

Digitimer

DS8R

BIPOLAR CONSTANT
CURRENT STIMULATOR



OPERATOR'S MANUAL

Applicable to DS8R with Mod. State 1 or higher



For Research Use Only

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Section 1 - General Information



DS8R Intended Usage & Description

The DS8R is an isolated, constant current, multi-mode, discrete pulse stimulator for use on human subjects in a research environment. The stimulator safely delivers brief duration (50-2000 μ s) current pulses for transcutaneous electrical stimulation and activation of nerves and muscles via surface electrodes. The current output of the DS8R is adjustable over the range 0mA to 1000mA, with a compliance voltage of up to 400V and an energy limit of 300mJ, making it suitable for demanding stimulation applications including studies of nociception (pain), behavioural psychology, sports medicine or rehabilitation research. The DS8R is for use by personnel competent to apply appropriate transcutaneous electrical stimuli or under the supervision and instruction of someone who is.

The DS8R is fully capable as a standalone stimulator, but control is also possible using the supplied Windows PC control software via a USB interface. The PC software provides the operator with the ability to trigger the stimulator and change stimulation parameters and other settings. The DS8R can also be triggered by (i) supplying a TTL-high voltage on the trigger input socket on the rear panel, (ii) pressing the manual trigger button on the front panel, (iii) activating a hand/footswitch connected to the rear panel 3.5mm jack socket, (iv) software commands accessing the DS8R application programming interface (API).

Control of pulse amplitude is also possible through an analogue voltage input at the rear of the stimulator. In this mode, the analogue voltage presented at this input will be proportional to the amplitude of the stimulus current delivered when the unit is triggered. The control voltage has no influence over the shape of the output pulse and merely determines the amplitude of the rectangular output stimulus pulse when a stimulus is delivered.

Two pulse modes enable stimulation using either monophasic or biphasic pulses. Additionally, when in biphasic mode the operator is able to adjust the amplitude ratio of the stimulus and recovery phases, thereby producing an asymmetric biphasic charge balanced stimulus. Stimulation protocols can involve repetitive monophasic stimulation lasting tens of minutes or hours resulting in unpleasant side effects for the subject, such as skin irritation or sensitivity. By applying biphasic stimuli in a charge-balanced manner, the DS8R may prevent polarisation of the stimulus site, reducing skin irritation and improving the comfort of the subject. The DS8R also features a polarity reversal control, which allows the operator to set the unit to deliver positive, negative or alternating polarity pulses.

The DS8R is not a medical device, does not have any medical device certification and is not suitable for treatment or diagnostic use. However, it has been designed for safe use in human research applications and meets all of the following standards.

- 60601-1 General requirements for basic safety and essential performance.
- 60601-1-2 General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances – Requirements and Tests.
- 60601-1-6 General requirements for basic safety and essential performance - Collateral standard: Usability.
- 60601-2-10 Particular requirements for the basic safety and essential performance of nerve and muscle stimulators.

All our devices are manufactured within our quality system, which is externally audited to ISO 13485 for medical devices. Additionally, each device is subjected to both high voltage isolation tests and electrical safety tests, during production.

Precautions and Warnings

Operator's Manual

Carefully study this Operator's Manual before using the DS8R Bipolar Constant Current Stimulator.

Indications for Use

The Digitimer DS8R is an electrical stimulator intended to be used to apply a stimulus to a human subject via surface electrodes. It can be used to elicit a response from peripheral nerve fibres or muscle during research studies of human physiology, psychology and neuroscience.

Risks to Subject Safety

Stimulating electrodes should not be placed thoracically or trans-thoracically as this may increase the risk of cardiac fibrillation. Care should be taken when selecting appropriate stimulating electrodes. If the current density of the chosen electrode is greater than 2mA rms/cm² then the operator should pay extra attention to stimulus parameters to ensure that the patient does not suffer burns at the stimulation site.

The DS8R is not suitable for use in close proximity to extreme magnetic fields, such as those generated by MRI scanners and is not classified as defibrillator proof.

Do NOT stimulate over the carotid sinus nerves, neck and mouth. Stimulation should not be applied over carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.

Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.

Subject Exclusion Criteria

Subjects fitted with an implanted electronic device such as a cardiac pacemaker should NOT be stimulated unless specialist medical opinion has been obtained.

Needle Electrodes

Please note that where “stimulation” or “transcutaneous stimulation” is referred to in this document, it means “electrical stimulation through the skin” and NOT the use of skin penetrating needle electrodes.

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

Electrode Isolation

The following generally applies to the use of nerve and muscle stimulators, and especially those designed for transcutaneous use. See, for example, the section on Safety of Apparatus in Guld et al, 1970¹. It is essential for safety that the connections from the stimulator to the subject are isolated from earth/ground, and this means that an 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 subject 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, or in any other way. As an instance of such dangers, it is likely that when using the DS8R 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 DS8R stimulator are only connected 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.

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.

Output Enable

An operational protocol should be established whereby the “Output Enable” switch of the DS8R is only switched to “ON / enabled” when delivery of a stimulus is specifically required.

Modification

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

Explosion and Fire

Do not use the DS8R in an explosive atmosphere or in the presence of flammable anaesthetic gases.

High Voltages

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

Damage

Do not use the DS8R and/or any accessories if there are any signs of external damage.

Temperature

The DS8R and/or accessories should be stored or transported at temperatures between -40°C and +70°C. The recommended usage temperature range is between +10°C and 40°C.

Moisture

The DS8R and/or any accessories must not be used if any parts are wet or damp.

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 all our products designed for human use are 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.

As no parts of the DS8R are expected to age the only limitation to the service life is likely to be the ongoing ability to replace electronic components that may randomly fail. The components chosen are used conservatively and are all well-established parts so availability can be expected for many years. However, guidance from the Biomedical Engineering Advisory Group of the South Australia Department of Health gives a life expectancy of 10 years for neuromuscular stimulators, such as the DS8R. This figure may be useful for lifespan planning purposes.

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 advise on best course of action.

Unpacking

After unpacking the DS8R 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 DS8R Bipolar Constant Current Stimulator:

- Mains Power Lead/Cord.
- USB Connection Cable (part code D-USBF).
- Operator's Manual.
- Test Record Sheet.
- Windows compatible virtual front panel software (supplied on USB Stick).

Please note that the USB cable supplied is specifically for use with the DS8R. 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 connection of electrodes, we offer the D185-HB4 Electrode Extension Cable. This provides a 4.5m (14.5ft) extension of the 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 DS8R, D185, DS7A and DS5 stimulators.

Mains Connections

The DS8R 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 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 Inlet Fuses

Check that the correct fuses have been inserted. Refer to the Specifications section for more details.

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

Specifications

Stimulus Output

Current Output: 0mA to 1000mA, incrementing in 0.1mA steps; accuracy $\pm 2\%$. For example, a set current of 100.0mA will be $100\text{mA} \pm 2\text{mA}$ and a set current of 10mA will be $10\text{mA} \pm 0.2\text{mA}$

Pulse Duration: 50-2000 μs , incrementing by 10 μs steps; accuracy $\pm 2\%$.

Interphase Interval: 1 μs – 990 μs in 10 μs steps; accuracy $\pm 2\%$.

Recovery Phase Ratio: 10%-100% in 1% steps; accuracy $\pm 2\%$.

Pulse Mode: Monophasic or Biphasic

Pulse Polarity: Positive/Negative/Alternating.

Current Amplitude Limit Range: 10mA to 999mA

Compliance Limit: 400V

Energy Limit: 300mJ per pulse

Output Enable: On/Off Momentary action toggle switch

Connections: 4mm shrouded sockets (red and black) on 3/4" centres

Trigger

Maximum hardware trigger rate is 1,000 pps (1 kHz); $\pm 1\%$

Maximum software (USB) trigger rate is 10pps (10Hz); $\pm 1\%$

Front panel: Push button

Rear panel: 3.5mm mono jack socket for hand or foot switch (contact closure)

TRIGGER INPUT Electrical via Rear Panel BNC socket: Triggers: Logic signal (+3 to 15V) +ve edge, TTL compatible. Minimum Pulse Duration is 5 microseconds.

SYNC OUTPUT Rear panel BNC, positive TTL pulse, $100\mu\text{s} \pm 20\%$ duration.

External Amplitude Control

Input range: 0V to +10V

Output range: 0mA to 1000mA*

** When the Current Amplitude Lock is enabled, the input voltage is rescaled to this new maximum i.e. if the Limit is set at 50mA, the input voltage input is re-scaled so that 0 to +10V gives 0 to 50mA.*

Lag: 1ms (i.e. the DS8R will respond to amplitude changes at a maximum frequency of 1kHz)

Accuracy: $\pm 1\text{mA}$

Indicators

TRIGGER LED - Amber, flashes for each trigger received

FAULT/ERROR LED – Steady Amber, indicating internal hardware fault. Flashing Amber, indicating firmware update in progress.

LCD Display Showing:

- Set Current, Set Pulse Duration, Set Recovery Phase Ratio, Set Interphase Interval
Pulse Mode, Polarity Mode, Amplitude Control Mode
- Pulse Measurements (Accuracy $\pm(5\% + 2)$)
 - Current (mA)
 - Energy (mJ)
 - Impedance (Ohms)
 - Volts (V)
- Stimulus Output Status Indicators
- USB Communication
- Muted Audible Out of Compliance Warning
- Current Output Limit Setting

External Fuses

Fuse type: T 1.25A L - 5 x 20 mm, 250 V (these should ONLY be changed by qualified persons)

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 - 240V @ 47-63 Hz

Rating: <30 VA

Case Material UL94 V-0 Flame Retardant


Section 2 - Hardware Overview

Tour of the Hardware

Front Panel Components



1. Output Enable Toggle Switch

This momentary action toggle switch is used to enable, disable or reset the DS8R. Upward deflection enables the output and downward deflection disables a previously enabled output. Downward deflection can also be used to reset the DS8R. When the output is successfully enabled, the green icon  is displayed on the front panel LCD screen.

2. Red & Black Isolated Output Sockets (4mm touch proof type)

In positive, monophasic mode, the RED (upper) socket will go positive with respect to the BLACK socket. The RED socket will be the ANODE and the BLACK socket the CATHODE. The opposite is true if the polarity is reversed or during the delivery of a negative going recovery phase.

3. Amber Fault LED.

Illuminated (steady) when the output has been disabled by a fault condition. Flashes in bootloader mode or during firmware updating and is briefly lit during startup.

4. Primary (Amplitude) Control Dial

Manually sets current amplitude from 0mA to 1000.0mA in 0.1mA steps. Pressing and holding this dial in for 4 seconds (while the stimulator output is disabled), toggles the [Current Amplitude Limit](#) on and off.

5. Secondary (Multi-mode) Control Dial

This dial adjusts the values of three stimulus parameters i.e. Pulse Duration, Recovery Phase Ratio and Interphase Interval.

6. Settings Blister Buttons

Four vertically arranged round blister buttons with white circular surrounds are associated with icons on the right of the LCD screen.

6.1 Pulse Mode

Allows selection of Monophasic or biphasic operating modes. In monophasic mode the settings specific to biphasic mode (recovery phase ratio and interphase interval) will have no effect even though they can still be adjusted.

6.2 Polarity

Positive, Negative and Alternating modes selectable. Positive is the standard stimulation mode, while negative reverses the polarity for all pulses. In alternating mode, each successive trigger will result in a polarity reversal.

6.3 Amplitude Control Source Selector

Used to switch between front panel (including software) control of pulse amplitude and external analogue voltage control. This button is also used to zero the analogue voltage control input.

6.4 Secondary Control Dial Mode Selector

Selects the action of the secondary control dial. Repeated presses of this button cycle through control of pulse duration, recovery phase ratio or interphase interval. The parameter under control is indicated by a yellow highlight on the LCD screen.











7. Trigger Button & LED

Upon pressing this button, a single stimulus is produced and the amber LED below the button will flash once per press. If the output is not enabled when the trigger is pressed, the DS8R will not give an output, the amber LED will not flash and the operator will be alerted with an audible beep.

8. LCD Screen

The DS8R is equipped with a colour LCD screen providing the operator with information relating to the stimulator settings as well as monitored pulses parameters (pulse current, pulse energy, resistance and pulse voltage). Please refer to Section 3 (Configuration & Operation) for more information.

Front Panel Printed Symbols

	Upward deflection of the toggle switch enables the output.		Plus; positive connection to subject (Anode).
	Downward deflection of the toggle switch disables the output.		Minus; negative connection to subject (Cathode).
	Caution, consult accompanying documents.		Type BF applied part
	Output (stimulus connection to subject).		Trigger LED; illuminates to indicate stimulus trigger is active.
	Output Stimulus. Adjustment for Stimulus strength in mA.		Consult operator documentation (this manual) before use of this equipment.

Rear Panel Components



1. Control Input

BNC socket for connection to external analogue voltage source (0V to +10V) when using analogue voltage control of current amplitude. If the Current Amplitude Limit is enabled, this input is re-scaled appropriately for the new maximum current e.g. if set to 50mA, the 0V to +10V equates to 0mA to 50mA.

2. Sync Output

Trigger OUT BNC socket that provides a 5V TTL compatible trigger output pulse whenever the unit receives a valid Trigger IN.

3. Trigger Inputs (BNC and 3.5mm)

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

3.5mm (mono) footswitch input allowing an optional foot switch (D185-FS1) or hand switch (DS7A-HS1) to trigger the unit.

4. USB Socket

Type B USB socket providing a USB interface COM port to link the DS8R to a remote personal computer running Windows 7 or higher. This socket allows for future updates to the DS8R firmware, control of DS8R settings via the DS8R Virtual front panel software and third party software control via API (not yet available). Only the USB cable supplied with the DS8R should be used in this socket.

5. Mains Inlet, Mains Fusing and Power Switch Combination

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.








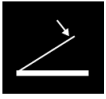


6. Potential Equalisation Connector




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.

7. Bootloader Mode Pinhole Switch

For use ONLY by or with the prior consent of Digitimer personnel.

Rear Panel Symbols

	Equipotentiality Connector.		Digitimer have declared that this equipment complies with European CE marking (LVD and EMC).
	Trigger Connector.		Output - signal output connector.
	Positive going pulse required (5V).		Input – signal input connector.
	Digitimer is a WEEE registered manufacturer. Contact us for advice		Foot switch connector.
	Off (power) - Indicates OFF position of Mains Power switch.		On (power) - Indicates ON position of Mains Power switch.

	Analogue control input. 10V input equates to 1000mA output.		Active "high" square wave pulse produced (5V, 500µs).
	Control Input – USB socket for connection to computer.		

Audible Alerts & Warnings

- Out of compliance alert.
- Unit triggered when the output is not enabled.
- Attempting to set the Current Amplitude Limit while the stimulator output is enabled.
- DS8R triggered too-fast for the defined output pulse settings.
- Hardware fault detected.

It is possible to disable the audible out of compliance alert via the virtual front panel software. All other audible warnings cannot be disabled.

Initial Hardware Check

Before installation and use of the DS8R, ensure that this manual has been read and understood.

Prior to use with a subject, the DS8R should be tested in its operational location using a simulated situation. 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 stimulator.

The DS8R should be situated near and within easy reach of the operator but beyond reach of the subject being stimulated.

The DS8R should be placed on a sturdy flat surface where the front panel can easily be viewed.

With the power switched off, connect the power cord between the DS8R and an appropriate outlet.

If required connect a trigger cable between the DS8R and the trigger chosen source.

Switch on the power to the DS8R, checking the DS8R briefly displays the “Digitimer DS8R” splash screen, carries out a self-test procedure and reverts to the default operating screen, showing stimulator settings.

Enable the stimulator output by pushing the orange output enable switch upwards and confirm the green output enabled icon is displayed on the front panel LCD screen.

Check that the trigger LED illuminates, for less than a second, each time the trigger button is pressed. If the output sockets are open circuit and a dummy load is not being used, the out of compliance warning should also be displayed (if the current is set >10mA). The DS8R will also beep to alert the operator of the out of compliance state.

Check that the stimulus mode (monophasic or biphasic) and polarity controls operate correctly in the normal, reverse and alternating polarity modes.

If the triggering is set for the DS8R to trigger a recording system - check that when the trigger button is pressed that the data acquisition system acquires a sweep of data or marks the delivery of a stimulus.

- or - If the triggering is set for the DS8R to be triggered by the data acquisition system or other device - check that when the data acquisition system sends a trigger pulse, the DS8R trigger indicator flashes.

To check that the DS8R and EMG amplifier/data acquisition system are synchronised using the stimulus artefact -

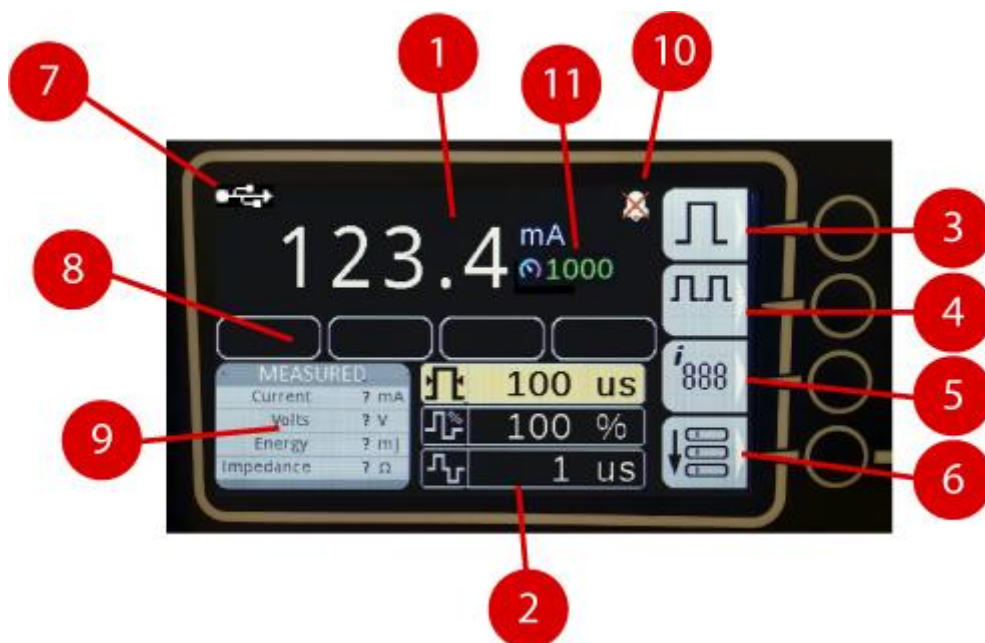
- remove any dummy load, connect two stimulating electrode leads into the DS8R output sockets and lay them on some insulating material. Connected together the "electrodes" to form a "short-circuit" and arrange the leads NOT to run parallel to each other;
- connect two recording leads into the input of one channel of an EMG amplifier 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 DS8R output enabled, a suitable stimulus intensity (start low at 5mA, and increase if necessary) and EMG system settings, the operator should be able to record the artefact from the stimulator. Check that this is at the time expected, which will usually be at the very start of the recording sweep.

Section 3 - Configuration & Operation

Main Operating Screen

Prominently positioned on the DS8R front panel is a backlit colour LCD screen providing the DS8R operator with an easy to read display of the stimulator settings and monitored stimulus parameters, including pulse current, energy and load impedance. All settings which are modifiable using the front panel controls can also be changed using the Windows PC virtual front panel software.

Overview of Operating Screen Zones



1. Current Amplitude Setting.
2. Pulse Duration, Recovery Phase Ratio and Interphase Interval Settings.
3. Stimulus Mode Status Icon and Assigned Button Identifier.
4. Polarity Mode Status Icon and Assigned Button Identifier.
5. Amplitude Control Mode Status Icon and Assigned Button Identifier.
6. Secondary Control Dial Assigned Button Identifier.
7. Computer USB Connection Status Indicator (displayed icon is only present when USB communication is occurring).

8. Output Status Indicators.
9. Pulse Measurements Panel.
10. Icon showing that the audible Out of Compliance alert is muted.
11. Current Amplitude Limit setting (shown as disabled i.e. 1000mA).

User Configurable DS8R Settings

The sections below provide further information relating to each of the user defined DS8R settings.

Most settings (including analogue control auto zero level) persist following power-cycling, so if the DS8R is powered off and back on again, the settings present at power off will remain at start up. The only exception is the role of the secondary control dial, which always reverts to Pulse Duration control upon start up.

Adjustments to settings made via the front panel, virtual front panel and CONTROL input are all reflected in the front panel display of the DS8R and the virtual front panel software.

Current Amplitude

With front panel amplitude control, the current amplitude is adjusted using the primary (amplitude) control dial. As the dial is turned clockwise, the current will increase in 0.1mA steps between 0mA and 1000mA.

Note that in analogue voltage control mode (see below), the primary control dial and virtual front panel software amplitude controls will have no effect as current amplitude changes can only be made via the rear panel analogue voltage input.

Current Amplitude Limit

As the DS8R has the capability of delivering currents from 0.1mA to 1000mA, an optional Current Amplitude Limit is provided, which allows the operator to set an absolute maximum current that can be delivered by the stimulator. For instance, users who are stimulating below 10mA can set the limit to 10mA in order to prevent inadvertent stimulation at higher values.


The limit can be set in mA increments between 10mA and 999mA. It is set by pressing and holding the Current Amplitude Control for 4s at the desired maximum current level. The limit is reset (reverting to a 1000mA maximum) by repeating this procedure. It can also be set and re-set from within the DS8R Front Panel Software. The value displayed in green numerals, to the right of the set current value, confirms what amplitude the limit is set to, showing 1000 when disabled.

Note that with the limit enabled, it is not possible to deliver a stimulus in excess of that set by the limit. This applies to ALL methods of stimulus amplitude control (front panel, virtual front panel, analogue voltage input and software API).

Pulse Duration

The DS8R is capable of delivering stimulus pulses of 50µs to 2000µs in duration, with a minimum increment of 10µs.



The pulse duration can be adjusted manually by pressing the lowest blister button to the right of the  icon until the pulse duration setting is within the grey highlight and then turning the secondary control dial to make adjustments. Pulse duration can also be adjusted using the virtual front panel software.


Recovery Phase Ratio (Biphasic Mode Only)

In biphasic mode, the recovery phase ratio is used to define the amplitude of the recovery phase as a percentage of the stimulus phase.



At 100%, the recovery phase will be identical to the stimulus phase in duration and amplitude. At 10%, the recovery phase will be 10% of the stimulus amplitude, but to preserve charge balancing will be ten times longer in duration. The value is adjustable from 10% to 100% in 1% increments.

Adjustments to the recovery phase ratio are only relevant when the stimulator is in biphasic mode and as with pulse duration are undertaken by use of the lower middle blister button and the secondary control dial. The recovery phase ratio can be adjusted manually by pressing the lowest


blister button to the right of the  icon until the recovery phase ratio setting is within the grey highlight and then turning the secondary control dial to make adjustments. The recovery phase ratio can also be adjusted using the virtual front panel software.

Interphase Interval (Biphasic Mode Only)

In biphasic mode, the interphase interval defines the dwell time between positive and negative phases when the DS8R is operating in biphasic mode.





It is adjustable from 1 μ s to 990 μ s in 10 μ s increments. The interphase interval can be adjusted by

pressing the lowest blister button to the right of the  icon until the interphase interval setting is within the grey highlight and then turning the secondary control dial to make adjustments. Interphase interval can be adjusted using the Virtual Front Panel Software.




Stimulus Mode

The DS8R can be operated in monophasic or biphasic modes. Pressing the top-most blister button to the right of the LCD screen cycles between these two modes and changes the icon associated with this control button. Once biphasic mode has been selected, the operator should adjust the recovery phase ratio and interphase interval to the desired values.

	Monophasic Mode
	Biphasic Mode


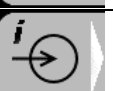
Polarity Mode

The DS8R can output pulses in positive, negative or alternating polarity. Pressing the upper middle blister button to the right of the LCD screen cycles between these three modes and changes the icon associated with this control button.

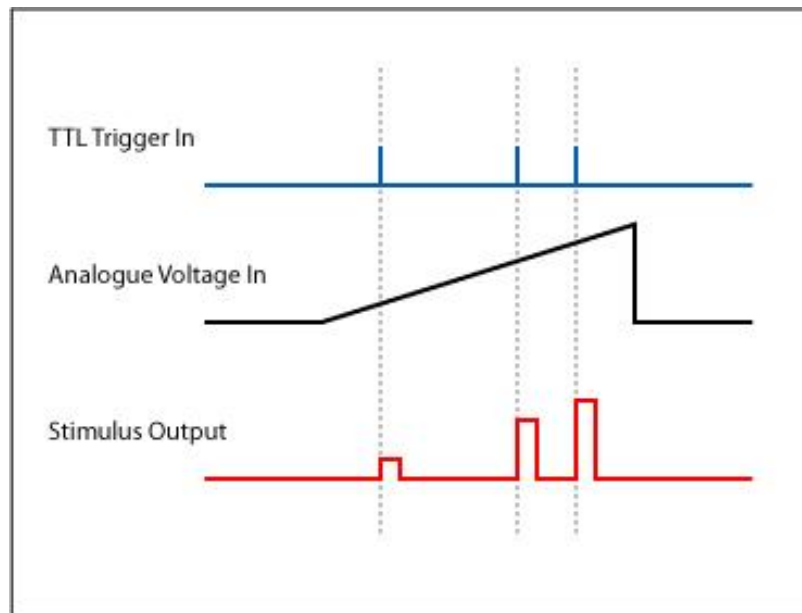
	Normal (Positive) Polarity
	Reverse (Negative) Polarity
	Alternating Polarity

Amplitude Control Mode


The current amplitude is manually controlled via the DS8R front panel dial or Virtual front panel software. It is also possible to control pulse amplitude through use of an analogue voltage input applied to the rear of the DS8R via the CONTROL socket. Briefly pressing the lower middle blister button cycles through the operating modes, sequentially displaying the two icons below.

	Front Panel Amplitude Control Mode (hardware or software).
	Analogue Voltage Control Mode.



The analogue voltage mode allows a connected computer data acquisition interface/software to vary the stimulus amplitude throughout a protocol without manual operator intervention. The CONTROL input accepts a voltage of 0V to +10V which is used to proportionately scale the stimulus output over the range of 0mA to 1000mA. For example, if the analogue voltage input is +2.5V, the stimulator will deliver a 250mA stimulus upon the next trigger. However, if the Current Amplitude Limit is enabled, this voltage input is re-scaled to match the set output range. If the Current Amplitude Limit is set to 10mA, +10V at the input will result in a 10mA stimulus, rather than 1000mA.



Configuring for Front Panel Amplitude Control


To use front panel controls, the lower middle blister button needs to be pressed until the front panel control icon  is displayed. It should then be possible to adjust the current amplitude with the primary control dial or Virtual front panel software. If external analogue control is to be used, the procedure below should be followed.

Configuring for Analogue Voltage Amplitude Control

1. Ensure that the voltage source is specified to deliver between 0V and +10V.
2. Make the necessary changes in software or hardware to bring this analogue voltage to 0V.
3. With the DS8R output disabled, connect the external voltage source to the CONTROL socket on the DS8R rear panel.
4. Press the lower middle blister button to the right of the LCD screen to enter the analogue voltage control mode, displaying the  icon. To zero the input, press and hold the button until there is an audible beep. During zeroing, the DS8R will display the  icon and sample the voltage signal at the CONTROL socket, using this level as a reference for the minimum possible output. This important step ensures that any small DC offsets from the control device are not translated into a stimulus current¹ when the DS8R is subsequently triggered.
5. Once the DS8R gives the audible beep, it should revert to external analogue control mode displaying the minimum stimulus current of 0mA on the LCD screen and changing the control mode icon to external analogue control.
6. Adjust the value of the voltage applied to the CONTROL socket to confirm that the current amplitude displayed on the DS8R changes as expected. For example, with the Current Amplitude Limit disabled, a +5V input should display a current amplitude of 500mA and a voltage of +10V should give 1000mA.

¹ We recommend that the auto zero mode is entered at regular intervals between stimulation sessions to ensure that any DC drift in the analogue voltage input is regularly corrected for.

Enabling the Output

The DS8R will not deliver a stimulus to the subject until the output is enabled. It is recommended that the output is kept disabled until a stimulus is required. The stimulator output is enabled by pushing the orange momentary action toggle switch upwards or clicking on the "Enabled" button in the virtual front panel software. To confirm that the output is enabled, the DS8R display will show a green icon  in the left most status indicator box. If used, a similar icon will appear in the virtual front panel software.

To disable the output, the orange toggle switch should be pushed downwards and released. The green icon should disappear from the status indicator box and the virtual front panel software.

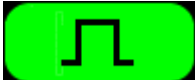
Pulse Measurements Panel





The pulse measurements panel displays stimulus parameters relating to the most recently delivered stimulus. Parameters displayed are Pulse Current², Pulse Energy, Impedance and Pulse Voltage. The "?" symbol is used in place of a numerical value if no stimuli have been delivered since the stimulator was last powered on.

²There can be a discrepancy between the current set on the stimulator and that displayed in the pulse measurements panel. This difference in values merely reflects an inability of the pulse measurement circuitry to measure accurately the amplitude of a brief current pulse. The actual current delivered will be within $\pm 2\%$ of the requested value.

Output Status Indicators & Warnings

Below the displayed current amplitude is a row of four rectangular status indicator boxes used to provide output status information. The position and roles of these status indicators are detailed in the table below.

Position	Icon	Explanation
Far Left		Output Enabled The DS8R output has been enabled and any valid trigger input will result in a stimulus pulse being delivered by the DS8R.

		<p>Output Disabled</p> <p>The DS8R output is disabled. This will be shown if an attempt to trigger the stimulator is made before the output is enabled. This icon will also be displayed if an over-energy condition or a hardware fault is detected. Recommendation: The operator should enable the output using the orange toggle switch, prior to triggering.</p>
Middle Left		<p>Out of Compliance Warning</p> <p>The load (skin/electrode) resistance is too high for the stimulator to deliver the requested current. Recommendation: The operator should examine ways to reduce electrode impedance through better skin preparation or larger electrodes or check for loose connections in electrode lead wires and connectors.</p>
Middle Right		<p>"Too fast" Warning</p> <p>The DS8R is being triggered too quickly for the settings being used i.e. successive trigger pulses are being delivered before the previous stimulus pulse (positive and negative phases) has terminated. Recommendation: Reduce the trigger frequency so the stimulus can complete before the next trigger is received by the DS8R.</p>
Far Right		<p>Pulse Energy Limit Warning</p> <p>The requested stimulus pulse would have exceeded the 300mJ energy limit. The pulse duration has been truncated to prevent the energy from exceeding 300mJ. Recommendation: Reduce current amplitude, pulse duration or electrode resistance to reduce the required pulse energy.</p>

Hardware Communication Connections

External Trigger Input

BNC Trigger IN socket in the "TRIGGER" panel on the rear of the DS8R. Allows an external voltage change to trigger the delivery of a single stimulus (Logic signal +3 to +15V, triggers on +ve edge, TTL compatible).

Footswitch Input

3.5mm (mono) footswitch input in the "TRIGGER" panel on the rear of the DS8R. Allows an optional foot switch (D185-FS1) or hand switch (DS7A-HS1) press to trigger delivery of a stimulus.

Sync Pulse Output

BNC socket in the "SYNC" panel on the rear of the DS8R. Produces a +ve TTL compatible output synchronous with each valid trigger input. This is useful for initiating a recording sweep by an amplifier or marking stimulus delivery in evoked response and other studies.

Analogue Voltage Amplitude Control Input

BNC input socket in the "CONTROL" panel on the rear of the DS8R. When in analogue voltage amplitude control mode, a voltage of 0V to +10V at this input is used to proportionately determine the stimulus current amplitude, subject to the setting of the Current Amplitude Limit (see [Amplitude Control Mode](#)).

PC Communication (USB)

Type B USB socket providing a USB interface COM port to link the DS8R to a remote personal computer running Windows 7 or higher. This socket allows for future updates to the DS8R firmware, control of DS8R settings via the DS8R virtual front panel software and third party software control via API. Only the USB cable (D.USB-F) supplied with the DS8R should be used in this socket. An icon is displayed on the front DS8R LCD screen during communication with a host computer.

Electrode Connection

Before proceeding with subject connection to the stimulator output it is critically important that the operator reads the safety precautions and warnings at the front of these instructions, 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 DS8R while a subject is connected to the stimulator.

Selecting Appropriate Stimulation Electrodes

Digitimer does not supply any electrodes with the DS8R 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 on the website and in other literature which we can supply upon request.

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 reusable 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 / cm². While electrodes with a surface area of ~1cm² are routinely used for peripheral nerve stimulation, we recommend that the operator uses electrodes with the largest surface area that still allows them to adequately stimulate particular nerves with precision.

Electrode Lead Wires

Electrode lead wires should be as short as possible in order 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

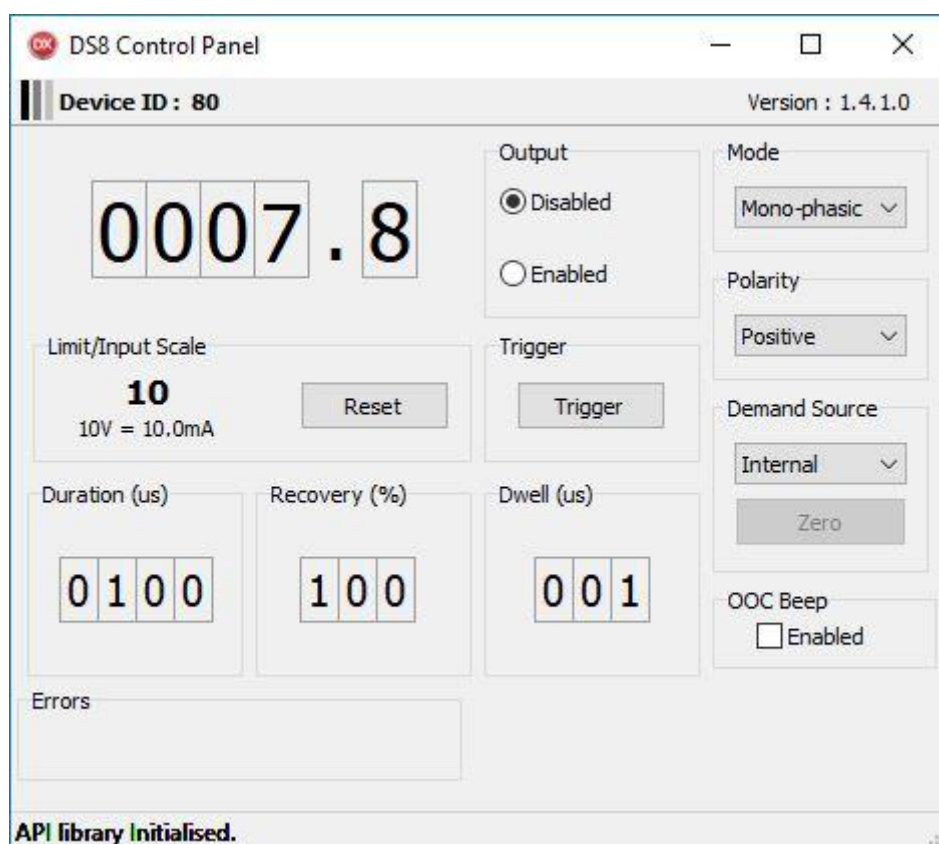
Correct electrode placement is determined by the location of the nerve or muscle that is being studied and as such the operator should have adequate anatomical knowledge to allow for the correct placement of stimulation and recording electrodes before proceeding to use the DS8R.

If necessary, a literature search of papers referring to peripheral nerve or muscle stimulation methods should be conducted or further training should be sought, before undertaking any human electrical stimulation protocols.

Section 4 - Virtual Front Panel Software

Introduction

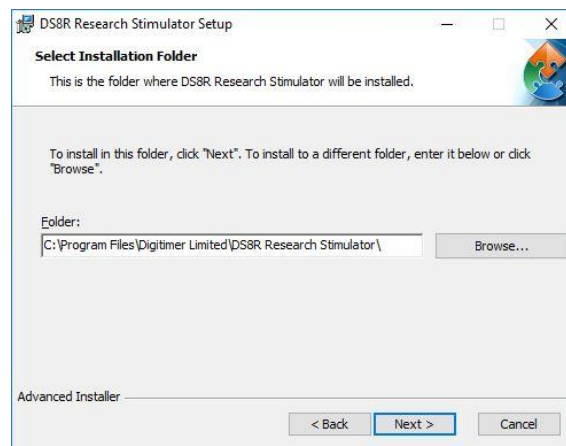
The DS8R is supplied with Windows™ compatible virtual front panel software, which allows the operator to adjust the settings of one or more DS8R stimulators from a single Windows™ PC. When connected via the supplied USB cable, the DS8R is detected by the Virtual Front Panel Software and a graphical representation of the stimulator settings and monitored pulse parameters is displayed. The software provides the user with complete control of all settings available via the hardware front panel, including triggering up to a maximum frequency of 10Hz.

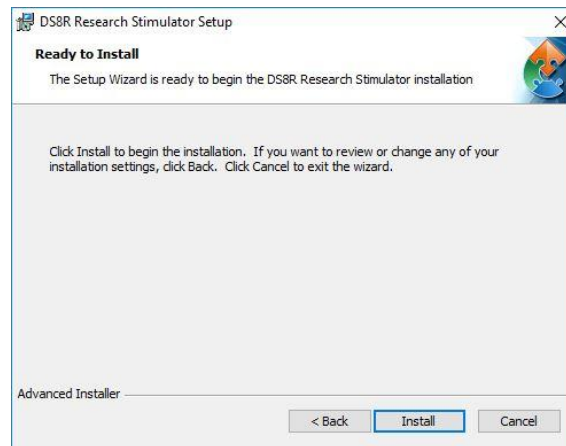


Software Installation

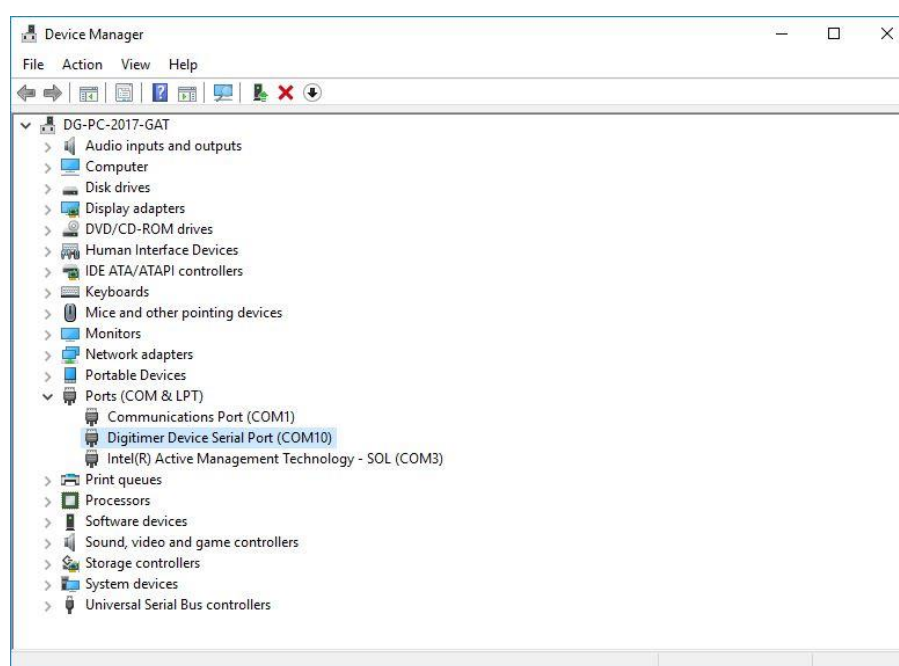
The DS8R virtual front panel software relies on a USB connection between the DS8R and a computer running Windows 7 or higher. In order to use the DS8R with a computer, the supplied DS8R virtual front panel software should be installed on the host PC, the DS8R connected using the supplied USB cable and powered on.

The virtual front panel software is supplied on a USB flash drive. Double-click on the installation file to initiate DS8R software installation and follow the onscreen instructions.



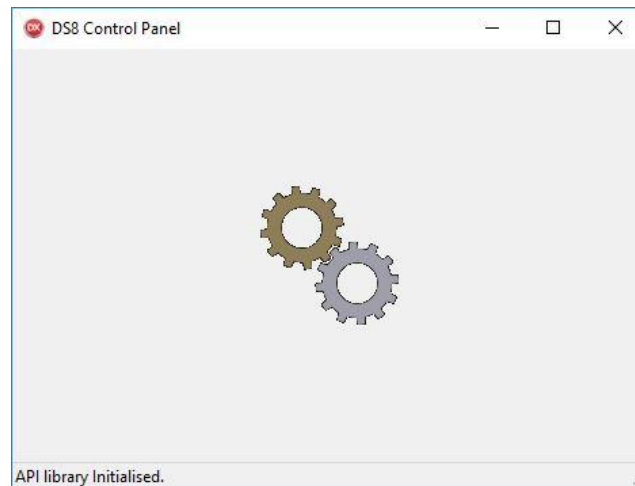


Once installation is complete, the DS8R should be installed in the Windows Device Manager as a "Digitimer Device Serial Port" (see below).



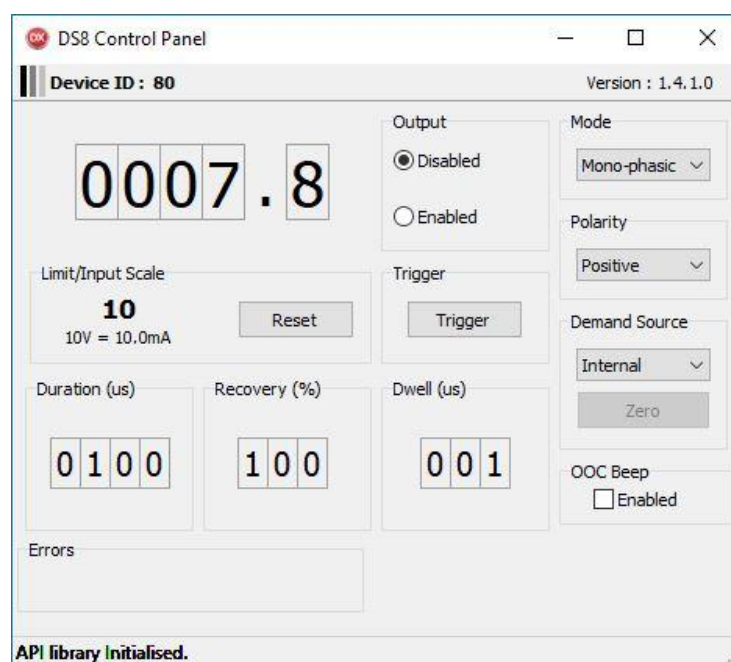
Running the Software

To run the DS8R software, double-click on the “DS8R” shortcut icon which has been placed on the desktop for ease of access. Within a few seconds you should be presented with a graphical representation of the DS8R front panel controls. If the DS8R software displays the “rotating gears” screen (see below) for more than a couple of seconds, please check the DS8R is powered on connected via the USB cable.



If the DS8R is powered on and connected to the PC, but the screen above persists, please check the Windows Device Manager to confirm that the DS8R driver has been correctly installed.

Tour of the Software



The DS8R virtual front panel software allows the operator of the DS8R to modify any of the front panel settings, including the pulse amplitude, duration, operating modes and triggering. Amplitude and timing settings can be adjusted by clicking on the numerical displays and adjusting values with the up and down arrows.

It is also possible to set and reset the Current Amplitude Limit via this software. The maximum current "Limit" and "Input Scale" values are displayed to assist the user. Drop-down menus, tick boxes and radio buttons are available to adjust all other settings. Any changes made using the software are reflected on the DS8R front panel display.

Muting the Out of Compliance (OOC) Beep

The DS8R virtual front panel software also allows the operator to mute the audible out of compliance alert (OOC Beep). When muted, a "crossed out bell" icon is displayed on the DS8R LCD screen. Note that this setting is persistent between power cycles and can only be changed using the software.

Triggering the DS8R from the software

The DS8R virtual front panel includes a trigger button, allowing the operator to manually trigger the DS8R using a mouse click. Note that unlike the physical trigger input on the rear of the DS8R, all triggering via software (i.e through the USB connection) is limited to a maximum frequency of 10Hz.

Firmware Update

Digitimer may release firmware updates for the DS8R. Below are the instructions for manually updating the firmware using a file supplied by Digitimer.

1. Turn off the DS8R.
2. Insert the end of an opened paperclip into the small hole located on the rear panel between the CONTROL and SYNC input panels. Power ON the DS8R, while pressing the paperclip against the switch within this hole.



3. The DS8R should enter bootloader mode, confirmed by a flashing the amber LED above the amplitude control dial.

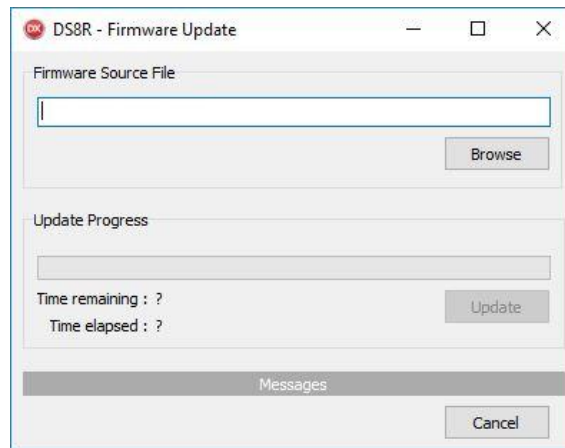


4. Once this LED is flashing, you can remove the paper clip from the hole at the rear of the DS8R.
5. In **Windows Explorer**, navigate to:

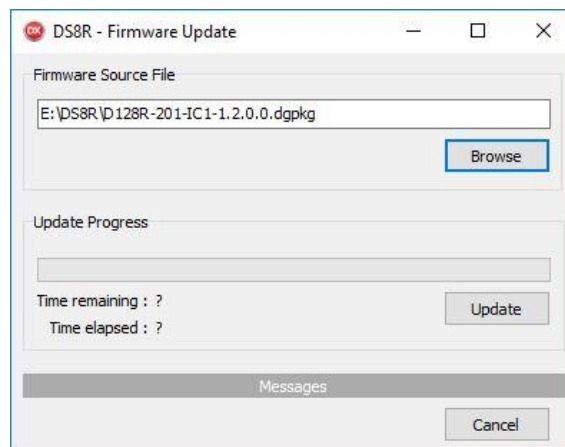
C:\Program Files\Digitimer Limited\DS8R Research Stimulator

Note: If the location of the DS8R software was changed from the default directory during installation, it will be necessary to navigate to the location chosen at that time.

6. To run the firmware updater, double-click on D128FWU.exe.



7. Browse to locate and select the newly supplied DS8R firmware source file, which will have the file format *.dpgkg.



8. Click "Update" and the firmware update process will proceed, taking approximately 6 minutes to complete. Do not power off the device during this time.
9. Once complete, turn the DS8R OFF and back ON again.
10. You can then run the new DS8R virtual front panel software, using the desktop shortcut icon or by directly running the executable file directly. By default the program is located at:-

C:\Program Files\Digitimer Limited\DS8R Research Stimulator\DS8R.exe
11. Verify that the new software is able to read and adjust the newly updated DS8R's settings.

DS8R API Programmer's References

The DS8R virtual front panel software also provides an API which is designed to allow third party programs to access the DS8R and control the stimulator settings. During installation of the DS8R

virtual front panel software, a programmer's reference and a sample application is installed on the host PC. These files are located in:-

C:\Users\<USERNAME>\Documents\Digitimer Limited

Where <USERNAME> is the user name of the Windows login account used for the DS8R software installation.

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