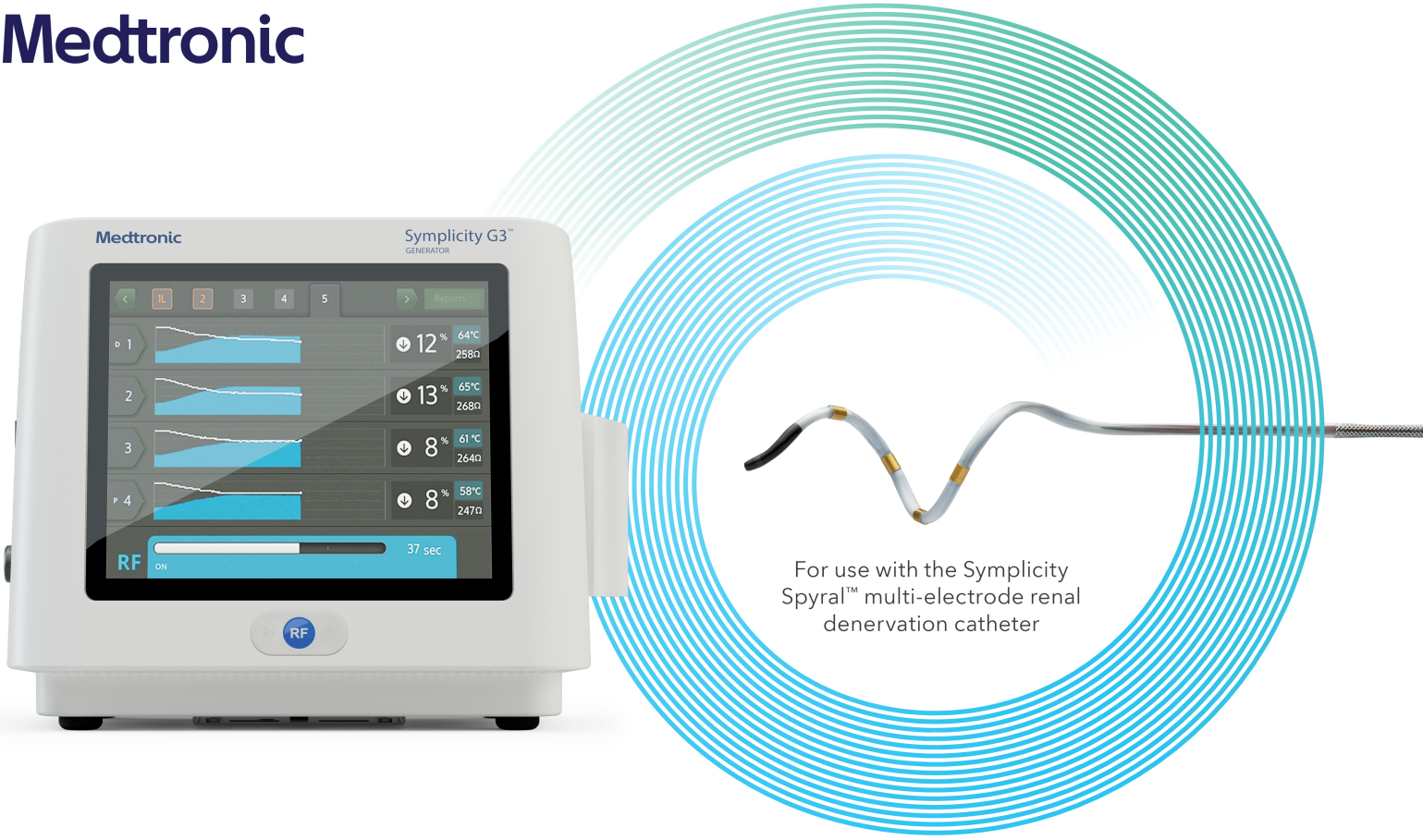
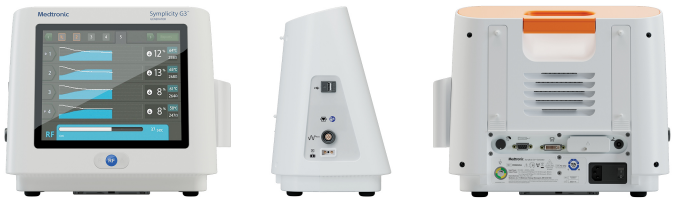
Medtronic



Symplicity G3™ renal denervation RF generator

Precise, safe, and effective†[1-5]

As part of the Symplicity Spyral™ renal denervation system, the **Symplicity G3 generator** employs a real-time responsive algorithm that automatically adjusts power by monitoring temperature and impedance for safe energy distribution.[5]



RDNG3A

- Dimensions: 29.9 cm x 36.7 cm x 18.9 cm (11.8 in x 14.5 in x 7.5 in)
- Weight: 20 lbs excluding accessories
- Display screen: 26.4 cm (10.4 in)

Materials

- Painted and nonpainted sheet metal
- Polycarbonate/acrylonitrile butadiene styrene blend (external covers)
- Thermoplastic elastomer (cord management strap)
- Glass (projected capacitance touchscreen)

Cart

ABS plastic

Accessories

AC power cables

NEMA 5-15	3.0 m

Included

- Remote control
- DVI-D cable

Optional

Mobile cart

Sold separately

- Symplicity Spyral catheter
- 0.014" guidewire (recommend non-hydrophilic with a supportive shaft and floppy tip)
- 4 F catheter‡ compatible with 6 F guide catheter (90 cm max length)
- Dispersive electrode for RDNG3A: Compatible with Polyhesive™ adult patient return electrode (Model E7507, E7507-DB)

Technical specs

- RF power output to a maximum of 6.5 W per electrode (26 W total)
- Delivers energy if measured impedance is ≥ 175 ohms and ≤ 1,200 ohms
- Input power of 100 to 240 V ~, 50 to 60 Hz universal power supply

Refer to the Instructions for Use (IFU) and User Manual for full product information.

†Results may vary.

‡Catheter dimension of 0.052" is average maximum diameter determined during design verification. Upper bound allowable is 0.061".

[1] Böhm M, Kario K, Kandzari DE, et al. Efficacy of catheter-based renal denervation in the absence of antihypertensive medications (SPYRAL HTN-OFF MED Pivotal): a multicentre, randomised, sham-controlled trial. *Lancet*. May 2, 2020;395(10234):1444-1451.

[2] Mahfoud F, Kandzari DE, Kario K, et al. Long-term efficacy and safety of renal denervation in the presence of antihypertensive drugs (SPYRAL HTN-ON MED): a randomised, sham-controlled trial. Lancet. April 9, 2022;399(10333):1401–1410.

[3] Townsend RR, Mahfoud F, Kandzari DE, et al. Catheter-based renal denervation in patients with uncontrolled hypertension in the absence of antihypertensive medications (SPYRAL HTN-OFF MED): a randomised, sham-controlled, proof-of-concept trial. *Lancet*. November 11, 2017;390(10108):2160-2170.

[4] Mahfoud F, Mancia G, Schmieder R, et al. Three-year safety and efficacy in the Global Symplicity Registry: Impact of antihypertensive medication burden on blood pressure reduction. Presented at PCR e-course 2020.

[5] Coates P, Tunev S, Trudel J, Hettrick DA. Time, Temperature, Power, and Impedance Considerations for Radiofrequency Catheter Renal Denervation. *Cardiovasc Revasc Med*. September 2022;42:171-177.

Indications
The Symplicity Spyral™ renal denervation system is indicated to reduce blood pressure as an adjunctive treatment in patients with hypertension in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure.

Contraindications
The Symplicity Spyral system is contraindicated in patients with any of the following conditions: • Renal artery diameter < 3 mm or > 8 mm • Renal artery fibromuscular dysplasia (FMD) • Stented renal artery (< 3 months prior to RDN procedure) • Renal artery aneurysm • Renal artery diameter stenosis > 50% • Pregnancy • Presence of abnormal kidney (or secreting adrenal) tumor • Iliac/femoral artery stenosis precluding insertion of the catheter.

Warnings and Precautions
A thorough understanding of the technical principles, clinical applications, and risks associated with vascular access techniques and percutaneous transluminal catheterization in renal arteries is necessary before using this device.

The safety and efficacy of the Symplicity Spyral system has not been established in patients with isolated systolic hypertension or in patients with prior renal artery interventions including renal stents, renal angioplasty, or prior renal denervation. The Symplicity Spyral system has not yet been studied in patients who are breastfeeding, under the age of 18, or with secondary hypertension. • Avoid treatment with the Symplicity Spyral™ catheter within 5 mm of any diseased area or stent. • Implantable pacemakers (IPGs) and implantable cardioverter defibrillators (ICDs) or other active implants may be adversely affected by RF ablation. Refer to the implantable device's *Instructions for Use*. • The patient's heart rate may drop during the ablation procedure. • Proper pain medication should be administered at least 10 min before ablating renal nerves.

Potential Adverse Events
Potential adverse events associated with use of the renal denervation device or the interventional procedures include, but are not limited to, the following conditions: • Allergic reaction to contrast • Arterial damage, including injury from energy application, dissection, or perforation • Arterial spasm or stenosis • Arterio-enteric fistula • AV fistula • Bleeding • Blood clots or embolism • Bruising • Cardiopulmonary arrest • Complications associated with medications commonly utilized during the procedure, such as narcotics, anxiolytics, or other pain or anti-vasospasm medications • Death • Deep vein thrombosis • Edema • Electrolyte imbalance • Heart rhythm disturbances, including bradycardia • Hematoma • Hematoma – retroperitoneal • Hematuria • Hypertension • Hypotension (may cause end organ hypoperfusion) • Infection • Kidney damage including renal failure or perforation • Myocardial infarction • Nausea or vomiting • Pain or discomfort • Peripheral ischemia • Pulmonary embolism • Proteinuria • Pseudoaneurysm • Radiocontrast nephropathy • Renal artery aneurysm • Skin burns from failure of the dispersive electrode pad • Stroke • Other potential adverse events that are unforeseen at this time.

Please reference appropriate product *Instructions for Use* and *User Manual* for more information regarding indications, contraindications, warnings, precautions, and potential adverse events.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

For further information, please call and/or consult Medtronic at 707-525-0111 or Medtronic's website at medtronic.com.

Medtronic.com/SymplicityProcedure

Medtronic