



Disposable Concentric Needle Electrodes for EMG

Quality. Reliability. Value.

- Sharp, 3-bevel tip design increases patient comfort by reducing insertion force
- Cannula is coated to reduce friction and required force, increasing patient comfort
- Stainless steel cannula provides strength for efficient penetration and flexibility for precise adjustments
- Precisely centered, insulated stainless steel core provides consistent signal detection
- Rigorous quality control assures clinical reliability
- Low impedance levels for accurate recordings
- Pre-sterilized



Stainless steel core assures reliable signal detection

Recording area 0.03 or 0.07 mm² depending on needle size

Color coded hub with security clip/recording area direction indicator

Orientation-free connection

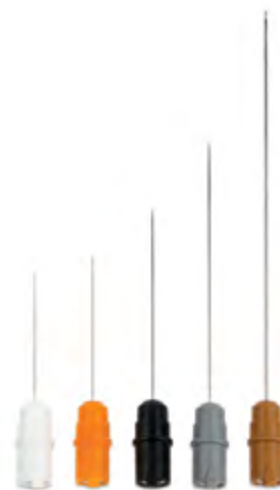
Technical Specifications

Part Number	Length	Needle diameter	Recording area (mm²)	Hub color	Quantity
25V30	1" (25mm)	0.30mm / 30G	0.03	White	1/pouch - 25/box
25V26	1" (25mm)	0.46mm / 26G	0.07	Orange	1/pouch - 25/box
37V26	1.5" (37mm)	0.46mm / 26G	0.07	Black	1/pouch - 25/box
50V26	2" (50mm)	0.46mm / 26G	0.07	Gray	1/pouch - 25/box
75V23	3" (75mm)	0.64mm / 23G	0.07	Brown	1/pouch - 25/box

Needle Holder (Cable)

Cables fit most EMG instruments.

Part Number	Length	Electrode End	Instrument end
15VCBL	59" (1.5m)	Pogo Pin	5-Pin DIN



Intended use

Designed for Electromyography (EMG) examinations, the sterilized disposable Concentric (DCN), are for Single Use Only. The Disposable Needle Electrodes are not designed for reuse. They are intended to be used on an individual patient during a single procedure, and then discarded. They are not intended to be reprocessed and used again, even on the same patient.

Materials

Electrode

Cannula	Stainless Steel
Cannula Coating	Silicone
Core	Stainless Steel
Insulator	Polyesterimide
Hub	Brass, Copper/Nickel Plating
Hub Color Cover	ABS
Protective Tube	Polyethylene
Packaging	
Quantity	25 needles per box
Pouch	Tyvek and EVA
Box	Cardboard

Sterilization

Type	Gamma Irradiation
Shelf Life	3 years

Environmental

Not made with natural rubber latex / RoHS Compliant	
Storage Temperature	0° – 132° F (-17.7° – 55° C)

Supplies

Natus offers a full range of neurodiagnostic supplies, featuring:

- Dedicated and knowledgeable customer service
 - Streamlined order processing
 - Convenient online ordering (US Customers only)
- Natus Medical Store – natusmedicalstore.com

To learn more about Natus products,
contact your local distributor or sales representative.

US Customers Call: **1-800-356-0007**

International Customers Call: **+1-608-829-8500**

Healthcare solutions with one thing in mind. You.

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All Sites	TITLE Declaration of Conformity to EU MDR for the Holder for Value Line DCN Disposable Concentric Needle Electrodes	REV B

Natus Manufacturing Limited
IDA Business Park
Gort, County Galway
Ireland

European Declaration of Conformity
to the Medical Device Regulation,
(EU) 2017/745 of the European Parliament,
and of the Council of 5 April 2017 on Medical Devices



Declaration Number: DOC-051800 Rev. B
Registered Product/Trade Name: Holder for Value Line DCN Disposable Concentric Needle Electrode
Single Registration Number: IE-MF-000000799
Product Catalog Number with associated UDI-DI: See Table 1, below
EMDN Code: N010101 ELECTROMYOGRAPHIC ELECTRODES

Intended Purpose:

Value Line DCN Holder is intended for use with Value Line DCN Needle Electrodes listed below (available in boxes of 25):

Order Number	Needle Length	Needle Diameter	Recording Area
25V30	25mm	0.30mm	0.02mm ²
25V26	25mm	0.46mm	0.07mm ²
37V26	37mm	0.46mm	0.07mm ²
50V26	50mm	0.46mm	0.07mm ²
75V23	75mm	0.64mm	0.07mm ²



Figure 1: Holder for Value Line DCN Disposable Concentric Needle Electrode

Natus Medical, Incorporated hereby declares that the above medical device(s), which bear the CE Mark, are in conformity with the applicable requirements of the Medical Device Regulation, (EU 2017/745 of the European Parliament, and of the Council of 5 April 2017 on Medical Devices).

Risk Classification/Rule: Class I / Annex VIII Rule I MDR 2017/745
Conformity Assessment Route: Annex II & III
Common Specifications Referenced: N/A

This declaration is based on Certification of a full Quality Assurance System and compliance to the MDR.

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natus	DOCUMENT NUMBER DOC-051800	Page 2 of 2
All Sites	TITLE Declaration of Conformity to EU MDR for the Holder for Value Line DCN Disposable Concentric Needle Electrodes	REV B

ISO Certificate No.: FM 603283 ISO 13485:2016

Issued by: BSI

Expiry Date: 04th November 2024

Additionally: Natus hereby declares conformity under its sole responsibility as Legal Manufacturer and not evaluated by the Notified Body listed above, that the product specified on this Declaration of Conformity is in conformity with Commission Delegated Directive 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances. It has been demonstrated that the requirements specified in Annex II of Directive 2015/863 have been met

Authorized Representative: N/A	Notified Body: N/A Class I device
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Table 1: Holder for Value Line DCN, Catalog Numbers

Category	Product Configuration/Model	Part (Catalog) Number	Basic UDI/DI	First lot produced
Reusable Lead Cable	Holder for Value Line DCN	15VCBL	038283NA00011DQ	210308-D03SM

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Job Title: *Senior Director, Regulatory Affairs*

Place: *Gort, Galway, Ireland*

Date of Issue: 13 Dec 2021

Signature:

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