sockets (4mm shrouded) terminating in a pair (2) of DIN 42 802-1 1.5mm "Touch Proof" sockets that are colour coded to the original sockets.

The D185-HB4 is specifically designed to meet the requirements of EN(IEC) 60601 and is suitable for use with our D185, DS7A and DS5 stimulators.

Mains Connections

The DS5 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 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

        Earth or Ground – Green/Yellow

A mains plug should be used which is so constructed that if the lead is pulled the earth/ground wire cannot come into contact with the line or neutral pins.
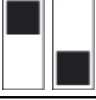
This instrument MUST be Earthed/Grounded.

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 3 Amps.

Mains Voltage Selector

The DS5 mains voltage selector should be correctly configured for the local mains voltage supply. Four voltage options are available (240V, 200V, 120V and 100V) and these are selected by appropriately positioning both jumpers located in the "Voltage Selector" panel on the rear panel of the DS5.

Mains Voltage Setting	Jumper Positions
240V (e.g. Europe & Australia)	■ ■ (top)
200V (e.g. Japan 200V)	■ (top right), ■ (bottom left)
120V (e.g. USA & Canada)	■ (top left), ■ (bottom right)
100V (e.g. Japan 100V)	■ ■ (bottom)

Mains Inlet Fuses

Check that the correct fuses have been inserted for your supply voltage. The factory setting is 200-240 volts and the alternative is 100-120V.

Mains Voltage	Correct Fuse
100-120V	T 500mA L
200-240V	T 250mA L

If replacing these fuses, please ensure the correct size, rating and type is used as a replacement.

Product Registration

For a speedy response to all your questions now and in the future, please take time out to register your new DS5 stimulator at www.digitimer.com/register now! Product registration permits us to quickly advise you of any safety matters or new product information. This web address is your point of contact for all questions regarding the DS5. The contents of this site are now growing rapidly, so please bookmark it so that you can visit it regularly to check out the new items.

Why Register Your Purchase?

Digitimer periodically offers enhancements and firmware 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 website.

Product Announcement Mailing List

Digitimer 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 DS5 mailing list through our www.digitimer.com/register website.

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                            Fax: +61 2942 77329

Please contact Digitimer for information regarding representation in other countries.

Purchase Information

A record of salient information will aid the operator should it be required in the future:-

Date of Purchase:
Dealer:
Dealers Telephone Number:
Dealers Fax Number:
Dealers E-mail Address:
Contact Name at Dealer:
Serial Number of Unit:
Other Notes (Service/Warranty Information etc):

Specifications

Output:	Bipolar constant current proportional to the input voltage (+ve input voltage gives rise to an output current where RED socket becomes +ve with respect to BLACK socket).
Output Ranges:	±10; ±25; ±50 mA for a full scale input
Input Ranges:	±1; ±2.5; ±5; ±10 V full scale
Connections:	**Output** - 4mm shrouded, touch-proof sockets (red and black) on 3/4" centres
	Monitor - Rear panel BNC sockets for "delivered current" and "applied voltage"
	Input - Rear panel BNC socket
	Firmware Update - USB socket on rear panel
Controls:	Four front panel push buttons labelled on LCD
	Output – On/Off-Reset – Momentary Action Toggle Switch
Safety Limits:	50mJ/300mJ pulse energy
	50µA average "idle" current
	10mA average pulse current
	50mA peak current
	1s/5s maximum pulse duration
Indicators:	Power ON LED Green
	Warning LED Amber
	LCD Display for setting up and checking:

- Peak current delivered*	- Input voltage range
- Output current range	- Peak Voltage*
- Error warnings	- Out of compliance
- Pulse energy (PE)	- Pulse duration (PD)
- Average idle current (AvL)	- Average pulse current (AvH)

Software:	Microsoft Windows™ compatible DS5 User Interface (USB control) software (Win2000 and WinXP).
Power:	100V, 120V, 200V or 240V (externally selected), 47-63Hz, 35VA
Classification:	Class I with Type BF applied part
Safety:	EN(IEC) 60601
Dimensions:	225mm x 100mm x 255mm (width x height x depth)
Weight:	4kg (approx.)

* These values are displayed graphically NOT numerically

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.

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.

CHAPTER 2
HARDWARE INSTALLATION

Tour of the Hardware

Introduction

The DS5 is an isolated bipolar constant current stimulator specifically designed for studies of the peripheral nervous system in both diagnostic and research settings and is ideal for excitability studies based on threshold tracking protocols. Unlike other percutaneous nerve stimulators such as our own DS7A, the DS5 does not produce a traditional "square" stimulus pulse but instead is able to receive a bipolar voltage waveform from another device and convert this into a bipolar constant current stimulus of the same shape and time course.

For optimum flexibility, the DS5 can accept four voltage input ranges (±1V, ±2.5V, ±5V, ±10V) from the waveform source, which it uses to produce an isolated output current up to a maximum ±50mA for patient stimulation. The input voltage signal is fed into the DS5 via a BNC socket on the rear of the stimulator. The other pair of BNC sockets, which are used for stimulus monitoring, output a voltage waveform proportional to the actual stimulus voltage or current supplied to the patient.

Appropriate stimulation electrodes should be connected via the pair of 4mm touch proof output sockets (red and black) on the front of the unit or 1.5mm DIN 42 802-1 style connectors via the optional D185-HB4 Electrode Extension Cable.

Stimulus parameters and settings, including the input and output ranges are displayed on a backlit LCD screen on the front of the unit. Modification of these parameters is made possible by use of the function keys (F1 to F4) situated at each corner of the display screen.

The front panel of the DS5 also features an output enable/disable switch, as well as both power and warning LEDs. The rear of the DS5 includes an equipotential connection point, mains IEC inlet (power) socket, fuses, mains voltage selector and a mains on/off switch.

Front Panel Components

1. **Function Keys** - Numbered F1 to F4. These keys are arranged at the four corners of the LCD display. Their functions are dynamically assigned depending upon the status of the DS5 LCD display.

2. **Green Power LED** - Indicates when the DS5 rear panel switch is in the ON position.

3. **Illuminated LCD Display** - This is the primary operator interface, displaying all current operating conditions as well as F key assignments, stimulation data and configuration menus.

4. **Red & Black Isolated Output Sockets (4mm touch proof type)** - The Red will go positive with respect to the Black socket when positive voltages are applied to the Voltage Input BNC socket on the rear of the DS5. The reverse will be true when negative voltages are applied at that socket.

5. **Output Enable/Disable/Reset Toggle Switch** - This momentary action toggle switch is used to enable, disable or reset the DS5. Upward deflection enables the output and downward deflection disables a previously enabled output. Downward deflection can also be used to reset the DS5 when

the output has been automatically disabled by a pre-set output limit being exceeded.

6. **Amber Warning LED** - Illuminated when the output has been disabled either by a fault condition or due to a pre-set output limit being exceeded (cleared by a power OFF/ON and full test cycle).
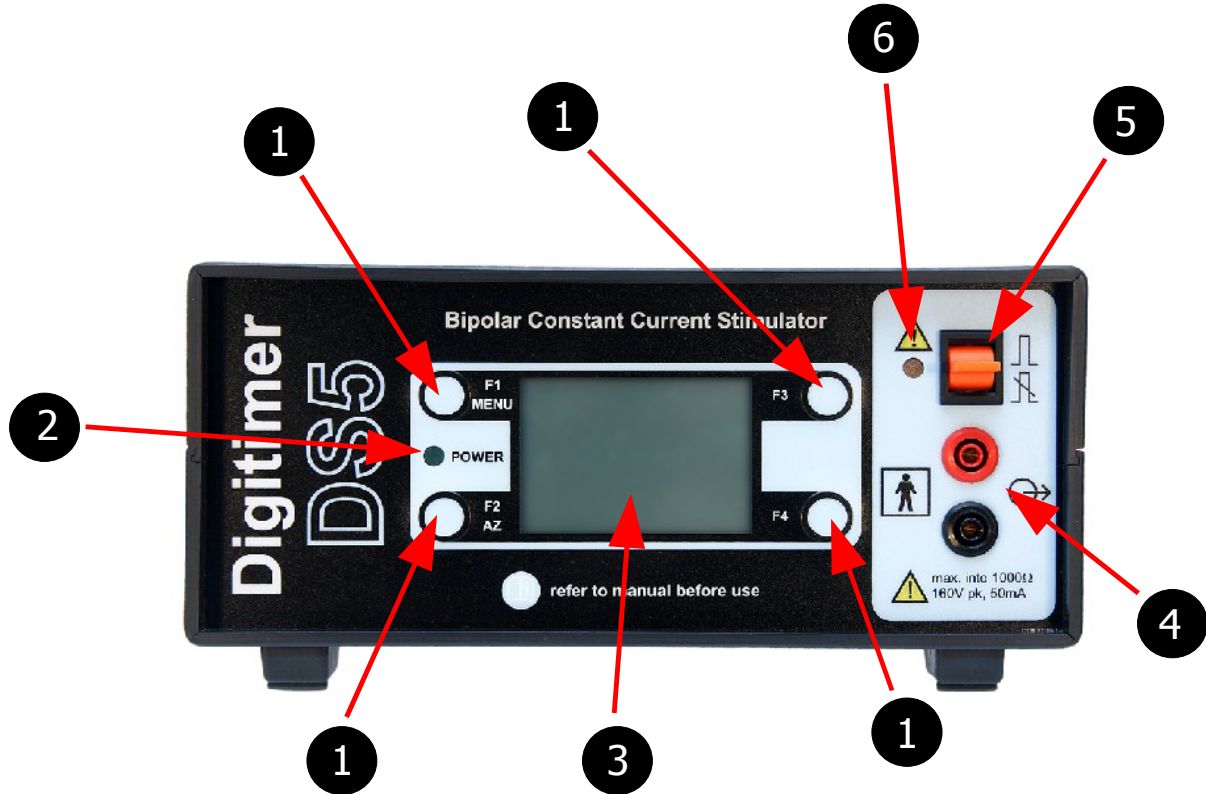

Figure 2.1 *Front Panel Components of the DS5 Stimulator*

Front Panel Symbols

The front panel of the DS5 has several symbols which the operator should become familiar with before starting to use the stimulator.

⎍	Upward deflection of the toggle switch enables the output.	⚠	Attention, consult accompanying documents.
⎍	Downward deflection of the toggle switch disables the output.	📖	Consult operator documentation (this manual) before use of this equipment.
👤	Type BF applied part.	⟳→	Output (stimulus connection to patient).

Table 2.1 *DS5 Front Panel Symbols*

Rear Panel Components

1. **Input** - BNC Socket for a bipolar voltage input. Full scale voltage is switchable between ±1V, ±2.5V, ±5V and ±10V

2. **Mon. Outputs** - Monitor outputs providing output voltages that are proportional in shape to the stimulus current (expressed as 1V/10mA) or voltage (expressed as 1V/20V). These outputs are ground referenced and isolated from the patient.

3. **Control** - Type B USB socket providing a USB interface COM port to link the DS5 to a remote personal computer running Windows 2000 or Windows XP. This socket allows for future updates to the DS5 firmware, as well as control of DS5 settings via the DS5 User Interface Software (refer to Chapter 4, Annex 2 BEFORE connecting). Only the USB cable supplied with the DS5 should be used in this socket.

4. **Mains Inlet, Mains Fusing and Power Switch Combination** - NOTE - Power supply cord must contain, and use, an Earth/Ground conductor.

5. **Potential Equalisation Connector** - Earth/Ground reference for unit and bonding point. This is to be used when the earth/ground conductor in the mains cord of all units in use cannot be relied upon or is not available.

6. **Voltage Selector** – The DS5 should be set to the appropriate mains supply voltage before the stimulator is switched on.
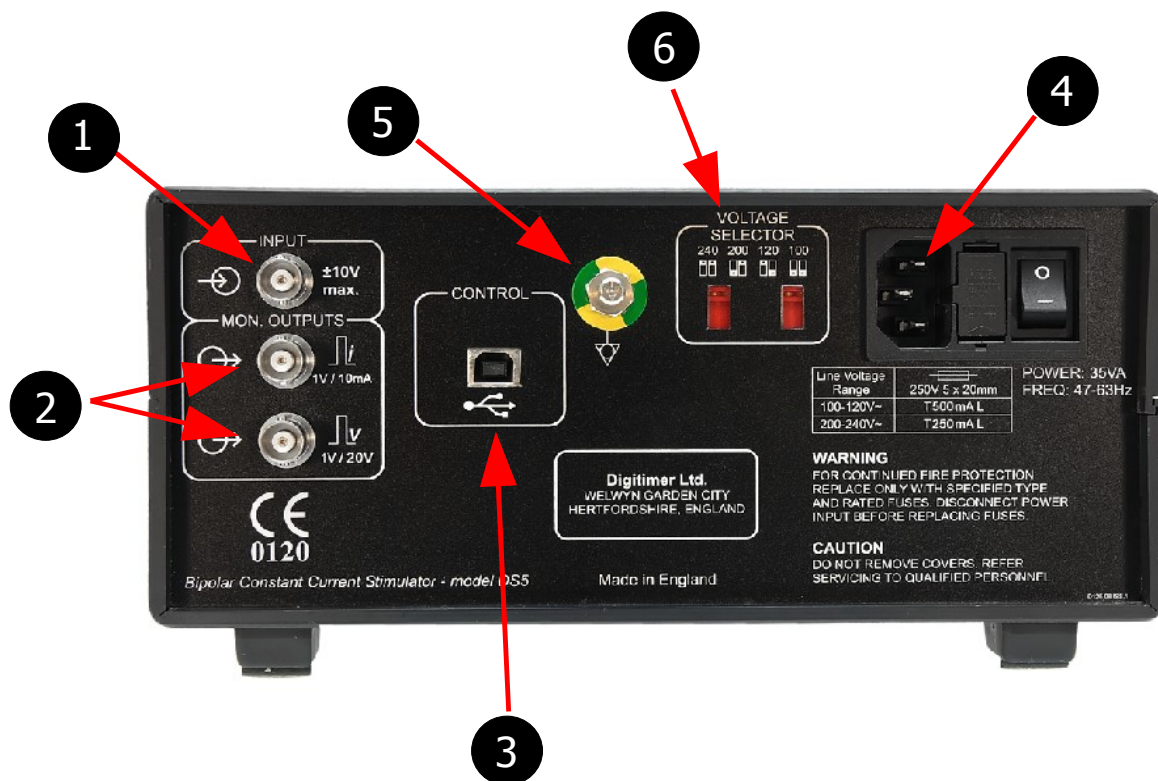

Figure 2.2 *Rear Panel Components of the DS5 Stimulator*

Rear Panel Symbols

The rear panel of the DS5 has several symbols which the operator should become familiar with before starting to use the stimulator.

CE 0120	Equipment complies with all current European Union directives.	(PEC symbol)	Potential Equalisation Connector (PEC).
(Signal Input symbol)	Signal Input (±10V max). The voltage applied at this input determines the shape of the stimulus waveform.	O	OFF (power) - Indicates OFF position of Mains Power switch.
(Monitor Output symbol)	Monitor Output – Voltage outputs which are calibrated to the stimulus current or voltage (see below)	I	ON (power) – Indicates ON position of Mains Power switch.
(symbol) i 1V / 10mA	Monitor Output (Current) Scaling – 1V/10mA.	(USB symbol)	Control Input – USB socket for connection to computer.
(symbol) V 1V / 20V	Monitor Output (Voltage) Scaling – 1V/20V.	(fuse symbol)	Mains inlet fuse – replace with type indicated for your local mains voltage, unless this has already been factory set.

Table 2.2 *DS5 Rear Panel Symbols*

Audible Alerts & Warnings

The DS5 produces two types of audible alert. A high pitched "information" beep serves as confirmation that the operator has toggled or pressed a front panel switch or button. A deeper pitched "warning" tone informs the operator that a safety limit has been reached/exceeded or that intervention is required in response to a warning icon which will be simultaneously displayed on the front panel screen. Audible alerts are switched on by default, but the "information" beep may be disabled by the user via the options menu. When disabled a (icon) icon is displayed on the front panel LCD screen.

Initial Hardware Check

Before connecting a voltage source, monitor output cables or electrodes to the DS5 it should be given an initial check out to ensure that it is powering up correctly.

1. Ensure that the power supply switch on the rear of the DS5 is in the OFF (O) position.

2. Ensure that the mains inlet fuses installed are appropriate for your mains supply voltage and that the voltage selector jumpers are in the correct position for your local mains supply voltage.

3. Connect the mains power lead to the DS5 mains inlet and switch on at the wall socket.

4. Switch the power switch on the DS5 to the ON (I) position.

5. The front panel LCD screen should illuminate and the Green Power and Amber Warning LEDs should light up.

6. After approximately 3 seconds the start-up screen should appear, displaying "Digitimer DS5".

7. Shortly afterwards the DS5 will run a system test, validating the firmware, stabilizing and finally executing a self-test. The lower half of the display should confirm that both the firmware and hardware tests have been passed successfully, at which point the Warning LED should extinguish. **If any errors are reported during the above tests, please discontinue use of the DS5 and contact your local Digitimer representative for further technical advice.**
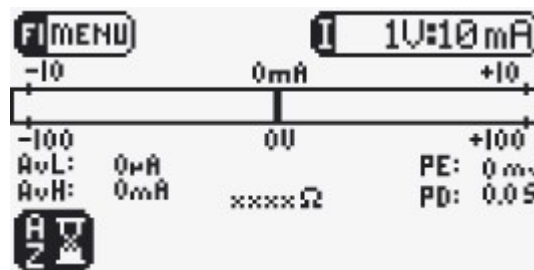
Figure 2.3 *Initial Main Operating Screen Display*

8. Once all tests have been successfully completed the Main Operating Screen (Fig 2.3) is displayed. In the bottom left corner of the screen a flashing icon indicates that the DS5 is ready for auto-zeroing using the front panel F2/AZ key.

9. We recommend that the DS5 is left switched ON for approximately one hour to "warm up" before use. This allows any temperature sensitive components to equilibrate.

10. The DS5 is now ready to be configured for the particular hardware it is to be interfaced with. Configuration should be carried out using the front panel Operator Interface, which is more thoroughly discussed in Chapter 3 – Configuration and Operation.

CHAPTER 3
CONFIGURATION AND OPERATION

The Main Operating Screen

The Main Operating Screen is the default screen when the DS5 is in use and it provides the operator with an instant display of various continuously measured parameters as well as the selected input voltage and output current ranges. Depending upon the status of the DS5 it will also display certain icons which are used to warn or prompt the operator of necessary action or excessive input/output conditions.
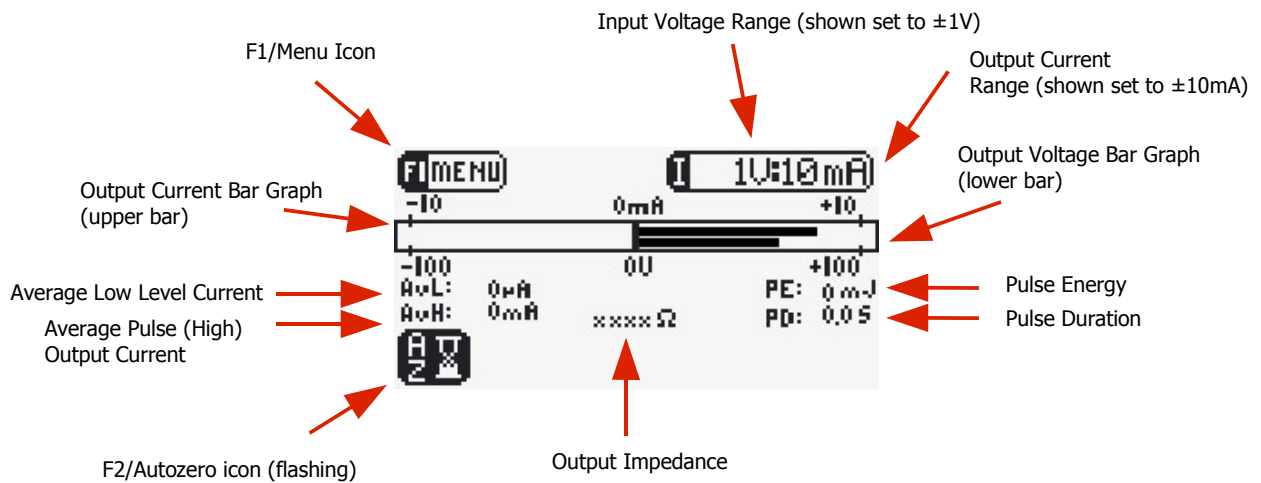
Figure 3.1 *DS5 Main Operating Screen Display*

Main Operating Screen Components & Icons
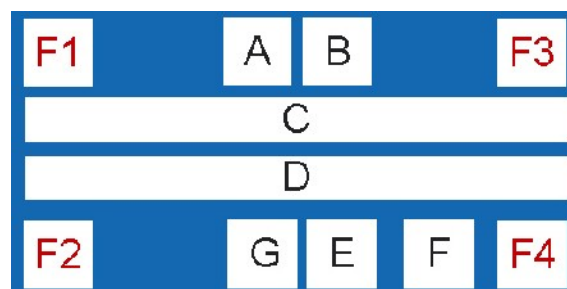
Figure 3.2 *Main Operating Screen Zones*

The main operating screen is divided into 10 zones which are used dynamically under different conditions. Zones F1 and F2 are generally used to indicate functions for the F1 and F2 keys, while the F3 and F4 zones tend to be used for purely informative purposes (although they are used to indicate the scroll up and scroll down functions of F3 and F4 in the Options Menu). Zones A to G display various icons, text and graphs which are fully described in Table 3.1.

Area	Icon/Display	F-Key Allocation or Display Icon Meaning
F1	FIMENU	Pressing F1 opens the "Options Menu".
F2	AZ	Flashing when Autozero required after timeout period.
	AZT AZT AZT	Autozero not possible due to +ve and -ve pulses on the input (left). Autozero not possible due to +ve pulses on the input (centre). Autozero not possible due to -ve pulses on the input (right).
	AZ AZV	Autozero not possible due to an excessive DC offset on the input (left). Autozero not possible due to oscillations on the input (right).
F3	I 10V:10mA	Iconic display of the following adjustable DS5 settings: Input Voltage Range:- ±1V, ±2.5V, ±5V or ±10V (shown) Output Current Range:- ±10mA (shown), ±25mA or ±50mA
F4	JL	Output Enabled:- Stimulation can proceed.
	AZX	Output Disabled:- Autozero operation is required.
	X	Output Disabled:- An initial DC stimulation >±10µA would result.
	LX	Output Disabled:- +ve and -ve pulses resulting in current peaks >400µA present.
	LX	Output Disabled:- +ve pulses resulting in current peaks >400µA present.
	TX	Output Disabled:- -ve pulses resulting in current peaks >400µA present.
	WX	Output Disabled:- Oscillation above +400µA or -400µA (peak) present.
A	⟿	Symbol when USB link with a computer is established.
B	⊞	Input Over Voltage Warning:- The three icons shown are used to indicate the polarity of the excessive input voltage.
C		Twin horizontal bar graphs illustrate the output current (upper display) and the output voltage. The scaling of the output current graph is adjusted when the output current range is changed.
D		Numerical display of the four limited parameters:- Average Low Level (baseline) Current (AvL:), Average High Level (Pulse) Current (AvH:), Pulse Energy (PE:) and Pulse Duration (PD:). If any of these are exceeded, the stimulator output is disabled and the parameter(s) responsible will be indicated by an arrow, exclamation mark as well as an audible warning. This area is also used to display the patient impedance (ohms).
E	⚠	Warning symbol indicating that one or more output limits has been disabled.
F	A!	Out of compliance warning (i.e the current requested cannot be provided due to limitations of the compliance voltage).
G	✕	Audio Off: - The audible information beep has been disabled.

Table 3.1 *Main Operating Screen Components and Icons*

Configuring the DS5

Configuration changes are made via the options menu which is accessed from the main operating screen by pressing the F1 key, indicated by the ◨menu icon. To access this menu the stimulator output must be disabled using the orange toggle switch and it will be necessary to re-enable the output before another stimulation protocol can commence. The options menu presents the operator with a scrollable list of menu choices (F3 key for up and F4 key for down). When an item of interest is identified, it can be selected using F1 (OK). When required, F2 (EXIT) allows the operator to exit to the main operating screen.
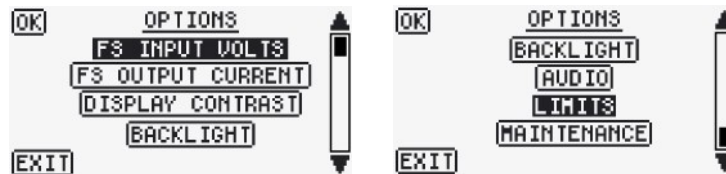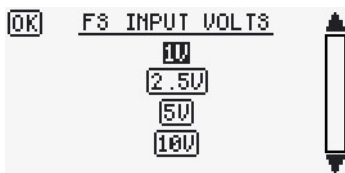

Figure 3.3 *Typical DS5 Options Menu Displays*

Most of the choices in the options menu provide the operator with an opportunity to modify the default settings of the DS5. The various choices are further described below and should be carefully defined before the DS5 is connected to any external devices or subjects.


Defining the Required Input Voltage Range

Full scale input voltage ranges are selectable between ±1V, ±2.5V, ±5V and ±10V so that the DS5 can be configured to interface with a range of signal generating hardware devices such as data acquisition interfaces with D/A outputs. F3 and F4 scroll through the choices and F1 confirms the selection and returns to the main Options Menu.
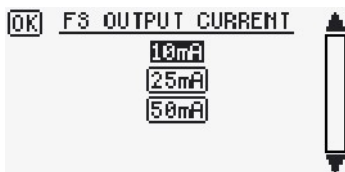
Defining the Required Output Current Range

The full scale output current ranges are selectable between ±10mA, ±25mA and ±50mA. This allows the operator to limit the output to a lower range when carrying out studies which require a lower stimulus amplitude. F3 and F4 scroll through the choices and F1 confirms the selection and returns to the main Options Menu.
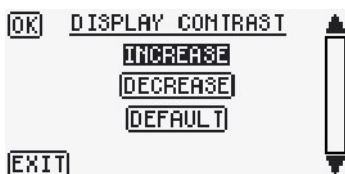
Adjusting the Display Contrast

The LCD screen display contrast can be increased or decreased to suit the user. F3 and F4 are used to scroll through the choices, while repeated pressing of F1 will increment a change in contrast. A default setting is available if required. F2 confirms the choice and returns to the main options menu.


Turning the LCD Backlight On and Off

This menu item allows the operator to turn off the LCD backlight if it is not desired. F3 and F4 scroll through the parameter choices. F1 accepts the hi-lighted setting and exits to the main options screen.

Enabling and Disabling the Audible "Information" Alerts

The DS5 will provide an "information" beep in response to all button presses and switch actions by default. It is possible for the operator to disable the "information" beep if they wish. F3 and F4 scroll through the parameter choices. F1 accepts the hi-lighted setting and exits to the main options screen.
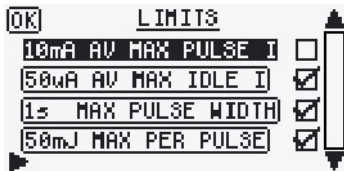
Enabling and Disabling the Output Limits

By default, four limited parameters are monitored by the DS5 and if the stimulus output exceeds any of these limits, the output is disabled and the warning LED illuminates. This screen allows the operator to remove some or all of these limits. F3 and F4 scroll through the parameter choices and F2 removes (un-ticked) or re-instates (ticked) the limit. F1 confirms the choices and returns to the main options menu. Refer to the Output Limits section below for further information.

Maintenance Options

The maintenance screen gives the operator the opportunity to access four further screens:-

Last Reset Cause - Displays the cause of the last reset.
Factory Defaults - Restores factory defaults to all options menu settings.
Diagnostics - Provides a scrollable list of internal memory which can be used by Digitimer engineers for test purposes.
Exception Tests – Used by Digitimer Engineers for test purposes.
About - Details the hardware and firmware versions.

F3 and F4 scroll through the parameter choices, F1 selects the screen to view while F2 exits to the main options menu.

Output Limits

Patient safety is of paramount importance when designing an electrical stimulator for clinical use. As a result the DS5 incorporates several layers of safety features, many of which will never be apparent to the operator. Amongst these are four output limits which control stimulus pulse energy, current and pulse duration. However, in order to allow for a degree of clinical freedom, some output limits can be deactivated by the operator. It should be noted that when these limits are deactivated, they generally do not remove the limits, they merely shift them to more flexible values, without compromising patient safety.

By default the DS5 is factory configured with four output limits enabled. Through use of the Operator Interface, these four limits can be toggled on and off. The Table 3.2 gives the values for these limits and those that are implemented when they are disabled.

Limits and the Definition of a Pulse

For the purposes of defining stimulation waveforms, the operator should note that the DS5 will identify a stimulus pulse as having been initiated when a current of over ±400µA is detected at the output, whereupon, the DS5 will stop monitoring the baseline current (AvL, Average Low Level Current) and start to monitor the parameters relating to a stimulation pulse (AvH, Average Pulse Current; PD, Pulse Duration and PE, Pulse Energy), disabling the output if any of these exceed the pre-set limits. If the amplitude drops below ±400µA then the DS5 reverts to monitoring AvL. If the polarity of the pulse was to change instantaneously then the DS5 would interpret this as the termination of a pulse and the initiation of another.

Exceeding an Enabled Limit

When an enabled output limit is exceeded the stimulator output will disable, a warning beep will sound and an arrow with an exclamation mark will appear on the main operating screen next to the exceeded parameter. The stimulator output will need to be re-enabled before a new stimulation protocol can begin (see Resetting & Re-enabling After Output Limit Error).

Exceeding a Disabled Limit

When a disabled output limit is exceeded, an arrow will appear on the display next to that parameter, but the stimulator will continue to produce an output until the higher (disabled) value or one of the other output limits is exceeded. At this point, the output will be disabled, an exclamation mark and an arrow will appear next to the parameter that caused the stimulator output to disable. As before, the stimulator output will need to be re-enabled before a new stimulation protocol can begin (see Resetting & Re-enabling After Output Limit Error).

Stimulus Parameter	Enabled	Disabled
Average output current (AvH)	10mA	55mA
Average Low level (baseline) current (AvL)	50µA	Not Limited*
Pulse duration (PD)	1s	5s
Pulse energy limited to 50mJ (PE)	50mJ	300mJ

* If the average low level (baseline) current limit is deactivated, patient protection is maintained as any current over 400µA is considered a pulse and would then be limited in duration, energy and average current.

Table 3.2 *DS5 Output Limits*

Hardware Connections

Voltage Input Connection

The DS5 will accept a voltage input of ±1V, ±2.5V, ±5V or ±10V. For correct operation, it is important that the DS5 is configured for the appropriate input voltage before it is used (see above).

1. The operator should first of all check what output voltage range is provided by the signal generator or computer interface to be connected to the DS5. This information should be available in the manual supplied with that equipment.

2. The DS5 input voltage range should then be configured for the same value via the operator interface. Once set, a full scale input voltage will generate a full scale output current output.

3. The voltage source should then be connected to the Voltage Input BNC socket on the rear of the DS5, using an appropriate cable.

4. Before a voltage signal is applied to the DS5, it is necessary to press the F2/AZ key to autozero the

stimulator output. This procedure ensures that any baseline voltage offset at the input socket is nulled and does not result in a DS5 stimulus output.

Monitor Output Connections

When connected to a suitable data acquisition device, the monitor outputs allows the operator to make a continuous record of the stimulation current and voltage. These records can be used to relate the stimulus time course to events observed within an evoked response. With appropriate analysis, this data would also allow the operator to record the output impedance throughout a study.

1. Before proceeding, the operator should confirm that the analogue input connection of the monitoring equipment is able to accept an input voltage of up to ±10V. If it is unclear whether the equipment will accept this voltage range, the manufacturer of the equipment should be consulted before any further use of the monitor feature.

2. If the operator of the DS5 is interested in monitoring the stimulus current, then the monitor output scaling is 1V/10mA i.e a +1V signal at the current monitor output will equate to a +10mA stimulation current. If the stimulus voltage is of more interest, then the voltage monitor output scaling is 1V/20V. Using these scaling factors it may be possible to calibrate the data acquisition software being used so that the computer displays a recording of the actual stimulus current and/or voltage.

3. Once the data acquisition system has been configured, the DS5 monitor output(s) can be connected to the appropriate analogue input(s) of the acquisition system.

USB Connection

Digitimer provide freely downloadable DS5 User Interface (DS5 UI) software which allows the operator to update the DS5 firmware, adjust, save and recall stimulator settings or view a "virtual DS5 front panel" on a computer during stimulation. Perhaps more importantly for some users, the USB connection also makes it possible for other software to modify DS5 settings via COM Interface.

Further details on how to download, install and use the DS5 UI are given in Chapter 4, Annex 2.

NOTE: The DS5 should **NOT** be connected to a computer via the USB cable until the DS5 UI Software has been successfully installed.

Connecting to a Dummy Load

We advise all new operators of the DS5 to simulate a protocol before a human subject is used. To do this we suggest that the operator fabricates a "dummy load circuit" by placing a 1kohm (11 Watt) resistor between the stimulus output sockets of the DS5 and applying a voltage waveform at the DS5 Voltage Input. The resulting pulse current, energy and pulse duration information will be displayed on the main operating screen. The operator should take care in handling the resistor after a pulse protocol has been applied, as it may heat up considerably during a protocol.

Patient Connection

Before proceeding with patient connection to the stimulator output it is critically important that the operator

reads the safety precautions and warnings at the front of this operator's manual, fully appreciates their meaning and is totally familiar with the operation of the stimulator and other equipment interfaced with it.

We recommend that the operator also carry out intended stimulation protocols with a dummy load before carrying out any studies on human subjects.

On no account should a grounded oscilloscope or other monitoring device be connected to the front panel output sockets of the DS5 while a patient is connected to the stimulator.

Selecting Appropriate Stimulation Electrodes

Digitimer does not supply any electrodes with the DS5 stimulator as it is expected that most operators will already be familiar with the type of electrodes suitable for transcutaneous peripheral nerve/muscle stimulation and will have a preferred supplier.

We do provide a range of optional accessories which include an output extension cable and these are more thoroughly described in the Optional Accessories section of this manual.

We provide the following electrode selection guidance based on the experiences of those more familiar with this form of electrical stimulation technique:-

Electrode Material – For patient safety, we recommend that electrodes should be of a non-polarizable construction e.g Ag/AgCl.

Electrode Fixation – Electrodes may be of the disposable self adhesive type or reuseable taped or self adhesive washer fixed type. Whichever method of fixation is used, the operator should ensure that the skin is well abraded and cleaned prior to fixation to minimise impedance. The operator should also ensure that there is low risk of the electrode becoming detached during a stimulation protocol. Regular visual inspection of the electrodes in parallel with checking of the patient impedance during stimulation would be beneficial in this regard.

Electrode Dimensions – The operator should take special care when the current density of any electrode is greater than 2mA rms / cm^2. While electrodes with a surface area of ~1cm^2 are routinely used for peripheral nerve stimulation, we would recommend that the operator uses electrodes with the largest surface area that still allows them to adequately stimulate particular nerves with precision.

Electrode Leadwires - Electrode leadwires should be kept as short as possible so as to reduce the chance of inadvertent trans-thoracic stimulation. We recommend use of our **D185-HB4 Electrode Extension Cable** as this brings a pair of DIN 42 802-1, 1.5mm Touch Proof sockets closer to the subject so that electrode lead wire can be shorter.

Electrode Placement Protocols

Correct electrode placement is determined by the location of the nerve or muscle that is being studied and as such the operator should have adequate anatomical knowledge to allow for the correct placement of stimulation and recording electrodes before proceeding to use the DS5.

If necessary a search of recent publications on peripheral nerve stimulation should be conducted. A bibliography is provided in this manual which may provide a good starting point for such a search, as it includes papers by those who have used a prototype model of the DS5 stimulator.

Applying a Stimulation Protocol

Introduction

All appropriate input and output connections should now have been made to the DS5, including connections to a dummy load or patient. The voltage source should be connected to the DS5 voltage input socket, but should not be delivering a stimulus waveform. The DS5 should have been powered ON for at least one hour prior to use in order to equilibrate temperature sensitive components. Whether the operator is preparing to stimulate a patient or a "dummy load" it is necessary to Autozero the DS5 prior to enabling the stimulator output. Both of these steps are detailed below.

The Autozero Function

The autozero function is used to ensure that the baseline input voltage is translated into zero current at the output even if there is a small DC offset present at the input. Autozeroing should be carried out by pressing the F2/AZ key once an external voltage source has been connected to the DS5, but BEFORE any stimulation voltage is applied to this input. The autozeroing procedure is prompted by the appearance of the autozero timeout icon in the F2 zone of the display upon startup, during use and whenever the output has been disabled.

If the stimulator does not autozero when the F2/AZ key is pressed, a warning beep will sound and an icon will be displayed in the F2 zone indicating the reason why the autozero could not be completed. If the autozero fails, please refer to Table 3.1 for an explanation of the displayed icon. Once autozeroed, the output can be enabled and a stimulation protocol can proceed.

If the output remains enabled for a 5 minute period, then the flashing autozero timeout icon re-apppears in the F2 zone of the display, prompting the operator to autozero the unit once again. If the operator fails to press the F2/AZ key, the DS5 will remain enabled until the user disables the output manually or it is disabled automatically due to an error or an output limit being exceeded. In this way, stimulation protocols can be completed without interruption, however, we do recommend that the DS5 is autozeroed regularly so as to minimise the chance of the low level (baseline) current safety limit being exceeded during a study. If the stimulator output is disabled either manually or automatically while the autozero timeout icon is displayed, it will not be possible to re-enable the output until the stimulator is autozeroed.

Enabling & Disabling the Stimulator Output

On the right hand side of the DS5 front panel, an orange momentary action toggle switch allows the operator to enable or disable the stimulator output. The stimulator will not pass a stimulus to a subject until it is enabled and this can only be accomplished if there are no warning icons displayed that require user intervention. For example, it will not be possible to enable the output if the DS5 requires autozeroing, or if a voltage has been detected at the voltage input socket. A warning icon will be dispayed in the F4 zone to indicate the reason why the output remains disabled. Once enabled, it is possible for the external voltage source to control the output of the stimulator.

Enabling Upon Startup

To enable the stimulator the orange toggle switch needs to be pushed transiently upwards (it will automatically return to the central position). The unit should give an audible confirmation beep and the output enabled icon should be displayed in the F4 zone of the display. The output can be disabled at any time by transiently pushing the orange toggle switch downwards, stimulation will cease and the output enabled icon will disappear from the display. We would suggest that the operator routinely disables the

output at the end of a stimulation protocol so as to minimise the chance of any inadvertent stimulation of the patient.

Resetting & Re-enabling After Output Limit Error

When an enabled output limit is exceeded the stimulator output is automatically disabled and the amber warning LED illuminates. In this state the stimulator cannot be autozeroed or re-enabled until the orange toggle switch is transiently pushed downwards – resetting the DS5. This action extinguishes the amber warning LED and prompts the user to autozero the input. Once autozeroed it is possible to once again re-enable the output by transiently pushing the toggle switch upwards.

Terminating a Stimulation Protocol

Once a stimulation protocol has been completed, the output enable toggle switch should be pushed transiently downwards to disable the output and prevent any inadvertent stimulation of the subject while other equipment is adjusted or electrodes are re-positioned. To start a new protocol it will be necessary to autozero the voltage input and re-enable the output as detailed above.

If any errors are reported during the actions above, please discontinue use of the DS5 and contact your local Digitimer representative for further technical advice, advising them of the serial number of the stimulator and the content of any error messages displayed.

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CHAPTER 4
TECHNICAL ANNEXES

ANNEX 1:- Recurrent Testing of the DS5

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 DS5 can, the suggested test intervals should be no more than 24 months.

Every DS5 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 DS5 by reading the Operator's Manual.

The DS5 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 DS5. All repair procedures should be referred to Digitimer or a local distributor.

Visual Inspection

Visually check for any damage to the enclosure of the DS5. Also carefully check for damage to the supply lead and any input or output cables.

Check that the voltage selectors on the rear panel are 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 DS5 are unbroken and un-disturbed. Evidence that the enclosure has been opened may indicate the need for more extensive testing.

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 DS5 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.

The visible shell of the USB connector MUST NOT be tested at 25A as damage will occur. The existence of earth continuity here may be tested only at 100mA.

Leakage Currents - Connect the DS5 to the test equipment according to the instructions for a Class 1 device with Type BF applied parts. The applied parts of the DS5 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 DS5 connected as described.

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

Functional Test

The DS5 completes a full self test every time that it is powered-up. Should it be felt necessary to conduct further tests, then the output should be loaded with a 11W 1kΩ resistor. An input signal suitable for the DS5 input settings should be applied and the output monitored across the load resistance.

CAUTION: The DS5 can generate output voltages of up to 160V; 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 DS5 may be returned to normal use. Check that the supply voltage selector and the supply fuses are correct for the intended site of operation.

ANNEX 2:- Installing & Using the DS5 User Interface (DS5 UI) Software

IMPORTANT - The DS5 should **NOT** be connected to the computer via the USB cable until the DS5 UI software has been successfully installed.
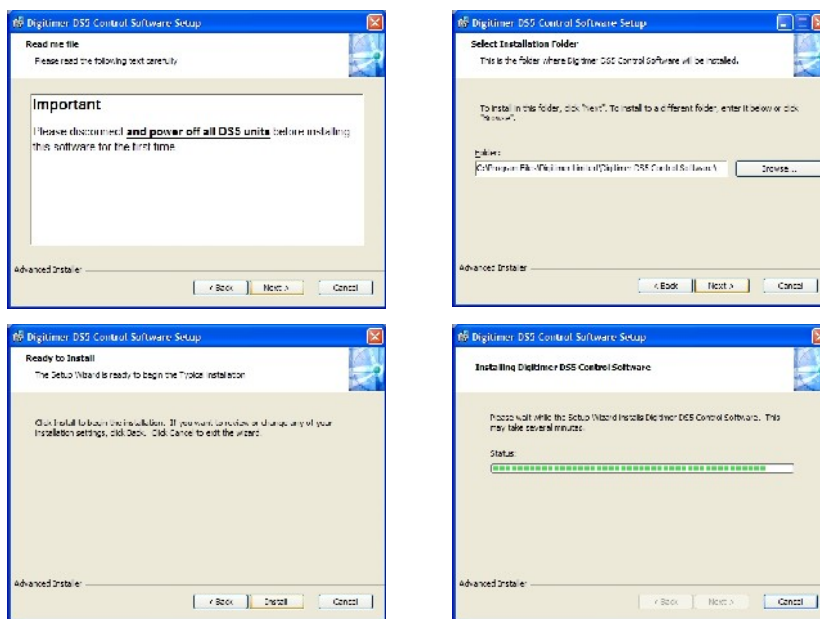
Installation of the DS5 UI Software

The first installation of the DS5 UI Software should be carried out on a computer which has an internet connection, as it may be necessary for the DS5 to install a remote firmware update as part of the installation process. Subsequent use of the DS5 UI Software does not require an internet enabled PC.

1. Please download the LATEST version of the Digitimer DS5 UI Software Installer from the Digitimer website (http://update.digitimer.com/DS5/software/latest/). Click once on "setup.exe" and save the file to a known location, such as the Desktop on the computer to be used with the DS5.
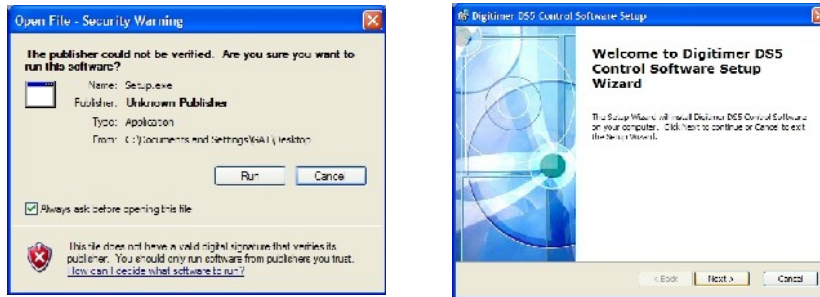
2. Double-click on setup.exe to install the DS5 UI Software. You may see a warning that the software publisher could not be verified, please ignore this by clicking on **Run** to proceed and then follow the on-screen instructions until the installation is completed.

3. Note that if the DS5 UI Software was already installed on this computer, the installer will ask you if you wish to modify, repair or uninstall the previous installation.


4. Once the software is installed, the DS5 can now be connected to the computer via the supplied USB cable and powered on.

5. Windows^{TM} should alert you that new hardware (Digitimer DS5) has been connected. Please follow the hardware installation process according to the illustrations below.
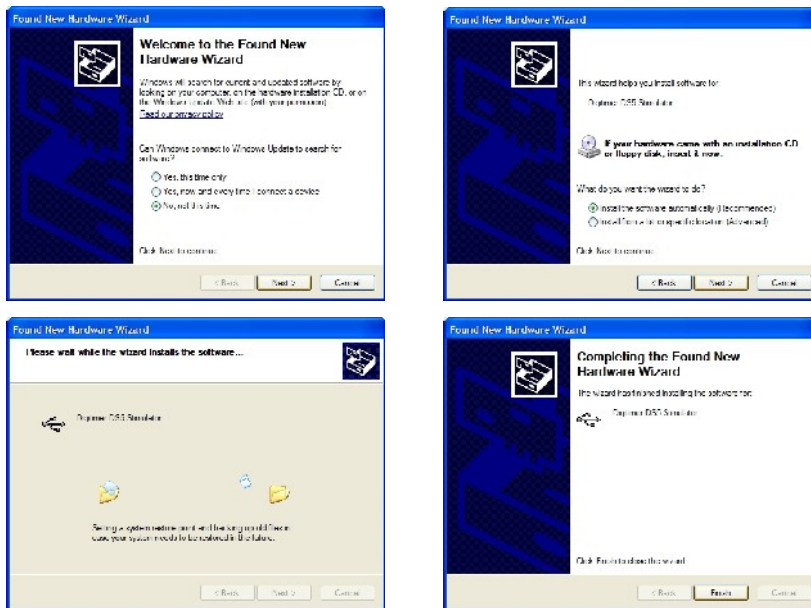

6. Once the DS5 is installed, the DS5 UI Software can be run via the Windows Start Menu under **START > All Programs > Digitimer DS5 Control Software > DS5UI**

7. Running the DS5UI opens two windows:-

> **(i) The DS5 Device List** - Lists information about the DS5 connected to the computer, including the firmware version and serial number.
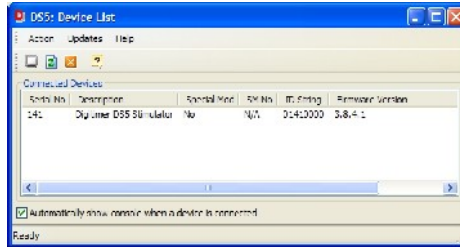
(**ii) The DS5 Console** - Control Panel/Virtual Front Panel of the DS5.
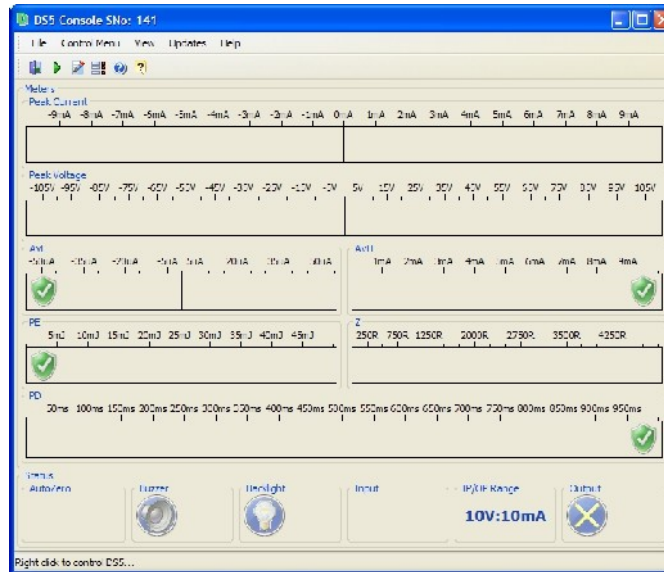
8. If the DS5 firmware is an early version it may not be supported by the latest DS5 UI Software. In this case, it will be necessary to update the firmware of the DS5 and this will be prompted in the DS5 Console Window (see below). The software will also ask you to check for updates of the DS UI Software version before proceeding with the update.
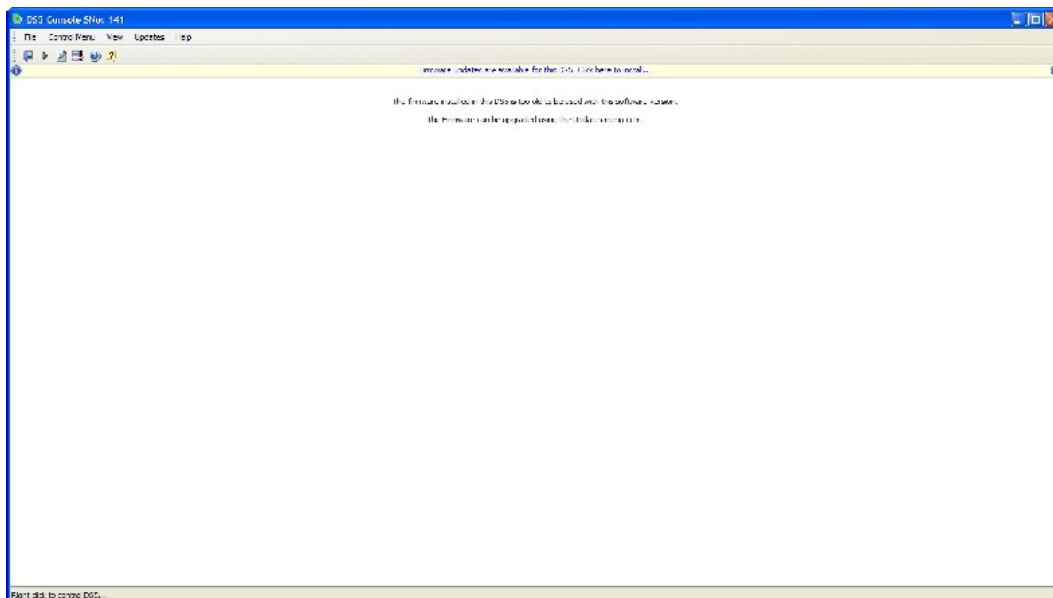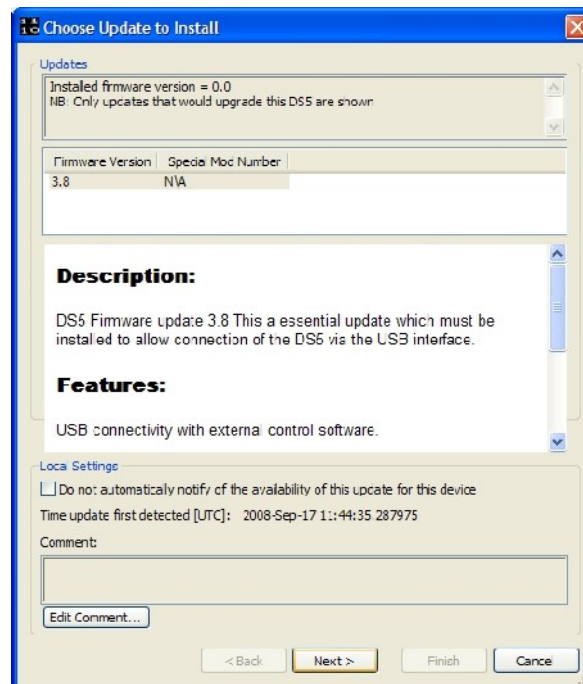
9. Once the firmware update has been complete, the DS5 should be powered off and back on again. The restarted DS5 should be listed in the Device List window with the updated firmware indicated. It should now be possible to use the DS5 UI to adjust the settings and control some features of the DS5.

If you encounter any problems during the software/firmware update process, please contact Digitimer or your local representative.

Using the DS5 UI Software

This section describes the features of the DS5 User Interface Software. The DS5 UI software is started from the Windows Start Menu using **START > All Programs > Digitimer DS5 Control Software > DS5UI**

Two windows are opened, the **DS5 Console** and the **DS5 Device List**. The DS5 Console provides the "vitual front panel" of the connected DS5 and the DS5 Device List, which minimizes to the Digitimer **D** taskbar icon, provides the operator with information about the DS5 itself, including the firmware status.

DS5 Device List

Displays the serial number and certain other characteristics relating to any DS5 stimulators connected to the computer via the USB connection. The DS5 Device List also provides the operator with the ability to update the DS5 UI software and configure automatic updates.
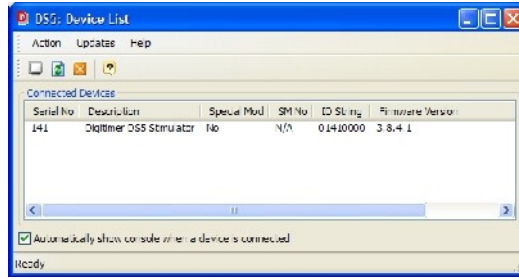
In the bottom left hand corner a tick box allows the operator to configure the software to show the DS5 Console whenever a DS5 is connected to the computer (or when the Refresh action is used). The DS5 Device List Window has three menu bar commands, Action, Updates and Help and four icons which are described below.

Action > Show DS5 Console (Ctrl + S)

Once a DS5 is selected from the "Connected Devices" list, the Console Window can be displayed by selecting this item from the menu bar or clicking on the Show DS5 Console icon . It is also possible to show the console by double-clicking on the DS5 within the device list.

Action > Refresh (Ctrl + R)

The display of "Connected Devices" can be refreshed at any time by selecting this item from the menu or clicking on the Refresh icon .

If the "Automatically show the console when a device is connected" is ticked, the device list will be minimized to the task bar when the refresh action is used.

Action > Exit

The DS5 UI software may be exited by selecting this option from the menu bar or clicking on the exit icon .

Updates > Check for Software Updates...

This menu option connects to the Digitimer server and checks if there is an update available for the DS5 UI software.

Updates > Configure Automatic Software Update Checks...

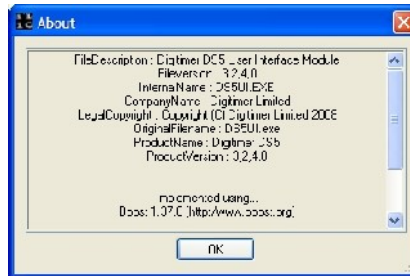Allows the operator to set their own software update preferences.
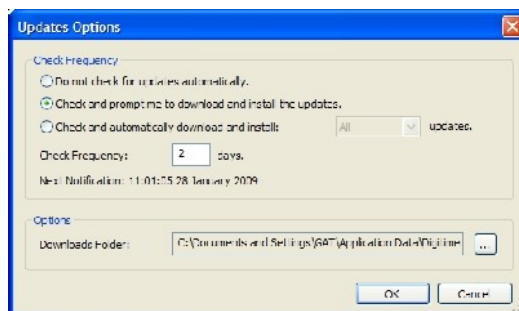
Help > Online Help

Opens a PDF copy of the DS5 Operators Manual.

Help > About

Displays information about the DS5 UI sotware. This can also be accessed via the [?] icon

DS5 Console

The DS5 Console provides the operator with the virtual front panel of the DS5 and is divided into three areas. At the top of the window is a **Menu and Toolbar** which provide the operator access to relevant settings and actions. Under the Toolbar, is the **Meters** section, consisting of bar graphs and meters similar to those present on the front panel of the DS5. At the bottom of the window is a row of **Status Indicator Icons**. Double clicking on these can in some cases alter the settings of the stimulator. These icons can also change to reflect the status of the DS5. Right clicking within the Console window will display the **Control Menu** which is used to load or alter previously saved DS5 settings profiles.
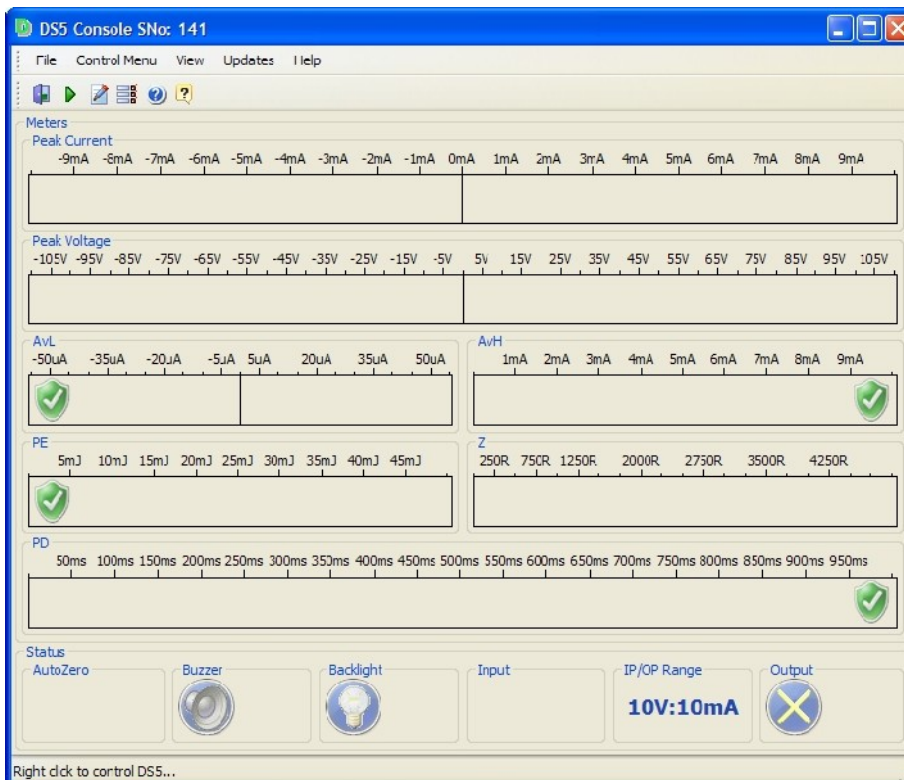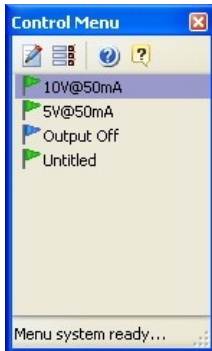
Menu & Tool Bar

File > Exit

Exits from the DS5UI Software.

Control Menu > Show Control Menu…

Right clicking on the Console window or selecting this menu item displays the Control Menu. The Control Menu consists of an icon toolbar above a list of saved profiles. Clicking on a profile will activate it, sending the appropriate commands to the DS5 via the USB connection.

The toolbar commands are Control Menu Editor…, Menu Options, Help, About. Each is discussed in more detail below.

Control Menu > Edit Control Menu…

When the DS5 UI is installed, the Control Menu includes one pre-defined profile, "Output OFF", indicated by a blue flag. Additional profiles can be added to the list from within the Menu Editor window and these will be given green flags.

The Menu Editor window consists of an icon toolbar, a list of saved profiles and a tabbed pane that displays the control settings and attributes of a selected profile. The toolbar items which are described below can also be displayed by right-clicking anywhere within the Menu Editor Window.

New	Adds a new "untitled" profile to the list of profiles.
Rename	Opens the profile title for editing.
Back	Move the highlight back (up) through the list of profiles.
Forward	Move the highlight forward (down) through the list of profiles.
Delete	Deletes the currently selected profile.
Read Only	Makes the currently selected profile read-only.
Show In Menu	Toggles display of selected profile in the Control Menu.
Help	Opens a PDF copy of the DS5 Operators Manual.
About	Displays information about the DS5 UI software.

Selected profiles can be edited by changing the status of the various tick boxes and radio buttons within the Control Tab. A green tick indicates that a particular state will be activated when the profile is loaded. An empty tick box indicates that the state will be deactivated. If the box has a green square inside it, that state will remain unchanged when the profile is loaded. The Attributes tab has a comment box for adding a more complete description of the profile as well as tick boxes to alter the profile visibility and read-only status.The stimulator settings available for modification within the DS5 UI software are the same as those found within the DS5 front panel menu. Further information on the effects these settings have is provided within Chapter

3 of this manual, which should be consulted before this software is used.
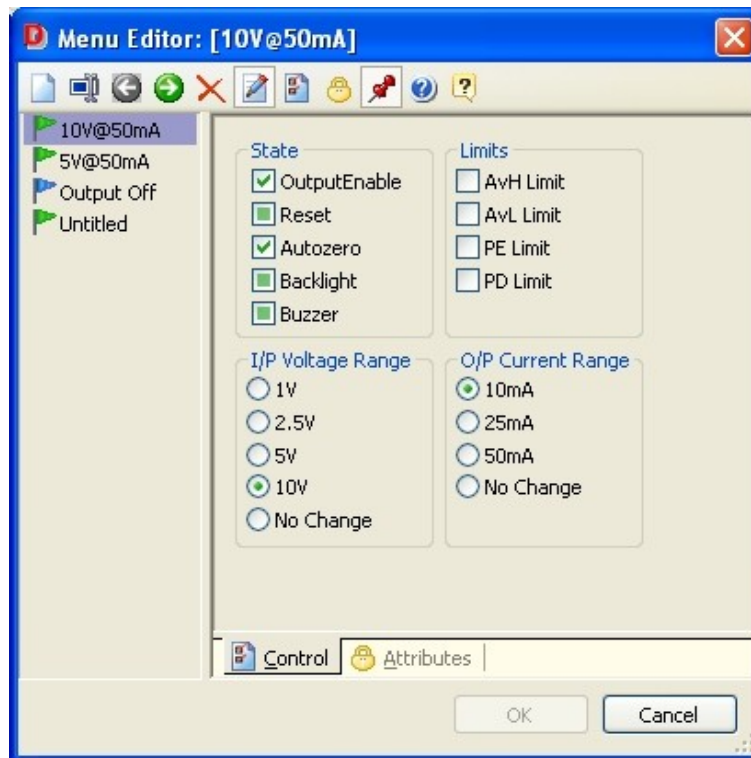
Defining profiles within the DS5 UI has certain advantages - (i) Particular stimulator settings can be quickly defined and activated in the correct order with a single mouse click (ii) The software is also useful in situations where multiple profiles are needed, as these can be stored for later recall.

Control Menu > Control Menu Properties...

Allows the DS5 operator to alter the transparency of the Control Menu as well as define how Tooltips are configured.
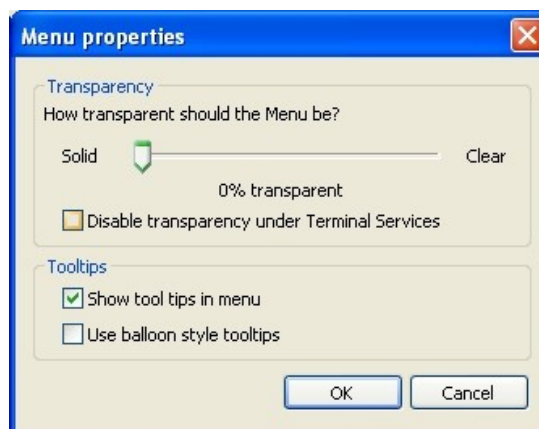
View > Toolbar

Toggles display of the toolbar icons.

View > Statusbar

Toggles display of the statusbar.

Updates > Check for Software Updates...

Connects to the Digitimer update server and checks if there is an update available for the DS5 UI software.

Updates > Configure Automatic Software Update Checks...

Allows the operator to set their own software update preferences.

Updates > Check for Firmware Updates...

Connects to the Digitimer update server and checks if there is an update available for the DS5 firmware.

Updates > Import Firmware Updates...

Firmware updates can be installed from a saved file rather than directly through the internet.

Help > Online Help

Opens a PDF copy of the DS5 Operators Manual.

Help > About

Displays information about the DS5 UI software. This can also be accessed via the ? icon.

Meters

The meters display provides a graphical representation of some of the stimulation parameters which the DS5 monitors continuously. Displayed parameters include Peak Current, Peak Voltage, Average Low Current (AvL), Average High Current (AvH), Pulse Energy (PE), Impedance (Z), Pulse Duration (PD).

Icons displayed within the AvL, AvH, PE and PD bar graphs indicate whether the normal ✅ or extended ⚠ output limits are enabled.

When values are within the normal limits and these limits are enabled, the bars are coloured blue. When the extended limits are enabled, the bars turn amber when values are between the normal and extended limits. If an enabled limit is exceeded, three events will occur:-

    (i)   The relevant bar will turn red.

    (ii) The green or amber shield will be replaced by a red shield with a white cross ❌.

    (iii) The stimulator output will be disabled.

Status Indicator Icons

These icons generally mirror those displayed on the DS5 front panel and provide information on the settings and status of the DS5.   For more information on the meaning of these icons, please consult Chapter 3 of the DS5 Operators Manual.

	Autozero – Under normal conditions this area is blank. A flashing autozero icon here indicates that 5 minutes has elapsed since the last autzero event. This area also displays other icons equivalent to those shown in the F2 zone of the DS5 front panel, please consult the DS5 Operators Manual for more information.
	Buzzer – Double-click to toggle the audible warning on or off. A yellow cross through the icon indicates the audible warning has been disabled.
	Backlight – Double-click to turn the backlight on or off. Turning the back-light off can reduce electrical noise from the stimulator. A yellow cross through the icon indicates the backlight has been disabled.
	Input – Under normal conditions, this area is blank, however, if the input voltage range is exceeded the icon shown is displayed. Equivalent to Zone B of the DS5 front panel
10V:10mA	**IP/OP Range** – Shows the active Input Voltage and Output Current ranges.
	Output Disabled – Double-click to disable the stimulator output. The output can only be re-enabled by using the orange momentary action toggle switch on the DS5 front panel.
	Output Enabled – Shown when the output has been enabled using the orange momentary action toggle switch.
	Other icons equivalent to those displayed in the F4 zone of the DS5 front panel display can also appear here. For more information on the meaning of these icons, please consult Chapter 3 of this manual.

ANNEX 3:- Guidance & Declarations on Electromagnetic Compatibility

Electromagnetic Emissions (Table 201)

The Digitimer DS5 is intended for use in the electromagnetic environment specified below. The customer or the user of the Digitimer DS5 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Group 1	The Digitimer DS5 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.
RF emissions CISPR 11	Class A	The Digitimer DS5 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.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Electromagnetic Immunity (Table 202)

The Digitimer DS5 is intended for use in the electromagnetic environment specified below. The customer or the user of the Digitimer DS5 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 DS5 requires continued operation during power mains interruptions, it is recommended that the Digitimer DS5 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 a.c. mains voltage prior to application of the test level.			

Electromagnetic Immunity (Table 204)

The Digitimer DS5 is intended for use in the electromagnetic environment specified below. The customer or the user of the Digitimer DS5 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	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the Digitimer DS5, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. 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 DS5 is used exceeds the applicable compliance level above, the Digitimer DS5 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 DS5.

[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 DS5 (Table 206)

The Digitimer DS5 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Digitimer DS5 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Digitimer DS5 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.

ANNEX 4:- Guidance on System Integration

The DS5 Stimulator relies for its action upon the simultaneous use of other pieces of equipment as it does not, itself, contain a signal generator. So, for example, when used for "threshold tracking" studies it would be used alongside an EMG recorder and a personal computer. The computer would be used to analyse the signal from the EMG recorder and produce the stimulation waveform from a fitted digital-to-analogue interface card. In this example the DS5 and the EMG recorder are equipment designed as Medical Electrical Equipment, while the computer is 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 DS5 involved in threshold tracking studies there are two methods by which this hazard can be eliminated.

I.   Power the computer via a separation or isolation transformer. This removes the leakage currents from the computer 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 DS5 this is easily achieved using the 4m Output Extension Lead, part number D185-HB4. 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 DS5 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 DS5 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.

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