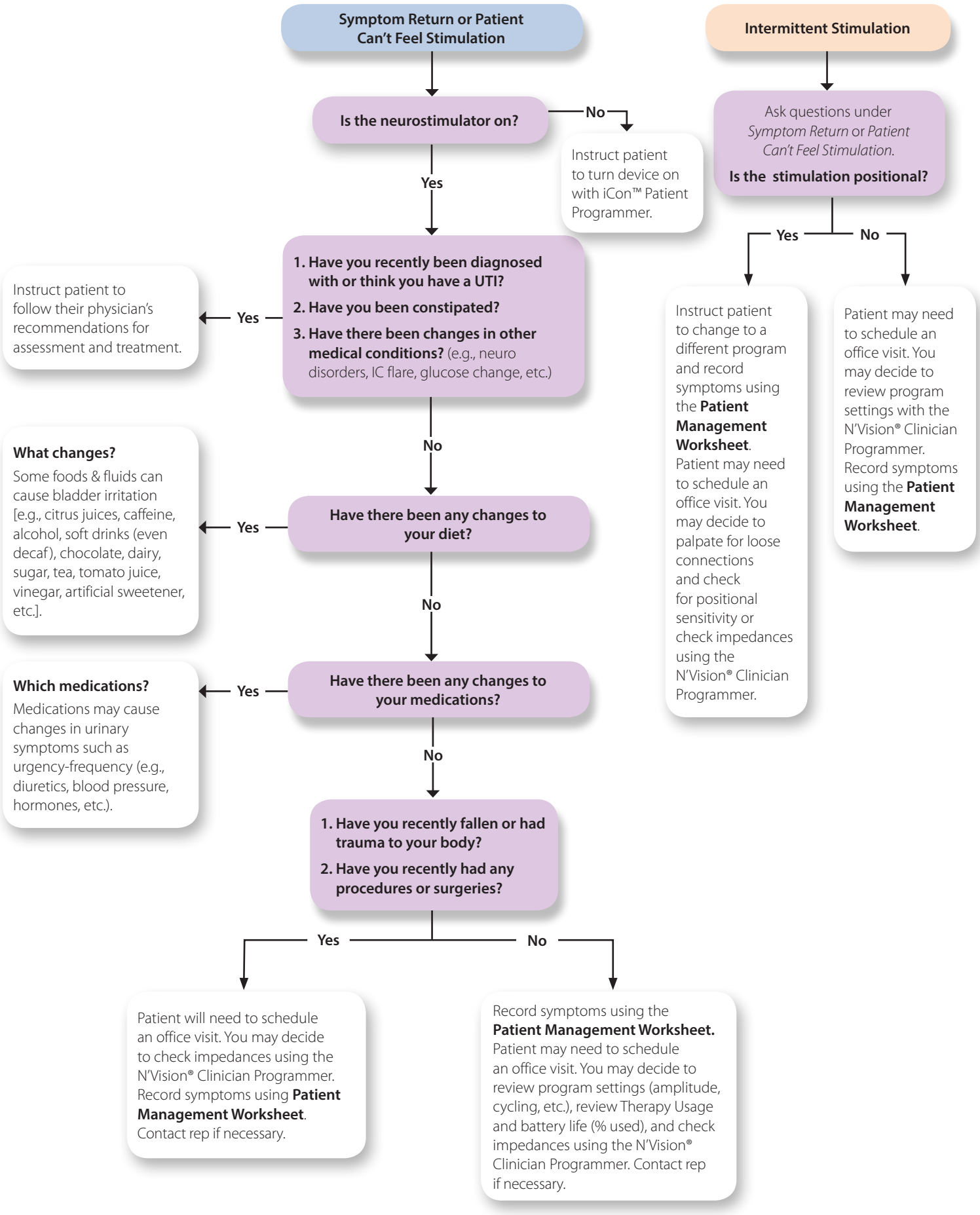
Medtronic

Sacral Neuromodulation with the InterStim® System

PATIENT MANAGEMENT GUIDE

Innovating for life.

This document offers suggested best practices for implementing Manage-By-Fact in a practice. Programming decisions are the responsibility of the clinician and are based on the ability to establish settings that will provide optimal patient symptom relief, minimize patient discomfort and maintain neurostimulator battery life to the best possible extent.



Pain in the INS pocket

Ask questions under *Symptom Return* or *Patient Can't Feel Stimulation.*

Instruct patient to turn device off.

Do you still feel pain?

Yes

The pain is unlikely related to stimulation. Rule out "non-stimulation" pain (e.g., incision healing/pulling, seroma, skin staples, infection, falls/trauma, etc.). Instruct patient to follow their physician's recommendations for assessment and treatment.

No

Patient will need to schedule an office visit. You may decide to change settings using the N'Vision® Clinician Programmer. If electrode setting is unipolar, program a bipolar setting using the standard programs. Record symptoms using **Patient Management Worksheet.** Contact rep if necessary.

Uncomfortable Stimulation

Ask questions under *Symptom Return* or *Patient Can't Feel Stimulation.*

Instruct patient to adjust to a comfortable level with iCon™ Programmer or change to a different program in iCon™ Programmer.

Do you still feel uncomfortable stimulation?

Yes

Patient will need to schedule an office visit. You may decide to adjust rate or pulse width to a comfortable level using the N'Vision® Clinician Programmer. Record symptoms using **Patient Management Worksheet.** Contact rep if necessary.

No

Educate patient on use of iCon™ Patient Programmer.

Shocking/Jolting Sensation

Ask questions under *Symptom Return* or *Patient Can't Feel Stimulation.*

Instruct patient to turn device off.

Do you still feel the shocking/jolting sensation?

Yes

The sensation is unlikely related to stimulation. Instruct patient to follow their physician's recommendations for assessment and treatment.

No

Patient will need to schedule an office visit. You may decide to adjust rate or pulse width to a comfortable level using the N'Vision® Clinician Programmer. Record symptoms using **Patient Management Worksheet**. Contact rep if necessary.

Patients <u>with</u> a Patient Management Worksheet on file:

1. Instruct patient to record symptoms using a Voiding Diary for a minimum of 3 days and call back with results.
   a. If >50% improvement from baseline: Review patient expectations. Reassure patient that stimulation is on. Turning device off may indicate therapy is working as intended.
   b. If <50% improvement from baseline: Instruct patient to try the other program(s) in iCon™ Programmer.
2. If necessary, repeat step 1 to evaluate other programs in the iCon™ Programmer. Advise patient to evaluate each program for a minimum of 3 days and record symptoms using a Voiding Diary.
3. If all 4 programs in iCon™ Programmer have been tried, schedule an office visit.

At appointment:

1. Review Voiding Diary information and fill out **Patient Management Worksheet**.
2. Run impedance check & review Therapy Usage using the N'Vision® Clinician Programmer.
3. Load other programs using the N'Vision® Clinician Programmer.
4. Advise patient to activate 1st program in iCon™ Programmer for a minimum of 3 days.

Post-appointment, instruct patient to:

1. If necessary, repeat with trying the other program(s) in iCon™ Programmer for a minimum of 3 days and record symptoms using a Voiding Diary.
2. Schedule an office visit if necessary.

Physicians can make the decision to REPROGRAM, REVISE or REMOVE the neurostimulator at any time.

Patients <u>without</u> a Patient Management Worksheet on file:

Instruct patient to:

1. Turn device off with iCon™ Patient Programmer (if device is on).
2. Record symptoms using a Voiding Diary for a minimum of 3 days.
3. Schedule an office visit.

At appointment:

1. Collect baseline diary information and fill out **Patient Management Worksheet**.
2. Run impedance check & review Therapy Usage using the N'Vision Clinician® Programmer.
3. Load 4 programs into iCon™ Programmer.
4. Advise patient to activate 1st program in iCon™ Programmer for a minimum of 3 days.

Post-appointment, instruct patient to:

1. If necessary, repeat with trying the other program(s) in iCon™ Programmer for a minimum of 3 days and record symptoms using a Voiding Diary.
2. Schedule an office visit if necessary.

Physicians can make the decision to REPROGRAM, REVISE or REMOVE the neurostimulator at any time.

Indications for Use:

InterStim® Therapy for Urinary Control is indicated for the treatment of urinary retention and the symptoms of overactive bladder, including urinary urge incontinence and significant symptoms of urgency-frequency alone or in combination, in patients who have failed or could not tolerate more conservative treatments.

The following Warning applies only to InterStim Therapy for Urinary Control:

Warning: This therapy is not intended for patients with mechanical obstruction such as benign prostatic hypertrophy, cancer, or urethral stricture.

InterStim® Therapy for Bowel Control is indicated for the treatment of chronic fecal incontinence in patients who have failed or are not candidates for more conservative treatments.

Contraindications for Urinary Control and for Bowel Control: Diathermy. Patients who have not demonstrated an appropriate response to test stimulation or are unable to operate the neurostimulator.

Precautions/Adverse Events:

For Urinary Control: Safety and effectiveness have not been established for bilateral stimulation; pregnancy, unborn fetus, and delivery; pediatric use under the age of 16; or for patients with neurological disease origins such as multiple sclerosis.

For Bowel Control: Safety and effectiveness have not been established for bilateral stimulation; pregnancy, unborn fetus, and delivery; pediatric use under the age of 18; or for patients with progressive, systemic neurological diseases.

For Urinary Control and for Bowel Control: The system may be affected by or adversely affect cardiac devices, electrocautery, defibrillators, ultrasonic equipment, radiation therapy, MRI, theft detectors/ screening devices. Adverse events include pain at the implant sites, new pain, lead migration, infection, technical or device problems, adverse change in bowel or voiding function, and undesirable stimulation or sensations, including jolting or shock sensations. For full prescribing information, please call Medtronic at 1-800-328-0810 and/or consult Medtronic's website at www.medtronic.com. Product technical manual must be reviewed prior to use for detailed disclosure.

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