

DS7AP

**Digitimer**

# DS7AP Muscle Stimulator

Electrical Stimulation for Correction of Anorectal Malformation

Constant Current Stimulation



Specially Designed Disposable Probes



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The Digitimer DS7AP Muscle Stimulator is an FDA cleared and medically CE certified isolated constant current stimulator for paediatric surgical use. It has been specially designed to meet the requirements of paediatric surgeons who need a reliable and easy to use muscle locating stimulator when carrying out the Peña, "Pull-through" or posterior sagittal anorectoplasty (PSARP) anorectal reconstruction technique. The DS7AP is used by a surgeon to identify underlying musculature and aid reconstruction of the anus in neonates born with anorectal malformations. **Used in over 40 countries, the DS7AP is the ONLY commercially available electrical stimulator FDA cleared (k172381) for this surgery.**

- Features Include:-**
- Very Simple Controls.
  - Fixed Stimulus Frequency (50Hz).
  - 0-100mA Constant Current Output.
  - 100V Compliance Voltage.
  - 200µs or 500µs Pulse Durations.
  - Compatible with disposable bipolar probes.
  - Optional footswitch for improved control.
  - FDA cleared & CE certified Medical Device.

## Footswitch (supplied)

This footswitch is is a medical grade foot switch that is sealed to IP68 so as to meet all the requirements of EN 60601 for use within operating theatres.

**Part code: D185-FS1**

## Electrode Connection Cable (supplied)

Supplied with each DS7AP, the distal end of the D185-HB4-2m 2m long extension cable features a pair of 1.5mm DIN 42802 sockets, compatible with the plugs fitted to the disposable Precision Bipolar Probe.

**Part code: D185-HB4-2M**

## Disposable Bipolar Stimulation Probe

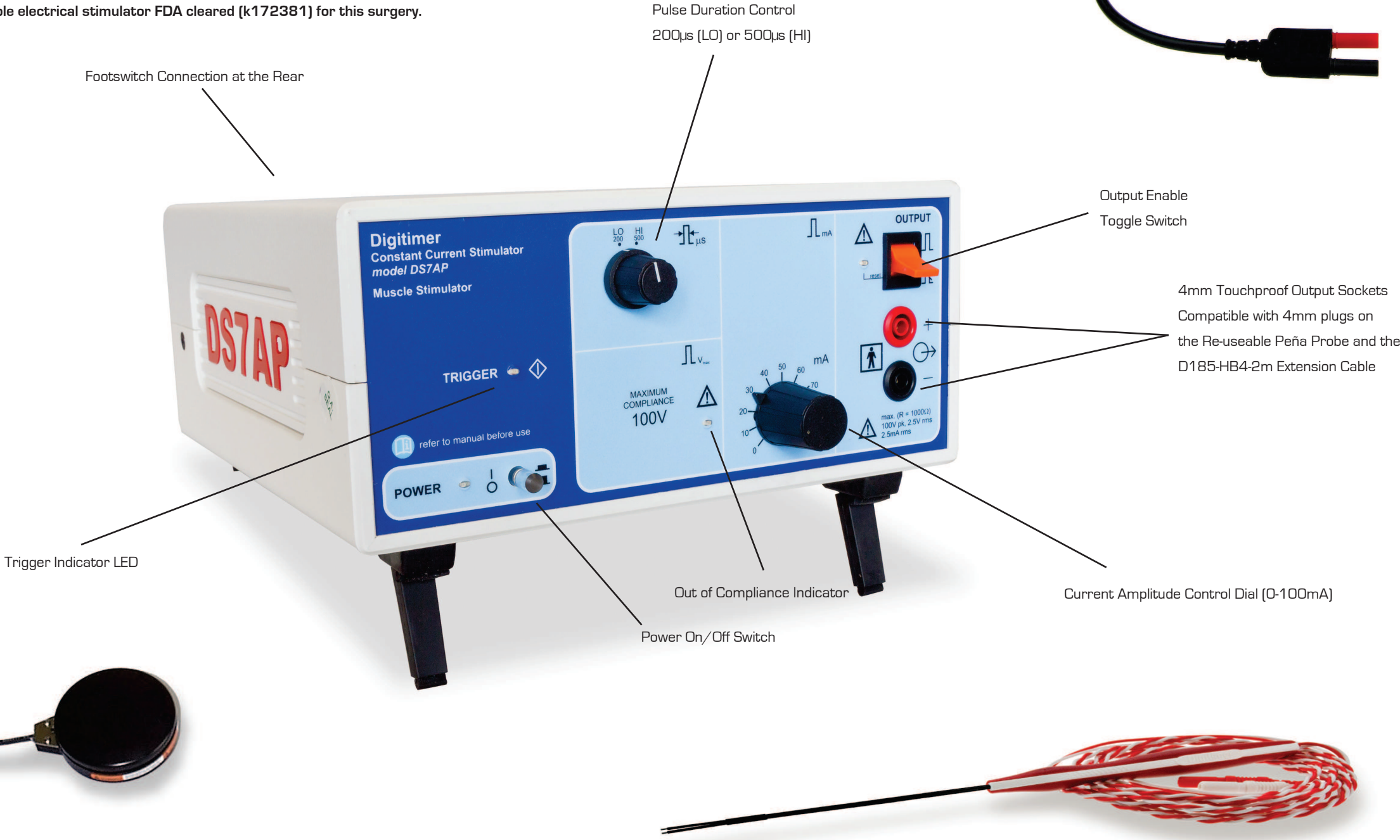
Available in packs of 10 probes, the Digitimer Bipolar Probe is a dedicated single-use probe for our DS7AP stimulator and PSARP surgery. The probes are fitted with 1.5mm DIN 42 802 connectors and **MUST** be used in conjunction with our 2m long **D185-HB4-2m Electrode Connection Cable** which is supplied with the stimulator.

**Part code: E.DS7AP-DP2**

## DS7AP Test Box (supplied)

This easy to use test box acts a "dummy patient" and is useful to carry our checks of the stimulator performance before commencing surgery.

**Part code: DS7AP-TB**



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## Specifications

|                       |                                                                                       |
|-----------------------|---------------------------------------------------------------------------------------|
| Power:                | Push rod On/Off switch.                                                               |
| Pulse Duration:       | LO (200µs) or HI (500µs), two position rotary switch.                                 |
| Current:              | 0-100mA, continuously adjustable dial.                                                |
| Compliance Voltage:   | 100V.                                                                                 |
| Output Frequency:     | 50Hz.                                                                                 |
| Output Enable:        | Toggle Switch (On is Up, Off/Reset is down)*.                                         |
| Output Connections:   | 4mm shrouded, touch-proof sockets (red and black) on 3/4" centres.                    |
| Footswitch Connection | Rear Panel 3.5mm mono jack socket (for optional D185-FS1 Contact Closure Footswitch). |

### Front Panel Indicators

|              |                                                                                                                                                           |
|--------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|
| Power:       | Green LED, illuminated for power ON.                                                                                                                      |
| Trigger:     | Amber LED, illuminated to indicate stimulus trigger is active.                                                                                            |
| Compliance:  | Amber LED, illuminated if the compliance limit is reached i.e the current requested cannot be delivered (e.g. due to high resistance between probe tips). |
| Reset/Fault: | Amber LED illuminated and latched for sensed over current and at power on.                                                                                |

### Other

|                 |                                                                                              |
|-----------------|----------------------------------------------------------------------------------------------|
| Power:          | 100-120V or 200-240V (externally selected), 47-63Hz, 12VA.                                   |
| Classification: | Class 1 with Type BF applied part.                                                           |
| Safety:         | EN 60601:2006.                                                                               |
| Regulatory:     | Europe: CE Certified to the European Medical Device Directive.<br>USA: FDA 510(k) (k172381). |

\* When used with a D185-FS1 Footswitch, the toggle switch "arms" the stimulator and the footswitch activates the stimulus when pressed.

## Installation

Our products do NOT require installation by Digitimer personnel as they are supplied with comprehensive instructions and are easy to set up & operate. However, in the event that installation by Digitimer or a local representative is requested, this would be a chargeable service, the cost of which is determined by the geographical location of the installation. For an estimate of installation costs, please contact us.

### CAUTION

Federal law restricts this device to sales by, or on order, of a practitioner licensed by the law of the State in which he/she practices to use or order use of the device.

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