



M8 Lead Adaptor Manual

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CE
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NEVRO CORP.

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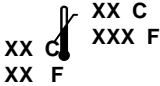






CE Mark effective on 4 May 2010

Nevro hereby declares that the Senza® System is in compliance with the essential requirements and other relevant provisions of the Radio Equipment Directive (2014/53/EU).

IMPORTANT: Do not change or modify any component of the Nevro® Senza system, unless expressly approved by Nevro Corp.

CAUTION: Federal law restricts this device to sale, distribution and use by or on the order of a physician.

Explanation of symbols. Refer to the product for symbols that apply.

Symbols	Description		
SN	Serial number		
LOT	Batch code		
	Date of Manufacture		
	Manufacturer		
	Caution		
REF	Catalog number		
	Temperature limitation (storage)		
<table border="1" data-bbox="144 1081 410 1136"> <tr> <td>STERILE</td><td>EO</td></tr> </table>	STERILE	EO	Sterilized using ethylene oxide
STERILE	EO		
	Use by		
	Do not use if package is damaged		
	Do not reuse		
	Do not re-sterilize		
	Keep dry		
R_x ONLY	Prescription only		
 www.nevro.com	Consult Electronic Instructions for Use		



Non-sterile



Non-ionizing radiation



Type B Applied Part



Type BF Applied Part



Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations.



Conditional

MR Conditional



MR unsafe



CE Marking of Conformity



Authorized representative in the European Community

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Device Description

The M8 Lead Adaptor is intended to connect a compatible Medtronic (MDT) neuromodulation lead or extension to the Nevro's Senza Spinal Cord Stimulation (SCS) system. This manual provides basic information for the operation of the M8 Lead Adaptor, model MADP2008-XXY (where $1\text{cm} \leq \text{xx} \leq 60\text{cm}$ in increments of 1 cm and Y represents the cable color).

The components included in the M8 Lead Adaptor Kit are:

- M8 Lead Adaptor
- M8 Torque Wrench

Indications for Use, Contraindications, Warnings, and Precautions

For Indications for Use, Contraindications, Warnings, and Precautions for the Senza system, refer to these sections of the Physician Implant Manual.

Storage and Transport

The M8 Lead Adaptor should be stored in temperature regulated areas within the acceptable temperature range. Excessively hot or cold temperatures may damage the adaptor, particularly high heat. The storage temperature for the adaptor should not exceed 0°C - 45°C (32°F - 113°F). Do not expose the adaptor to liquids or excessive moisture.

Sterilization

1. Prior to opening the sterile package, inspect the sterilization indicator and the sterile package.
2. Do not use the contents if the package is broken or torn, or if contamination is suspected because of a defective sterile package seal.
3. Do not use any component that shows signs of damage.
4. Do not re-sterilize the package or the contents. There is risk of infection and device malfunction.
5. Do not use if "Use by" date has passed.
6. All implanted components are intended for single use only. Do not re-use.
7. Note:
 - The product is sterilized using ethylene oxide.
 - The product should not be re-sterilized

Compatibility

The M8 Lead Adaptor is compatible with the following Medtronic lead and extension models:

- 1X8 subcompact lead kit model numbers: 3776 and 3876
- 1X8 standard lead kit model numbers: 3777 and 3877

- 1X8 compact lead kit model numbers: 3778 and 3878
- 1X8 subcompact trial lead kit model numbers: 3875
- 1X8 standard trial lead kit model number: 3873
- 1X8 compact trial lead kit model number: 3874
- Specify™ 2x8 lead kit model numbers: 39286-30 and 39286-65¹
- Specify 5-6-5 lead kit model numbers: 39565-30, 39565-65¹
- 1X8 extension kit model numbers: 37081-20, 37081-40 and 37081-60.
- Bifurcated stretch coil extension kit model numbers: 37082-20, 37082-40 and 37082-60.
- Single stretch coil extension kit model numbers: 37083-20, 37083-40 and 37083-60.
- The single stretch coil extension and the bifurcated stretch coil extension can be connected to the following 4-electrode MDT leads.
 - Pisces™ Quad lead kit model numbers: 3487-33, 3487-45 and 3487-56
 - Pisces Quad Compact lead kit model numbers: 3887-33, 3887-45 and 3887-56
 - Pisces Quad Plus lead kit model number: 3888-33, 3888-45 and 3888-56
 - Specify lead kit model number: 3998
 - 2X4 Specify Hinged lead kit model numbers: 3999-30, 3999-45 and 3999-60
 - Resume® II lead kit model number: 3587A-25
 - Resume TL lead kit model number: 3986A
 - Symmix lead kit model number: 3982A

Instructions for Use

For full directions for use of the Senza system, refer to the Physician Implant Manual.

1. Confirm that the MDT lead that you wish to connect to is listed above.
2. Visually inspect the proximal end(s) of the Medtronic lead to ensure that there is no damage.

Note: MDT Specify 2X8 and Specify 5-6-5 leads are designed to have 16 electrodes on the distal end and two proximal connectors, where each proximal connector corresponds to eight electrodes. Two M8 lead adaptors are needed to ensure that Nevro therapy can be delivered through all electrodes on these leads. The proximal connector with a differentiation band corresponds to electrodes 1-8 on these leads and the other proximal connector corresponds to electrodes 9-16.
3. Wipe fluids (e.g. blood) from the proximal end(s) of the lead.
4. Fully insert the proximal end(s) of the lead into the M8 Lead Adaptor's connector(s).
5. Take impedance measurements using Nevro OR cable (kit# ACCK4000) to ensure that the lead is fully inserted into the connector(s).
6. Fully insert the M8 torque wrench into the setscrew.

Notes:

 - Ensure that the setscrew is not removed from the connector.

¹ These MDT leads have 16 electrodes. For these leads, two M8 Lead adaptors are needed to ensure Nevro therapy can be delivered through all electrodes.

- If the lead does not fully insert into the M8 Lead Adaptor's connector, check to see whether the setscrew is not impeding the progress of the lead. If it is, use the torque wrench to loosen the setscrew by turning it counter-clockwise and then re-insert the lead.
- If the setscrew does not tighten smoothly, try the following:
 - Use the torque wrench to loosen the setscrew by turning it counter-clockwise and then re-tighten by turning it clockwise.
 - Check to see that the lead is fully inserted into the M8 Lead Adaptor's connector before tightening.
- Use only the included M8 torque wrench to ensure that the proper torque is applied to the setscrews.

7. Rotate the torque wrench handle clockwise until it clicks.

Note: Clicking indicates that it is fully tightened. Do not try to tighten beyond the clicking as this could damage the lead.

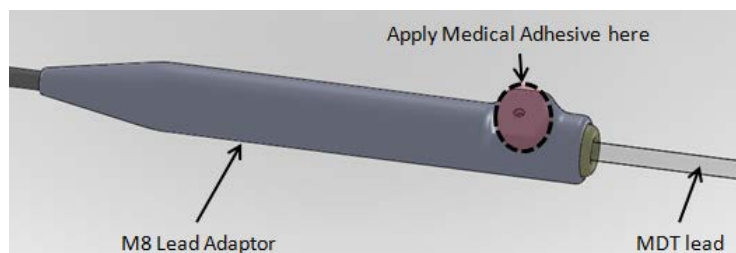
8. Connect the proximal end of the M8 Lead Adaptor(s) into the Nevro IPG port(s).

Notes:

- For MDT Specify 2X8 and Specify 5-6-5 leads, ensure that the M8 Lead Adaptor connected to the MDT lead's proximal leg with the differentiation band is inserted into the bottom port of the Nevro IPG. Connect the proximal end of the other M8 Lead Adaptor to the top port of the IPG.
- Tighten the IPG's setscrew using the torque wrench from the IPG kit. Clicking indicates that it is fully tightened. Do not try to tighten beyond the clicking as this could damage the lead.
- Do not use the M8 torque wrench to tighten the setscrew on the IPG. This may result in incomplete tightening of the setscrew.
- Typical connection configuration is illustrated below.



9. Prior to closing the wound, seal the hole on the top of the M8 Lead Adaptor housing using medical adhesive (Dow Corning Silastic Medical Adhesive (Type – A, sterile) is recommended). After the adhesive has been applied to the M8 Lead Adaptor, please wait for 5 minutes (in order for the adhesive to cure) before closing the wound.



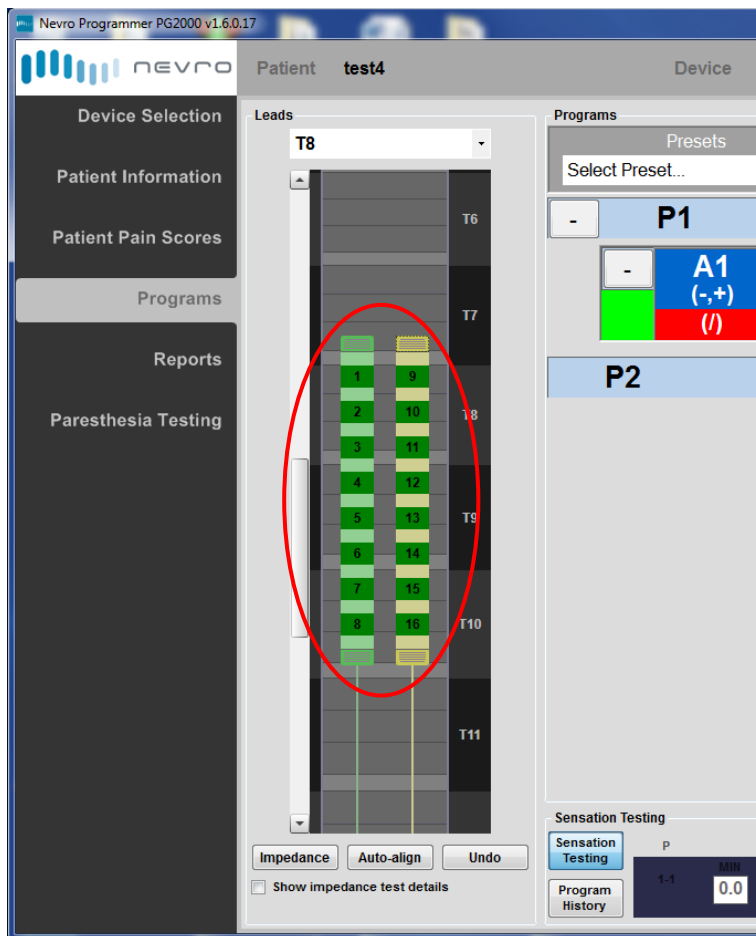
10. Conduct programming

- Refer to the lead reference table below.


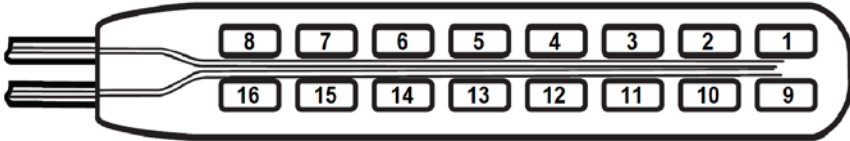
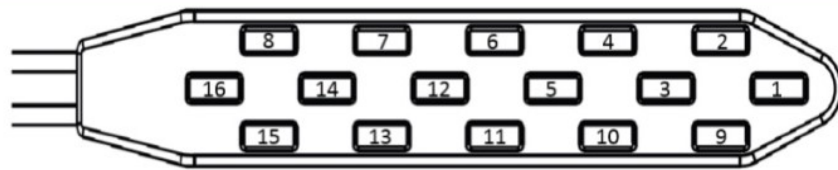

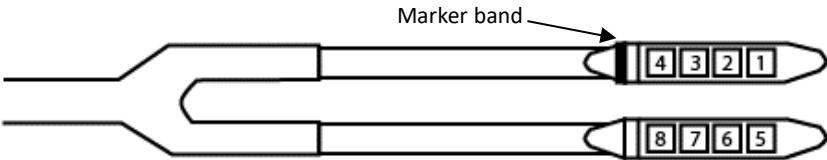
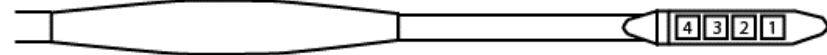

- Program as shown in the Programmer Manual.

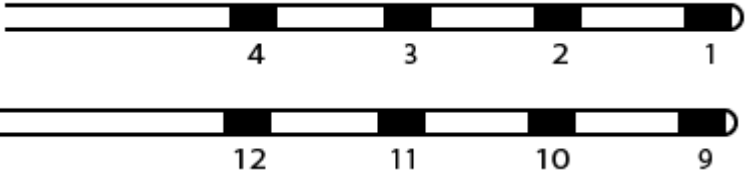
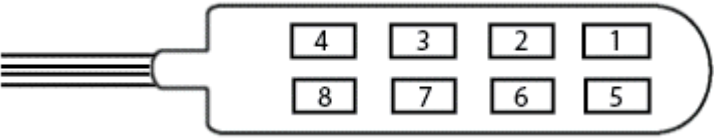
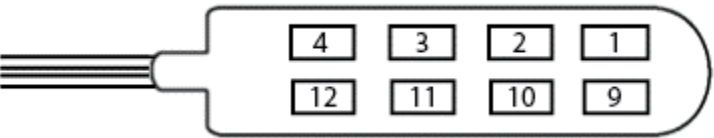
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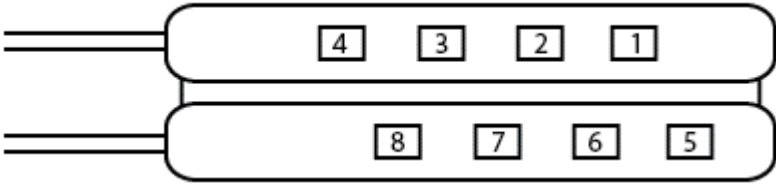
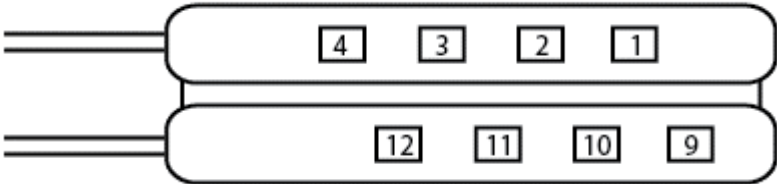
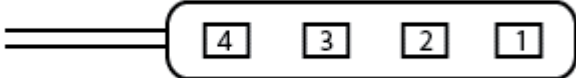
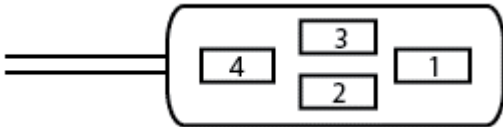
- As noted in the previous steps, the MDT leads will need to be connected to the Nevro IPG through the M8 Lead Adaptors.
- It is important the connections are made properly as described above. Otherwise, the MDT electrode numbers shown in the diagrams below will not correspond to the electrode numbers in the programmer.
- A screenshot of the programmer shows the numbers from 1 to 16, which specifies the electrodes on the lead(s).



- The electrode numbers on the programmer correspond to the electrode numbers in the diagrams of the MDT leads below. For example, programming electrode #1 in the programmer would control electrode #1 in the diagrams of the leads below.

Name	Model #	Electrode Configuration (All electrodes are shown face-down)
<ul style="list-style-type: none"> 1x8 Subcompact Lead 1x8 Standard Lead 1x8 Compact Lead 1x8 Subcompact Trial lead 1x8 Standard Trial Lead 1x8 Compact Trial Lead 	3776 3876 3777 3877 3778 3878 3875 3873 3874	
<ul style="list-style-type: none"> Specify 2x8 Lead 	39286-30 39286-65	
<ul style="list-style-type: none"> Specify 5-6-5 Lead 	39565-30 39565-65	
<ul style="list-style-type: none"> 1 X 8 Extension 	37081-20 37081-40 37081-60	
<ul style="list-style-type: none"> Bifurcated Stretch Coil Extension 	37082-20 37082-40 37082-60	
<ul style="list-style-type: none"> Single Stretch Coil Extension 	37083-20 37083-40 37083-60	
<ul style="list-style-type: none"> Pisces Quad Lead Pisces Quad Subcompact Lead Pisces Quad Plus Lead 	3487-33 3487-45 3487-56 3887-33 3887-45 3887-56 3888-33 3888-45 3888-56	<p>Scenario 1: Using one Quad Lead</p> <ul style="list-style-type: none"> - Connect a Quad Lead to ta Single Stretch Coil Extension. - Connect the Single Stretch Coil Extension to the distal end of the M8 Lead Adaptor. - Connect the proximal end of the M8 Lead Adaptor to the bottom port of the IPG. 

Name	Model #	Electrode Configuration (All electrodes are shown face-down)
		<p>Scenario 2: Using two Quad Leads</p> <ul style="list-style-type: none"> - Connect a Quad Lead to a Single Stretch Coil Extension. - Connect a Single Stretch Coil Extension to the distal end of a M8 Lead Adaptor. - Connect the proximal end of the M8 Lead Adaptor to the bottom port of the IPG. The four contacts of this Quad Lead will be contacts 1 to 4. - Connect the second Quad Lead a Single Stretch Coil Extension. - Connect this Single Stretch Coil Extension to the distal end of another M8 Lead Adaptor. - Connect the proximal end of this M8 Lead Adaptor to the top port of the IPG. The four contacts of this Quad Lead will be contacts 9 to 12. 
<ul style="list-style-type: none"> Specify Lead 	3998	<p>Scenario 1: Using a Bifurcated Stretch Coil Extension</p> <ul style="list-style-type: none"> - Specify Lead (Model number 3998) has two proximal ends. The proximal end corresponding to contacts 1 to 4 has a white mark. Locate this proximal end. - Insert this proximal end into the Bifurcated Stretch Coil Extension leg with the marker band. - Insert the other proximal end (without the white mark) into the second Bifurcated Stretch Coil Extension leg. - Connect the Bifurcated Stretch Coil Extension to a distal end of the M8 Lead Adaptor. - Insert the proximal end of the M8 Lead Adaptor to the bottom of the IPG.  <p>Scenario 2: Using two Single Stretch Coil Extensions</p> <ul style="list-style-type: none"> - Specify Lead (Model number 3998) has two proximal ends. The proximal end corresponding to contacts 1 to 4 has a white mark. Locate this proximal end. - Insert this proximal end into a Single Stretch Coil Extension. Keep track of this extension and then connect it to the distal end of a M8 Lead Adaptor. Connect the proximal end of this M8 Lead Adaptor to the bottom port of the IPG. - Insert the other Specify Lead's proximal end (without the white mark) into a second Single Stretch Coil Extension. Keep track of this extension and then it connect to the distal end of the M8 Lead Adaptor. Connect the proximal end of this M8 Lead Adaptor to the top port of the IPG. 

Name	Model #	Electrode Configuration (All electrodes are shown face-down)
<ul style="list-style-type: none"> 2x4 Hinged Lead 	3999-30 3999-45 3999-60	<p>Scenario 1: Using a Bifurcated Stretch Coil Extension</p> <ul style="list-style-type: none"> - 2x4 Hinged Lead (Model numbers 3999-30, 3999-45, 3999-60) has two proximal ends. The proximal end corresponding to contacts 1 to 4 has a white mark. Locate this lead connector. - Insert this proximal end into the Bifurcated Stretch Coil Extension leg with the marker band. - Insert the other proximal end (without the white mark) into the second Bifurcated Stretch Coil Extension leg. - Connect the Bifurcated Stretch Coil Extension to a distal end of the M8 Lead Adaptor. - Insert the proximal end of the M8 Lead Adaptor to the bottom of the IPG.  <p>Scenario 2: Using two Single Stretch Coil Extensions</p> <ul style="list-style-type: none"> - 2x4 Hinged Lead (Model numbers 3999-30, 3999-45, 3999-60) has two proximal ends. The proximal end corresponding to contacts 1 to 4 has a white mark. Locate this proximal end. - Insert this proximal end into a Single Stretch Coil Extension. Keep track of this extension and then connect it to the distal end of a M8 Lead Adaptor. Connect the proximal end of this M8 Lead Adaptor to the bottom port of the IPG. - Insert the other Specify Lead's proximal end (without the white mark) into a second Single Stretch Coil Extension. Keep track of this extension and then it connect to the distal end of the M8 Lead Adaptor. Connect the proximal end of this M8 Lead Adaptor to the top port of the IPG. 
<ul style="list-style-type: none"> Resume II Lead Resume TL Lead 	3587A-25 3986A	
<ul style="list-style-type: none"> Symmix Lead 	3982A	

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