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Boston Scientific Deep Brain Stimulation Reference Guide

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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 the 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 the 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

This Reference Guide provides information for the DBS System in a table format. Use the highlighted rows to locate the information of interest to you (e.g. indications, implantable pulse generator, or programming).

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>
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>
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>
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 • Kit Contents • 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	
<ul style="list-style-type: none"> • Clinician Programmer • Programming leads 	<i>Vercise DBS Programming Manual</i>
<ul style="list-style-type: none"> • Instructions for using the Remote Control 	<i>Vercise DBS Physician Manual</i>

Leads: Standard	
<ul style="list-style-type: none"> • Intraoperative testing using the OR Cable Assembly and External Trial Stimulator • Kit contents • Lead implantation • Specifications and Technical data 	<i>Vercise DBS Physician Manual</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 Physician Manual</i>
<ul style="list-style-type: none"> • Tunneling Tool 	<i>Vercise DBS Physician Manual</i>
Warranty: IPG, Leads, Extensions, Externals	
<ul style="list-style-type: none"> • Limited Warranty 	<i>Vercise DBS Physician Manual</i>
Labeling Symbols	
<ul style="list-style-type: none"> • Labeling Symbols 	<i>Vercise DBS Physician Manual</i>

Compatible Products

Model	Description
Implantable Products	
<ul style="list-style-type: none"> • DB-1110-C • DB-2201-30-DC and DB-2201-30-AC • DB-2201-45-DC and 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 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 • DB-4100A and SC-4100A • DB-2500-C • DB-4605-C • DB-4252 and SC-4252 • DB-4254 and SC-4254 • SC-4320 and DB-4320 • NM-6105 	<ul style="list-style-type: none"> Vercise DBS External Trial Stimulator (ETS 1) O.R. Cable and Extension Vercise Physician's Spare Kit SureTek Burr Hole Cover Spares Kit 28cm Straw Tunneling Tool 35cm Long Tunneling Tool Medical Adhesive ETS Battery
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 For Charger
Clinician Programming	
<ul style="list-style-type: none"> • DB-7101-204 • DB-7161 and NM-7161 • DB-7161-R, NM-7161-R • NM-4500 • NM-4511 and DB-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 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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