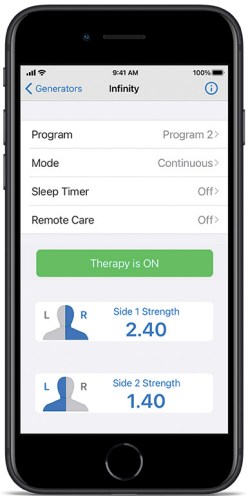
Abbott

St. Jude Medical™ Patient Controller

4.6. Model 65600 iPhone‡ SE Mobile Digital Device



Compatibility

- Model 6660 Infinity™ 5 IPG
- Model 6661* Infinity™ 5 IPG with Medtronic‡ Header
- Model 6662 Infinity™ 7 IPG
- Model 6663* Infinity™ 7 IPG with Medtronic‡ Header

PRODUCT SPECIFICATIONS

SPECIFICATION	METRIC	IMPERIAL
Height	13.84 cm	5.45 in
Width	6.73 cm	2.65 in
Depth	0.73 cm	0.29 in
Weight	148 g	5.22 oz

HARDWARE SPECIFICATIONS	
Device	Apple‡ iPhone‡ SE mobile digital device, 2nd generation
Display	4.7 in widescreen, retina HD display
Resolution	1334 × 750 at 326 pixels per inch
Battery	Built-in rechargeable lithium ion
Wireless	Bluetooth® 5.0 wireless technology
Input	Touch-screen, on-screen keyboard

SOFTWARE SPECIFICATIONS	
iOS‡ App	Patient Controller compatible with iOS‡ software version 12.4 or later
Description	Enables patient-controlled therapy adjustment of the Infinity™ DBS System
Developer	Abbott

IPG = implantable pulse generator

*Models 6661 and 6663 are directly compatible with Medtronic‡ lead models 3387 or 3389 and extension models 37085-40, 37085-60, 37086-40, 37086-60 and 37086-95 available before May 5, 2015. Models are not MR Conditional.

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Brief Summary: Prior to using Abbott devices, please review the Clinician's Manual for a complete listing of indications, contraindications, warnings, precautions, potential adverse events, and directions for use. The system is intended to be used with leads and associated extensions that are compatible with the system.

Indications for Use: Unilateral or bilateral stimulation of the thalamus, internal globus pallidus (GPi), or subthalamic nucleus (STN) in patients with levodopa-responsive Parkinson's disease, unilateral or bilateral stimulation of the ventral intermediate nucleus (VIM) of the thalamus for the management of disabling tremor, and unilateral or bilateral stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) for the management of intractable, chronic dystonia, including primary and secondary dystonia, for patients who are at least 7 years old.

Contraindications: Patients who are unable to operate the system or for whom test stimulation is unsuccessful. Diathermy and magnetic resonance imaging are contraindicated for patients with a deep brain stimulation system.

Warnings/Precautions: Return of symptoms due to abrupt cessation of stimulation (rebound effect), excessive or low frequency stimulation, risk of depression and suicide, implanted cardiac systems or other active implantable devices, magnetic resonance imaging (MRI), electromagnetic interference (EMI), proximity to electrosurgery devices and high-output ultrasonics and lithotripsy, ultrasonic scanning equipment, external defibrillators, and therapeutic radiation, therapeutic magnets, radiofrequency sources, explosive or flammable gases, theft detectors and metal screening devices, case damage, activities requiring excessive twisting or stretching, operation of machinery and equipment, and pregnancy. Loss of coordination is a possible side effect of DBS Therapy, exercise caution when doing activities requiring coordination (for example, swimming), and exercise caution when bathing. Patients who are poor surgical risks, with multiple illnesses, or with active general infections should not be implanted.

Adverse Effects: Loss of therapeutic benefit or decreased therapeutic response, painful stimulation, persistent pain around the implanted parts (e.g. along the extension path in the neck), worsening of motor impairment, paresis, dystonia, sensory disturbance or impairment, speech or language impairment, and cognitive impairment. Surgical risks include intracranial hemorrhage, stroke, paralysis, and death. Other complications may include seizures and infection. Clinician's Manual must be reviewed for detailed disclosure.

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