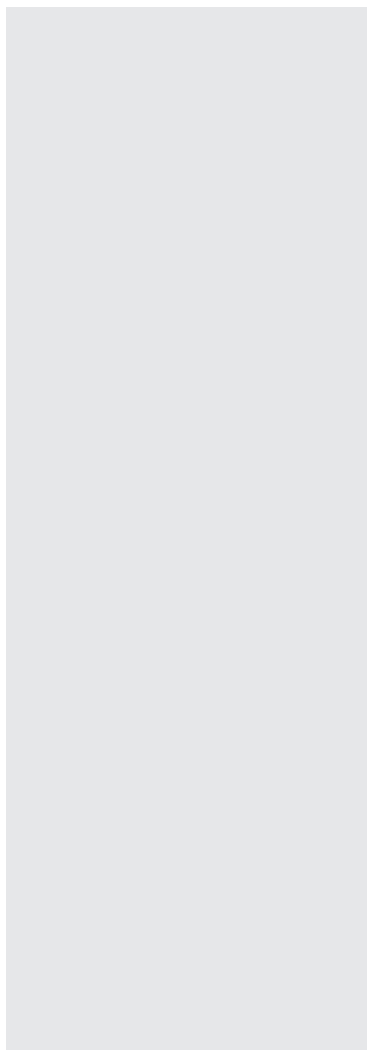


Boston Scientific

Advancing science for life™

Boston Scientific Deep Brain Stimulation Reference Guide



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

Guarantees

Boston Scientific Corporation reserves the right to modify, without prior notice, information relating to its products in order to improve their reliability or operating capacity.

Trademarks

All trademarks are the property of their respective holders.

Technical Support

There are no user serviceable parts. If you have a specific question or issue, please contact your sales representative or call (833) DBS-INFO or (833) 327-4636.

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Introduction

The Reference Guide provides the list of Directions for Use (DFU) available for each Boston Scientific Deep Brain Stimulation (DBS) System. These manuals are designed for clinicians and other health care providers. The Reference Guide also provides device-specific information, such as the list of compatible leads for each DBS system.

IMPORTANT: Please note that only the DFUs that are appropriate for your region will be provided with your DBS system.

The Boston Scientific DFUs are provided either online (as directed in your product packaging) or with your DBS system.

How to Use this Reference Guide

In this Reference Guide, information is provided for each DBS System in a table format. Follow the instructions below to find information for your DBS system:

1. Find the appropriate table for your DBS system. For example, if you are using the Vercise PC DBS System, find the table labeled “Vercise PC DBS System”.
2. Use the highlighted rows to locate the information of interest to you (e.g. indications, implantable pulse generator, or programming).

Vercise Gevia™ DBS System

List of Directions for Use (DFU)

Information	DFU
Intended Use/Indications for Use	
<ul style="list-style-type: none"> • Indications for Use 	<i>Vercise Gevia Information for Prescribers DFU</i>
Contraindications, Safety Information, General Device Information	
<ul style="list-style-type: none"> • Adverse Events Summary • Component Disposal • Contraindications • Device Description • Information for Contacting Boston Scientific • MRI Information • Precautions • Sterilization • Storage and Handling • Warnings • Electromagnetic Compatibility 	<i>Vercise Gevia Information for Prescribers DFU</i>
MRI Guidelines	
<ul style="list-style-type: none"> • MRI Guidelines 	<i>ImageReady™ MRI Guidelines for Boston Scientific DBS Systems</i>
Summary of Clinical Data	
<ul style="list-style-type: none"> • Summary of Clinical Data 	<i>Deep Brain Stimulation for Parkinson's Disease Clinical Summary</i>
Vercise Gevia Implantable Pulse Generator (IPG) and Lead Extensions	
<ul style="list-style-type: none"> • Explant of Leads, Extensions, and IPG • IPG and Extension Implantation • IPG Registration • Stimulator Battery Information • Kit Contents • Specifications and Technical Data • Stimulator Programmable Characteristics • Vercise Gevia System Revisions and Replacement 	<i>Vercise Gevia 16 Contact Implantable Pulse Generator DFU</i>
OR Cable, OR Cable Extensions, External Trial Stimulator (ETS) and ETS Adapter	
<ul style="list-style-type: none"> • Connection to OR Cable • Connection to External Trial Stimulators (ETS) and ETS Adapter 	<i>Vercise™ DBS Leads DFU</i>

Programming: Clinician Programmer, Wand, and Remote Control	
<ul style="list-style-type: none"> Clinician Programmer Programming Leads 	<i>Vercise Neural Navigator 2.1 Programming Manual</i> <i>Vercise Neural Navigator 2.1 Programming Tutorial</i>
<ul style="list-style-type: none"> Connection of the Clinician Programmer to the External Trial Stimulator and IPG by Programming Wand 	<i>Vercise DBS Programming Wand DFU</i>
<ul style="list-style-type: none"> Instructions for Using the Remote Control 	<i>Vercise DBS Remote Control 3 DFU (Clinician)</i>
Leads: Standard and Directional Leads	
<ul style="list-style-type: none"> Intraoperative Testing Using the OR Cable Assembly, ETS and ETS Adapter Kit Contents Lead Implantation Specifications and Technical Data 	<i>Vercise DBS Leads DFU</i>
Adapters	
<ul style="list-style-type: none"> Vercise M8 Adapter 	<i>Vercise M8 Adapter DFU</i>
Surgical Tools and Accessories	
<ul style="list-style-type: none"> SureTek™ Burr Hole Cover 	<i>Burr Hole Cover DFU</i>
<ul style="list-style-type: none"> Suture Sleeves Lead Boot Lead Stop 	<i>Vercise DBS Leads DFU</i>
<ul style="list-style-type: none"> Tunneling Tool 	<i>Vercise Gevia 16 Contact Implantable Pulse Generator DFU</i>
Labeling Symbols	
<ul style="list-style-type: none"> Labeling Symbols 	<i>Vercise DBS Labeling Symbols for Clinicians</i>
Quick Start Guides for Patient Externals	
<ul style="list-style-type: none"> Instructions for Using the Remote Control 	<i>Using Your Vercise PC and Vercise Gevia Remote Control</i>
<ul style="list-style-type: none"> Charging the Stimulator 	<i>Using Your Vercise DBS Charging System</i>

Compatible Products

Model	Description
Implantable Products	
<ul style="list-style-type: none"> • DB-1200-S • DB-2201-30-DC • DB-2201-45-DC • DB-2201-30-AC • DB-2201-45-BC • DB-2202-30 • DB-2202-45 • NM-3138-55 • DB-4600-C • DB-9218-15 • DB-9218-55 	<p>Vercise Gevia 16 Contact Implantable Pulse Generator Kit 30cm Lead Kit 45cm Lead Kit 30cm Lead Kit 45cm Lead Kit Vercise Cartesia™ 30cm 8 Contact DBS Directional Lead Kit Vercise Cartesia™ 45cm 8 Contact DBS Directional Lead Kit 55cm 8 Contact Extension Kit SureTek Burr Hole Cover Kit 15cm Vercise M8 Adapter 55cm Vercise M8 Adapter</p>
Accessories and Spares	
<ul style="list-style-type: none"> • DB-5132-S • DB-9315 • DB-4100-A and SC-4100-A • DB-2500-C • DB-4605-C • DB-4252 and SC-4252 • DB-4254 and SC-4254 • DB-4320 and SC-4320 • DB-4108 and SC-4108 • SC-4275 • SC-4401 	<p>Vercise DBS External Trial Stimulator 2 (ETS 2) Vercise ETS Adapter OR Cable 1X8 and Extension Vercise Physician's Spare Kit SureTek Burr Hole Cover Spares Kit 28cm Straw Tunneling Tool 35cm Long Tunneling Tool Medical Adhesive O.R. Cable 2x8, 61cm and Extension Hex Wrench Precision Spectra™ IPG Port Plug</p>
Patient Products and Spares	
<ul style="list-style-type: none"> • DB-5552-1 • DB-5250-S • NM-6210 • NM-6315 • NM-6310 • NM-6600 • DB-64125-US • DB-6300-C • DB-6200-C • DB-6100-C • NM-6350 • NM-5312 • NM-5305 • NM-6300 and SC-6300 	<p>Vercise DBS Remote Control 3 Kit Vercise DBS Remote Control 3 Remote Control Holster USB Power Supply, Remote Control, Universal USB Power Supply, Remote Control, North America Patient Travel Case Vercise Charging System Vercise Charger Collar Accessories Vercise Charger Collar, Small Vercise Charger Collar, Medium Adhesive Kit Charger Base Station Power Supply & Adapter For Charger</p>

Clinician Programming	
• DB-7161 and NM-7161	Clinician Programmer
• DB-7161-R and NM-7161-R	Clinician Programmer (refurbished)
• DB-7105-N21	Vercise Neural Navigator 2.1 Installer
• DB-7101-S	SP3 Platform Update Installer
• DB-7190 and NM-7190	Programming Wand
• DB-7162 and NM-7162	CP Keyboard
• NM-7113	Tablet Pen
• NM-6317	Tablet Power Supply
• NM-4512	USB Splitter

A System that includes the Vercise PC or Vercise Gevia IPG and Vercise Cartesia Directional Lead (s) form the Vercise Directional System.

Vercise™ PC DBS System

List of Directions for Use (DFU)

Information	DFU
Intended Use/Indications for Use	
<ul style="list-style-type: none"> • Indications for Use 	<i>Vercise PC Information for Prescribers DFU</i>
Contraindications, Safety Information, General Device Information	
<ul style="list-style-type: none"> • Adverse Events Summary • Component Disposal • Contraindications • Device Description • Electromagnetic Compatibility • Information for Contacting Boston Scientific • MRI Information • Precautions • Sterilization • Storage and Handling • Warnings • Stimulator Battery Information 	<i>Vercise PC Information for Prescribers DFU</i>
MRI Guidelines	
<ul style="list-style-type: none"> • MRI Guidelines 	<i>ImageReady™ MRI Guidelines for Boston Scientific DBS Systems</i>
Summary of Clinical Data	
<ul style="list-style-type: none"> • Summary of Clinical Data 	<i>Deep Brain Stimulation for Parkinson's Disease Clinical Summary</i>
Vercise PC Implantable Pulse Generator (IPG) and Lead Extensions	
<ul style="list-style-type: none"> • Explant of Leads, Extensions, and IPG • IPG and Extension Implantation • IPG Registration • Stimulator Battery Information • Kit Contents • Specifications and Technical Data • Stimulator Programmable Characteristics • Vercise PC System Revisions and Replacement 	<i>Vercise PC Implantable Pulse Generator DFU</i>
OR Cable, OR Cable Extensions, External Trial Stimulator (ETS) and ETS Adapter	
<ul style="list-style-type: none"> • Connection to OR Cable • Connection to ETS and ETS Adapter 	<i>Vercise DBS Leads DFU</i>

Programming: Clinician Programmer, Wand, and Remote Control	
<ul style="list-style-type: none"> Clinician Programmer Programming Leads 	<i>Vercise Neural Navigator 2.1 Programming Manual</i> <i>Vercise Neural Navigator 2.1 Programming Tutorial</i>
<ul style="list-style-type: none"> Connection of the Clinician Programmer to the External Trial Stimulator and IPG by Programming Wand 	<i>Vercise DBS Programming Wand DFU</i>
<ul style="list-style-type: none"> Instructions for Using the Remote Control 	<i>Vercise DBS Remote Control 3 DFU (Clinician)</i>
Leads: Standard and Directional Leads	
<ul style="list-style-type: none"> Intraoperative Testing Using the OR Cable Assembly, ETS and ETS Adapter Kit Contents Lead Implantation Specifications and Technical Data 	<i>Vercise DBS Leads DFU</i>
Adapters	
<ul style="list-style-type: none"> Vercise M8 Adapter 	<i>Vercise M8 Adapter DFU</i>
Surgical Tools and Accessories	
<ul style="list-style-type: none"> SureTek Burr Hole Cover 	<i>Burr Hole Cover DFU</i>
<ul style="list-style-type: none"> Suture Sleeves Lead Boot Lead Stop 	<i>Vercise DBS Leads DFU</i>
<ul style="list-style-type: none"> Tunneling Tool 	<i>Vercise PC Implantable Pulse Generator DFU</i>
Labeling Symbols	
<ul style="list-style-type: none"> Labeling Symbols 	<i>Vercise DBS Labeling Symbols for Clinicians</i>
Quick Start Guides for Patient Externals	
<ul style="list-style-type: none"> Instructions for Using the Remote Control 	<i>Using Your Vercise PC and Vercise Gevia Remote Control</i>

Compatible Products

Model	Description
Implantable Products	
<ul style="list-style-type: none"> • DB-1140-S • DB-2201-30-DC • DB-2201-45-DC • DB-2201-30-AC • DB-2201-45-BC • DB-2202-30 • DB-2202-45 • NM-3138-55 • DB-4600-C • DB-9218-15 • DB-9218-55 	<p>Vercise PC Implantable Pulse Generator Kit</p> <p>30cm Lead Kit</p> <p>45cm Lead Kit</p> <p>30cm Lead Kit</p> <p>45cm Lead Kit</p> <p>Vercise Cartesia™ 30cm 8 Contact DBS Directional Lead Kit</p> <p>Vercise Cartesia™ 45cm 8 Contact DBS Directional Lead Kit</p> <p>55cm 8 Contact Extension Kit</p> <p>SureTek Burr Hole Cover Kit</p> <p>15cm Vercise M8 Adapter</p> <p>55cm Vercise M8 Adapter</p>
Accessories and Spares	
<ul style="list-style-type: none"> • DB-5132-S • DB-9315 • DB-4100-A and SC-4100-A • DB-2500-C • DB-4605-C • DB-4252 and SC-4252 • DB-4254 and SC-4254 • DB-4320 and SC-4320 • DB-4108 and SC-4108 • SC-4275 • SC-4401 	<p>Vercise DBS External Trial Stimulator 2 (ETS 2)</p> <p>Vercise ETS Adapter</p> <p>OR Cable 1X8 and Extension</p> <p>Vercise Physician's Spare Kit</p> <p>SureTek Burr Hole Cover Spares Kit</p> <p>28cm Straw Tunneling Tool</p> <p>35cm Long Tunneling Tool</p> <p>Medical Adhesive</p> <p>O.R. Cable 2x8, 61cm</p> <p>Hex Wrench</p> <p>Precision Spectra™ IPG Port Plug</p>
Patient Products and Spares	
<ul style="list-style-type: none"> • DB-5552-1 • DB-5250-S • NM-6210 • NM-6315 • NM-6310 • NM-6600 	<p>Vercise DBS Remote Control 3 Kit</p> <p>Vercise DBS Remote Control 3</p> <p>Remote Control Holster</p> <p>USB Power Supply, Remote Control, Universal</p> <p>USB Power Supply, Remote Control, North America</p> <p>Patient Travel Case</p>
Clinician Programming	
<ul style="list-style-type: none"> • DB-7161 and NM-7161 • DB-7161-R and NM-7161-R • DB-7105-N21 • DB-7101-S • DB-7190 and NM-7190 • NM-7162 and DB-7162 • NM-7113 • NM-6317 • NM-4512 	<p>Clinician Programmer</p> <p>Clinician Programmer (refurbished)</p> <p>Vercise Neural Navigator 2.1 Installer</p> <p>SP3 Platform Update Installer</p> <p>Programming Wand</p> <p>CP Keyboard</p> <p>Tablet Pen</p> <p>Tablet Power Supply</p> <p>USB Splitter</p>

Vercise DBS System

List of Directions for Use (DFU)

Information	DFU
Intended Use/Indications for Use	
<ul style="list-style-type: none"> • Indications for Use 	<i>Vercise DBS Physician Manual</i>
Summary of Clinical Data	
<ul style="list-style-type: none"> • Summary of Clinical Data 	<i>Deep Brain Stimulation for Parkinson's Disease Clinical Summary</i>
Contraindications, Safety Information, General Device Information	
<ul style="list-style-type: none"> • Adverse Events Summary • Component Disposal • Contraindications • Device Description • Electromagnetic Compatibility • Information for Contacting Boston Scientific • MRI Information • Package Contents • Precautions • Sterilization • Storage and Handling • Warnings 	<i>Vercise DBS Physician Manual</i>
MRI Guidelines	
<ul style="list-style-type: none"> • MRI Guidelines 	<i>ImageReady™ MRI Guidelines for Boston Scientific DBS Systems</i>
Charging System	
<ul style="list-style-type: none"> • Charging System Instructions 	<i>Vercise DBS Physician Manual</i>
Vercise Implantable Pulse Generator (IPG) and Lead Extensions	
<ul style="list-style-type: none"> • Explant of Leads, Extensions, and IPG • IPG and Extension Implantation • IPG Registration • Specifications and Technical Data • Stimulator Battery Information • Stimulator Programmable Characteristics • Vercise System Revisions and Replacement 	<i>Vercise DBS Physician Manual</i>
OR Cable, OR Cable Extensions, External Trial Stimulator	
<ul style="list-style-type: none"> • Connection to 1x8 OR Cable • Connection to External Trial Stimulator 	<i>Vercise DBS Physician Manual</i>

Programming: Clinician Programmer and Remote Control	
• Clinician Programmer	<i>Vercise DBS Programming Manual</i>
• Programming Leads	<i>Vercise DBS Programming Quick Start Guide</i>
• Instructions for Using the Remote Control	<i>Vercise DBS Physician Manual</i>
Leads: Standard	
• Intraoperative Testing Using the OR Cable Assembly and External Trial Stimulator	<i>Vercise DBS Physician Manual</i>
• Kit Contents	
• Lead Implantation	
• Specifications and Technical Data	
Adapters	
• Vercise M8 Adapter	<i>Vercise M8 Adapter DFU</i>
Surgical Tools and Accessories	
• SureTek Burr Hole Cover	<i>Burr Hole Cover DFU</i>
• Suture Sleeves	<i>Vercise DBS Physician Manual</i>
• Lead Boot	
• Lead Stop	
• Tunneling Tool	<i>Vercise DBS Physician Manual</i>
Labeling Symbols	
• Labeling Symbols	<i>Vercise DBS Labeling Symbols for Clinicians</i>
Quick Start Guides for Patient Externals	
• Instructions for Using the Remote Control	<i>Vercise Remote Control Quick Start Guide</i>
• Charging the Stimulator	<i>Using Your Vercise DBS Charging System</i>

Compatible Products

Model	Description
Implantable Products	
<ul style="list-style-type: none"> • DB-1110-C • DB-2201-30-DC • DB-2201-45-DC • DB-2201-30-AC • DB-2201-45-BC • NM-3138-55 • DB-4600-C • DB-9218-15 • DB-9218-55 	<ul style="list-style-type: none"> Vercise Implantable Pulse Generator Kit 30cm Lead Kit 45cm Lead Kit 30cm Lead Kit 45cm Lead Kit 55cm 8 Contact Extension Kit SureTek Burr Hole Cover Kit 15 cm Vercise M8 Adapter 55 cm Vercise M8 Adapter
Accessories and Spares	
<ul style="list-style-type: none"> • DB-5110-C • NM-6105 • DB-4100-A and SC-4100-A • DB-2500-C • DB-4605-C • DB-4252 and SC-4252 • DB-4254 and SC-4254 • DB-4320 and SC-4320 • SC-4275 • SC-4400 	<ul style="list-style-type: none"> Vercise DBS External Trial Stimulator (ETS 1) ETS Battery O.R. Cable, 1x8 and Extension Vercise Physician's Spare Kit SureTek Burr Hole Cover Spares Kit 28cm Straw Tunneling Tool 35cm Long Tunneling Tool Medical Adhesive Hex Wrench Precision™ IPG Port Plug
Patient Products and Spares	
<ul style="list-style-type: none"> • DB-5500-1 • DB-64125-US • DB-6300-C • DB-6200-C • DB-6100-C • NM-6350 • DB-5212-C • NM-3100 • NM-6600 • NM-5312 • NM-5305 • NM-6300 and SC-6300 	<ul style="list-style-type: none"> Vercise Remote Control Kit Vercise Charging System Vercise Charger Collar Accessories Vercise Charger Collar, Small Vercise Charger Collar, Medium Adhesive Kit Vercise Remote Control Remote Control Case Patient Travel Case Charger Base Station Power Supply & Adapter For Charger
Clinician Programming	
<ul style="list-style-type: none"> • DB-7101-204 • DB-7101-S • DB-7161 and NM-7161 • DB-7161-R and NM-7161-R • NM-4500 • DB-4511 and NM-4511 • NM-4512 • NM-4502 • DB-7162 and NM-7162 • NM-7113 • NM-6317 	<ul style="list-style-type: none"> Bionic Navigator 2.04 Installer SP3 Platform Update Installer Clinician Programmer Clinician Programmer (refurbished) IR Interface USB Serial Cable USB Splitter IR Interface Holder CP Keyboard Tablet Pen Tablet Power Supply

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