

Medtronic

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AUTHOR


Luke Munroe

REVISIONS

REV	DESCRIPTION	DATE
A	Initial release	10 May 2021

SPEC NUMBER	REV	SHEET
B05631	A	1 of 5

1. This specification is a representation of the final Label Design Output generated from a combination of label parts within the associated PDM BOM.
2. These label images are the combinations of the Transform template file, LDS (Label Model Data) record, sample trigger data and representative views of the label die lines.
3. The Serial Number, Use-By Date, Lot Number, Date Of Manufacture, PIN Number, GTIN, GTIN Version (if used), Product Number (REF) and Barcodes are shown for example only. These fields are variable and are to be supplied by Manufacturing at the time of printing. Not all fields will be used for all labels.
4. The Label Set is to be printed using a 600 DPI LaserJet printer or equivalent. The individual labels and PIC are to be printed using a 300 DPI Zebra thermal transfer printer.
5. The Trigger Data shown on the Label Set Image might differ from the printed label.
6. Spacing and text wrapping shown in the image may differ slightly from actual printed label. Content of printed version is accurate.
7. The label printed in Manufacturing must be at an equal or later Model Data and Template revision as shown on the image.
8. This specification is controlled by Neuromodulation Package Engineering.
9. This specification has been assessed for key design characteristics which are defined as
 - Critical KC_C - Identified characteristic is classified as Critical and impacts safety.
 - Major KC_M - Identified characteristic is classified as Major and impacts safety and/or performance.

 MEDTRONIC, MINNEAPOLIS, MINNESOTA USA	TITLE LABEL IMAGE SPECIFICATION NEURO 97800 CE MARK				
	MEDTRONIC CONFIDENTIAL This document is the property of Medtronic, and must be accounted for. Information hereon is confidential. Do not reproduce it, reveal it to unauthorized persons or send it outside Medtronic without proper authorization.				
IMAGE SPEC TEMPLATE: A86694_c					
DATE 10-May-2021	SCALE N/A	ENGINEERING Luke Munroe			
MODEL 97800	Size B	SPEC NUMBER B05631	REV A	SHEET 2 of 5	

Medtronic 97800
InterStim™ X
YYYY-MM-DD
REF 97800 Implantation date

SN WWW000000W

FOR YOUR PATIENT FILES MR Conditional

Medtronic 97800
InterStim™ X
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Medtronic 97800
InterStim™ X
REF 97800 SN WWW000000W
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MD
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STERILE EO
CE0123 Rx Only
Medtronic, Inc., 710 Medtronic Parkway
Minneapolis, MN 55432 USA
Manufactured in: Juncos, Puerto Rico, USA
Country of Origin: USA
M014347C001 B - M020161C001 A

Medtronic 97800
InterStim™ X
REF 97800 SN WWW000000W
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M014347C001 B - M020161C001 A

Data P/N
M020161C001 A

Template P/N
M014347C001 B

Medtronic REF 97800
InterStim™ X
SN WWW000000W
YYYY-MM-DD
M014347C001 B - M020161C001 A
END LABEL 1

Medtronic M014347C001 B - M020161C001 A REF 97800
FCC ID: LF597800
This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
END LABEL 2

SHELF BOX LABEL

Trigger Data

```

TemplateNumber: M014347C001_B
ImageSpecID: B05631
ImageSpecRev: A
SpecPgName: B00590 Txt
ImageSpecTemplate: A86694
LabelSeqNo: B05631-007
OrientationLabel: L
ImageSpecTitle: LABEL IMAGE SPECIFICATION NEURO 97800
Engineering: CE MARK
PrinterName: Lake Monroe
Printer: Prt Bmp
PIN: W000WWW00W
MatrixID: 9876543210
QuantityofLabels: M020161C
DocumentNumber: A
DocumentRevision: A
UPNDOC: 01234567891234
GTIN: 00000000000000
UBD: YYYYMMDD
LotSerial: YYYMMDD
LotSerialNumber: S WWW000000W
AddressCode: 007
QualificationStatus: 90
BusinessUnit: NRI
LabelPrinter: Prt Bmp
PICPrinter: Prt Bmp
ProductNumber: 97800
TemplateType: Neuro_Label_Templates
ArchiveTrigger: 210510_145131-9b64-B05631-M014347C001_B
  
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UNIVERSAL LABEL SET (DEVICES) Rev. : E

* A 1 4 6 3 2 0 0 1 *

LOT NUMBER

LASER



InterStim™ X

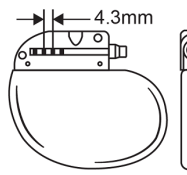
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SN WWW000000W

YYYY-MM-DD

YYYY-MM-DD

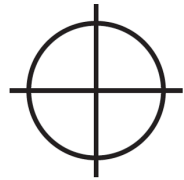
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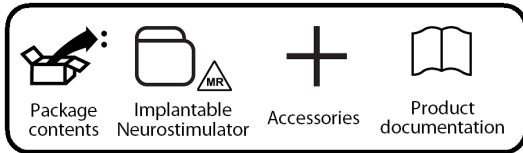
MD



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STERILE EO



CE0123

Medtronic, Inc., 710 Medtronic Parkway
Minneapolis, MN 55432 USA

Manufactured in:
Juncos, Puerto Rico, USA

Rx Only

EC REP Medtronic B.V., Earl Bakkenstraat 10
6422 PJ Heerlen, The Netherlands

Country of Origin:
USA

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M014347C001 B - M020161C001 A



Shelf Box Label



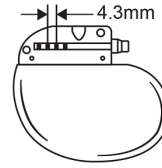
InterStim™ X

REF 97800

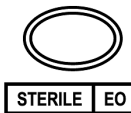
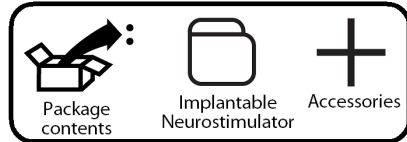
SN WWW000000W

YYYY-MM-DD

YYYY-MM-DD



Sacral
Neuromodulation



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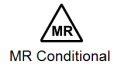


Sterile Pack Label

M014347C001 B - M020161C001 A



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Medtronic 97800	MR	SN WWW000000W YYYY-MM-DD
Medtronic 97800	MR	SN WWW000000W YYYY-MM-DD
Medtronic 97800	MR	SN WWW000000W YYYY-MM-DD
Medtronic 97800	MR	SN WWW000000W YYYY-MM-DD
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Medtronic 97800	MR	SN WWW000000W YYYY-MM-DD
Medtronic 97800	MR	SN WWW000000W YYYY-MM-DD

FYR Labels

Medtronic 97800

InterStim™ X

YYYY-MM-DD

REF 97800

Implantation date



SN WWW000000W



FOR YOUR PATIENT FILES



Medtronic 97800

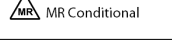
InterStim™ X

SN WWW000000W

Implantation date



FOR YOUR PATIENT FILES



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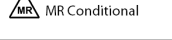
InterStim™ X

SN WWW000000W

Implantation date



FOR YOUR PATIENT FILES



InterStim™ X

REF 97800

SN WWW000000W

YYYY-MM-DD



(01)00000000000000(17)YYMMDD(21)WWW000000W

M014347C001 B - M020161C001 A



End Label 1



M014347C001 B - M020161C001 A

REF 97800

FCC ID: LF597800

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation



End Label 2

ZEBRA

NOTE: IMAGES NOT TO SCALE

SPEC NUMBER	REV	SHEET
B05631	A	4 of 5

en Stimulator / **fr** Stimulateur / **de** Stimulator / **es** Estimulador /
nl Stimulator / **it** Stimolatore / **no** Stimulator / **fi** Stimulaattori /
sv Stimulator / **el** Διεγέρτης / **da** Stimulator / **pt** Estimulador /
pl Stymulator / **cs** Stimulátor / **hu** Stimulátor / **sk** Stimulátor /
ro Stimulator / **bg** Стимулатор / **sl** Stimulator / **hr** Stimulator

MD 97800 InterStim™ X

UDI



UDI-DI: (01)00000000000000



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M014347C001 B
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PIC

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SPEC NUMBER	REV	SHEET
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