

Anexa 2 Stimulator de localizare musculară

DS7AP, Digitimer Ltd, Marea Britanie

Parametri solicitati	Parametri oferiti
<p>Stimulator de localizare musculară</p> <p>Descriere Dispozitiv utilizat pentru stimularea chirurgicală, locală cu curenți constanți pentru efectuarea tehnicilor de reconstrucție a rectului sau sfincterului anal la copii: Peña, Pull-through sau PSARP</p> <p>Parametru Specificația</p> <p>Tip Portabil</p> <p>Frecvența de stimulare 50 Hz</p> <p>Intensitatea curentului 0 - 100 mA</p> <p>Posibilitatea de ajustare a curentului în trepte Da</p> <p>Durata impulsurilor 200 și 500 μs</p> <p>Posibilitate de lucru fără pedală Da</p> <p>Posibilitate de control cu pedală Da</p> <p>Indicator de rezistență de contact ridicată Da</p> <p>Alimentare 220 V, 50Hz</p> <p>Accesorii Cablu de alimentare tip Schuko</p> <p>Pedala de comandă</p> <p>Cablu de interconectare 2 buc.</p> <p>Electrod bipolar pentru stimulare de unică utilizare 30 buc.</p>	<p>Stimulator de localizare musculară DA</p> <p>Descriere Dispozitiv utilizat pentru stimularea chirurgicală, locală cu curenți constanți pentru efectuarea tehnicilor de reconstrucție a rectului sau sfincterului anal la copii: Peña, Pull-through sau PSARP DA</p> <p>Cu următoarele componente - D185-HB4-2m, D185-FS1, DS7AP-TB, DS7AP-DP</p> <p>Parametru Specificația</p> <p>Tip Portabil DA</p> <p>Frecvența de stimulare 50 Hz DA</p> <p>Intensitatea curentului 0 - 100 mA DA</p> <p>Posibilitatea de ajustare a curentului în trepte DA</p> <p>Durata impulsurilor 200 și 500 μs DA</p> <p>Posibilitate de lucru fără pedală DA</p> <p>Posibilitate de control cu pedală DA</p> <p>Indicator de rezistență de contact ridicată DA</p> <p>Alimentare 220 V, 50Hz DA</p> <p>Accesorii Cablu de alimentare tip Schuko DA</p> <p>Pedala de comandă DA</p> <p>Cablu de interconectare 2 buc. DA</p> <p>Electrod bipolar pentru stimulare de unică utilizare 30 buc. E.DS7AP-DP</p>

DS7AP

Digitimer

DS7AP Muscle Stimulator

Electrical Stimulation for Correction of Anorectal Malformation

Constant Current Stimulation



Specially Designed Disposable Probes



DS7AP

Digitimer DS7AP

The Digitimer DS7AP Muscle Stimulator is an FDA cleared and MDD 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 30 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 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 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 Precision Bipolar Stimulation Probe

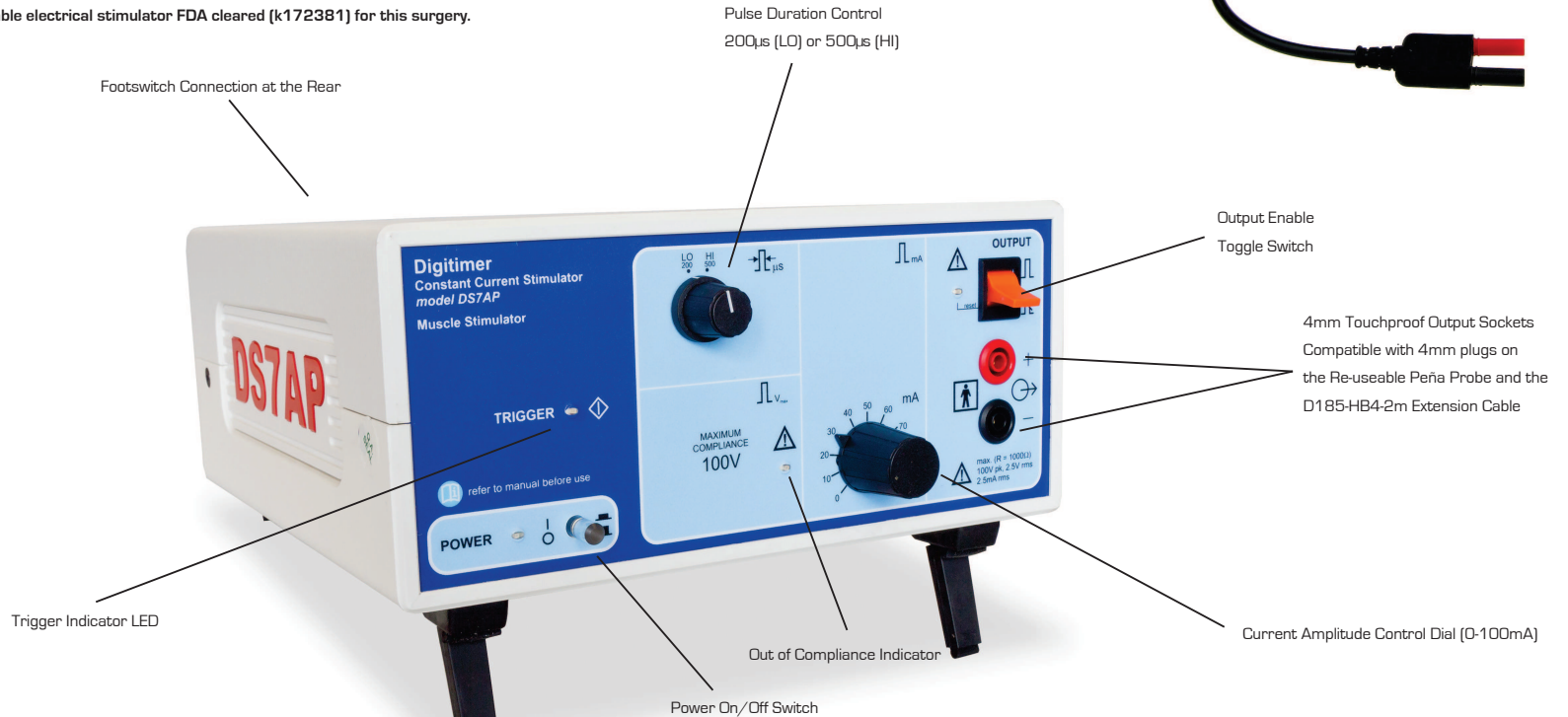
Available in packs of 10 probes, the Digitimer Precision Bipolar Probe is a dedicated single-use probe for our DS7AP stimulator and PSARP surgery. The probes are fitted with 1.5mm DIN 42 802 connectors and MUST be used in conjunction with our 2m long **D185-HB4-2m Electrode Connection Cable** which is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

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

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**



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. 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.

Digitimer Ltd.

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EU DIRECTIVES 93/42/EEC AND 2011/65/EU
(CE-marking)

Declaration of Conformity

Scope: Disposable Bipolar Probe, Precision, Digitimer branded

Technomed Europe does hereby declare:

1. that the above mentioned device, further detailed on the next page, sold with the CE-marking affixed in the European Union, meet all the essential requirements of ISO 13485:2016 and the Medical Device Directive 93/42/EEC, Annex II for Class IIa devices for the versions current at issue date of this declaration, and that all conformity assessment procedures, as required by the Medical Device Directive 93/42/EEC Annex II for Class IIa devices, have been completed for the above mentioned devices. CE-certification was performed and approved by Notified Body DEKRA Certification B.V. (0344) with reference to the CE certification number: 2109122CE01.
2. that the above mentioned devices are in conformity with the requirements of Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment for the version current at issue date of this declaration. CE-certification for this Directive is performed by Technomed Europe under its own responsibility.
3. that the above mentioned devices have been designed, manufactured and tested in accordance with the technical documentation on file with Technomed Europe.

Technomed Europe hereby also declares that the CE mark can be affixed on all products within scope of this declaration. All technical documentation to support this declaration is available for review and is kept on file at Technomed Europe.

Technomed Europe

Date

12 December 2018



Authorizing Signature

Nick van Goethem

Regulatory Affairs Specialist

Model Designation	Description
DS7AP-DP	Digitimer Disposable Bipolar Probe, Precision

Declaration of Conformity

for DS7 Constant Current High Voltage Stimulators

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	DS7 Constant Current High Voltage Stimulators
Legal Manufacturer:	Digitimer Ltd, 37 Hydeway, Welwyn Garden City AL7 3BE UK
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	For use during neurological monitoring and assessment in a clinical environment
MDD Classification:	Class IIa
Notified Body:	SGS Belgium NV, SGS House, Nooderlaan 87, 2030 Antwerp, Belgium - Notified Body Number 1639
CE Certificate Reference:	GB19/964554
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2 nd Flr., Tower Street, Swatar, BKR 4013 Malta.
MDD Conformity Assessment Route:	Full Quality Assurance in accordance with Annex II of the Medical Device Directive

Name J P Cooper **Position** Technical Director

Signed  **Date** 01/03/2021

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied
EN 60601-1:2006 + A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability
EN 62366-1:2015	Medical devices-Part1: Application of usability engineering to medical devices

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code	UDI-DI
DS7A	DS7A Constant Current High Voltage Stimulator	35729	5060490360003
DS7AH	DS7AH Constant Current High Voltage Stimulator	35729	5060490360010
DS7AP	DS7AP Constant Current High Voltage Stimulator	35729	5060490360058

Version History

Version	Compiled by	Date	Description
6.0	KFJ	01/03/2021	Sixth issue

Certificate GB17/873542

The management system of
Digitimer Ltd

37 Hydeway, Welwyn Garden City, Hertfordshire, AL7 3BE UK

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design, manufacture, sales and servicing of electro-stimulators, and isolated patient amplifiers for use during diagnostics of the nervous system.

Design, manufacture, sales and servicing of medical pressure transducers and data loggers.

Contract manufacture and test of electronic sub-assemblies and instruments for the medical devices market including material procurement.

The supply of subcontract services for the design and prototyping of medical devices.

Distribution and servicing of clinical measurement and diagnostic equipment and associated disposables.

This certificate is valid from 27 November 2020 until 27 November 2023 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 14 October 2023

Issue 4. Certified since 27 November 2017

Authorised by

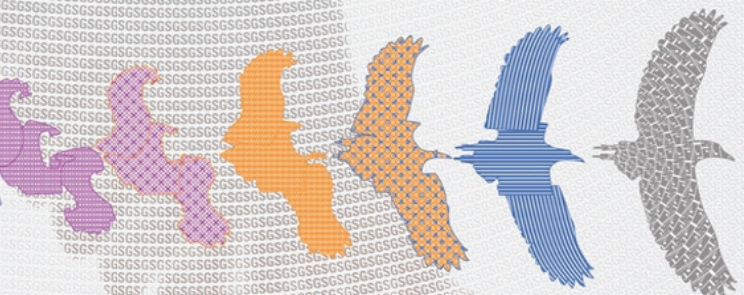


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