MEDTRONIC IS COMMITTED TO THE BRAIN MODULATION BUSINESS

We alleviate pain, restore health and extend life by delivering a Medtronic brain modulation solution to every eligible patient.

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Off Label Disclosure Slide

Thank you for participating in this educational event!

This program, sponsored by Medtronic, is intended to *educate* and *train* customers regarding the **approved** or **cleared** uses of Medtronic products. As such, unapproved products or indications may not be presented or discussed during the program.

You may contact Medtronic's Office of Medical Affairs at 800.876.3133 ext. 6044 or rs.msdoma@medtronic.com for any specific clinical questions you may have.

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MEDTRONIC DBS THERAPY—
IMPROVING LIVES THEN, NOW, TOMORROW.

1980s

1987
Medtronic DBS Therapy is implanted for the first time in Grenoble, France.

1st implant

1990s

1995
10,000th person worldwide implanted with Medtronic DBS Therapy.

CE Mark approval in Europe for treating essential tremor and tremor associated with Parkinson's disease.

PD and ET Tremor

1997
Medtronic DBS Therapy receives Food and Drug Administration (FDA) approval to treat essential tremor and tremor associated with Parkinson's disease.

1998
Medtronic DBS Therapy approved in Europe for Parkinson's disease.

2000s

2002
Medtronic receives FDA approval of DBS Therapy for the treatment of Advanced PD.

Advanced PD

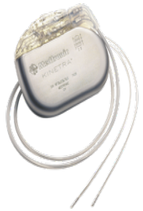
2003
Medtronic DBS Therapy receives approval in Europe and Humanitarian Device Exemption (HDE)* approval in the U.S. for managing the symptoms of primary dystonia.

Dystonia

2007
50,000th person worldwide implanted with Medtronic DBS Therapy.

2009
Medtronic DBS Therapy receives approval in Europe and an HDE* approval in the U.S. for the treatment of Obsessive-Compulsive Disorder.

OCD



2010s

2010
European approval of Medtronic DBS Therapy to treat medically refractory epilepsy patients with partial-onset seizures.†

2012
Medtronic DBS Therapy receives approval in Australia and Canada for the treatment of medically refractory epilepsy patients with partial-onset seizures.†

2015
CE Mark in Europe and FDA approval of full-body MR Conditional MRI scans under specific conditions. FDA Approval of Expanded Labeling

2016
140,000th person worldwide implanted with Medtronic DBS Therapy.

US Launch of Expanded PD Labeling

EU and US Launch of Full Body MRI Labeling (2015) US Launch of Expanded PD Labeling (2016)

2017
160,000th person worldwide implanted with Medtronic DBS Therapy

2018
Medtronic DBS Therapy receives Food and Drug Administration (FDA) approval to treat as an **adjunctive treatment for reducing the frequency of partial-onset seizures in those who are refractory to ≥3 antiepileptic medications.**

*Humanitarian device exemption (HDE) in the United States; the effectiveness of this device for the treatment of dystonia and obsessive-compulsive disorder (OCD) has not been demonstrated.

DBS for Refractory Epilepsy

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IMPLANTABLE SYSTEM COMPONENTS

Three Components*

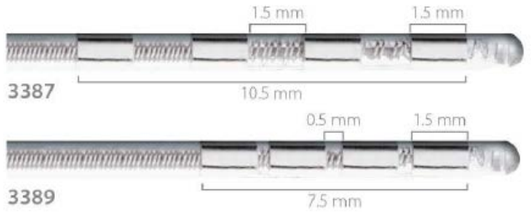
1. Implantable Neurostimulator (INS): Power
2. Extension: connects the INS to the lead
3. Lead: Implanted in the brain, electrodes in contact with target tissue

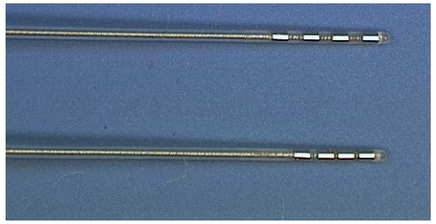
*Some systems may include a pocket adaptor

MEDTRONIC DBS SYSTEM FOR EPILEPSY

- **Activa PC Model 37601 Neurostimulator**

- **Model 3387/3389 DBS Lead**
  - The DBS Leads have four electrodes





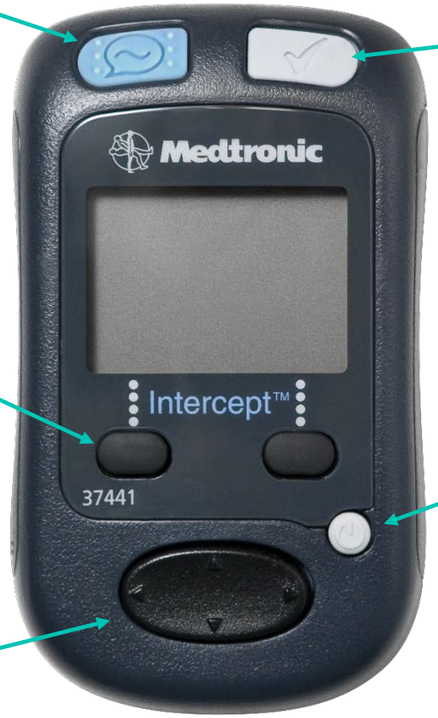
- **Model 37086 Extension**
  - Distal (Extension connection) end has four contacts
  - Available in lengths
    - 40 cm
    - **60 cm**
    - 95 cm
  - Stretch coil extension allows for up to15% extensibility

INTERCEPT™ PATIENT PROGRAMMER PC ONLY

Seizure Key
Used to log occurrence of a seizure or aura and restart stimulation cycle

Selection Keys
Used to turn therapy on and off
Clears the Seizure Confirmation screen

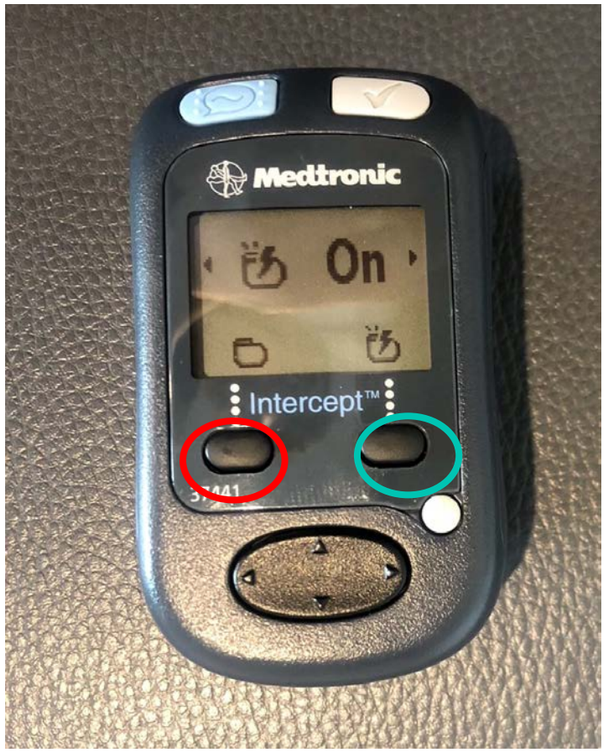
Navigator Key
Used to navigate to next available screen
Clears Information screens



Check Key
Used to synchronize the neurostimulator and patient programmer

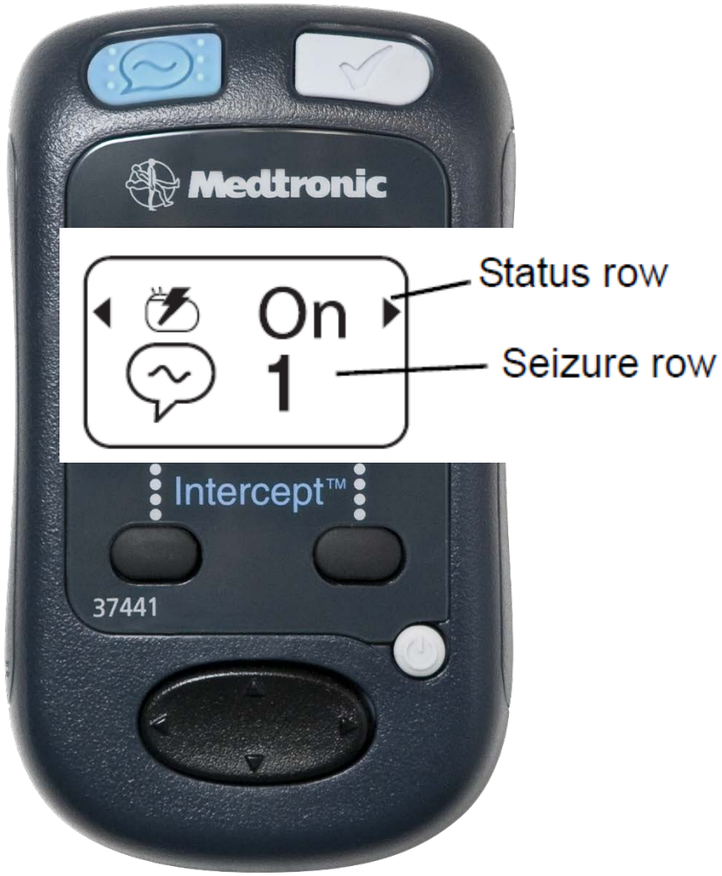
Power/Backlight On/Off Key
Used to turn the patient programmer and backlight on or off

HOW TO TURN NEUROSTIMULATOR ON AND OFF

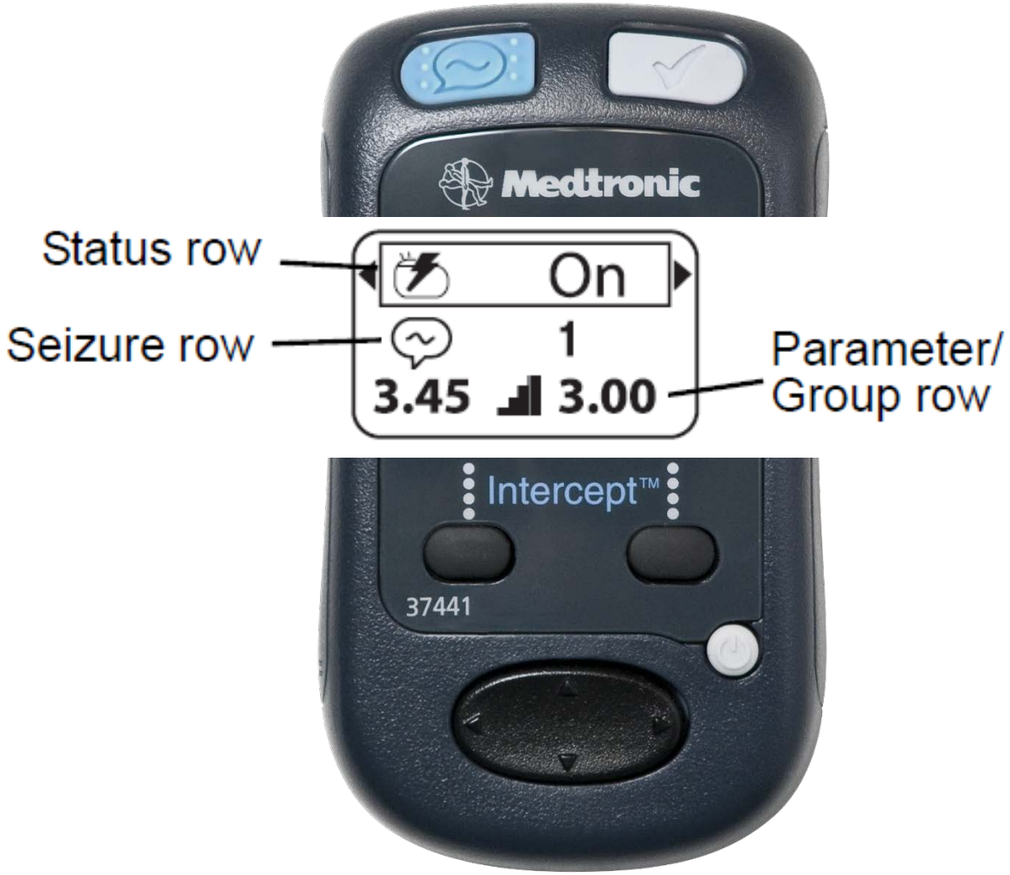


MODE THERAPY SCREEN

- **Simple Mode Therapy Screen shows:**
  - Therapy ON/OFF status
  - Seizure Count



- **Advanced Mode Therapy Screen shows:**
  - Therapy ON/OFF status
  - Seizure Count
  - Parameter settings and active group



INTERCEPT™ PATIENT PROGRAMMER MODES

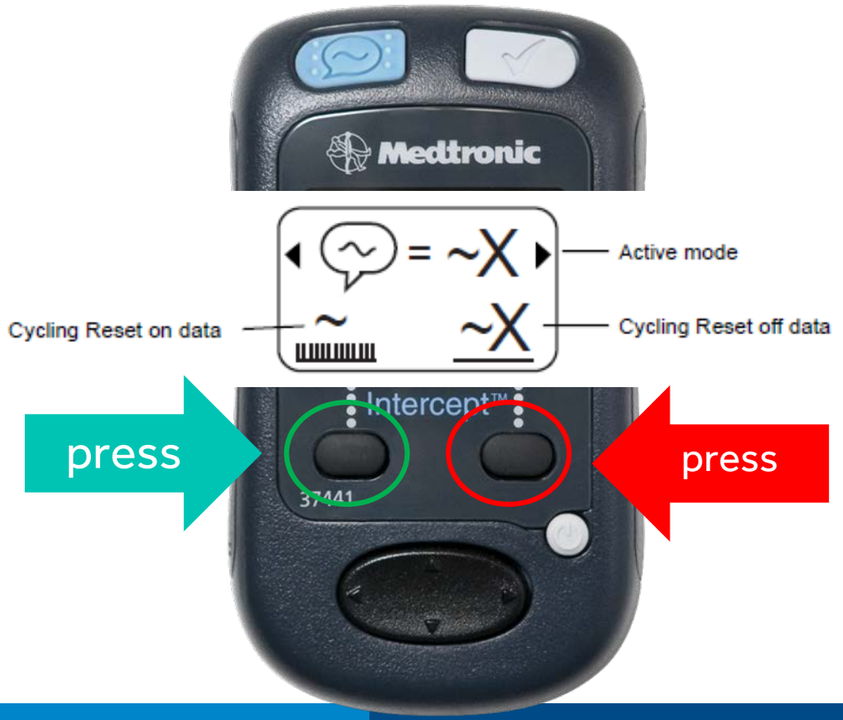
- There are three modes available
  - Simple Mode
  - Advanced View
  - Advanced Adjust
- Mode is determined by clinician based on patient needs

	Simple Mode	Advanced View	Advanced Adjust
Turn therapy ON/OFF	●	●	●
Check INS Battery Status	●	●	●
Daily Battery Check Reminder	●	●	●
Additional Patient Programmer Features	●	●	●
View Therapy Parameters		●	●
Change Groups		●	●
Ability to adjust stimulation within the patient limits that are set for one or more group(s).			●

SETTING SEIZURE MODE

- Turn patient programmer ON (do not interrogate)
- Press and hold Selection Keys until Lead Connections Screen Appears
- Navigate to Seizure Mode Screen
- Set to on or off
- This is meant to be utilized by HCP programmers only and NOT the patient

Note: Default setting for Seizure mode is off



DBS THERAPY FOR EPILEPSY
INITIAL PROGRAMMING ACTIVITIES

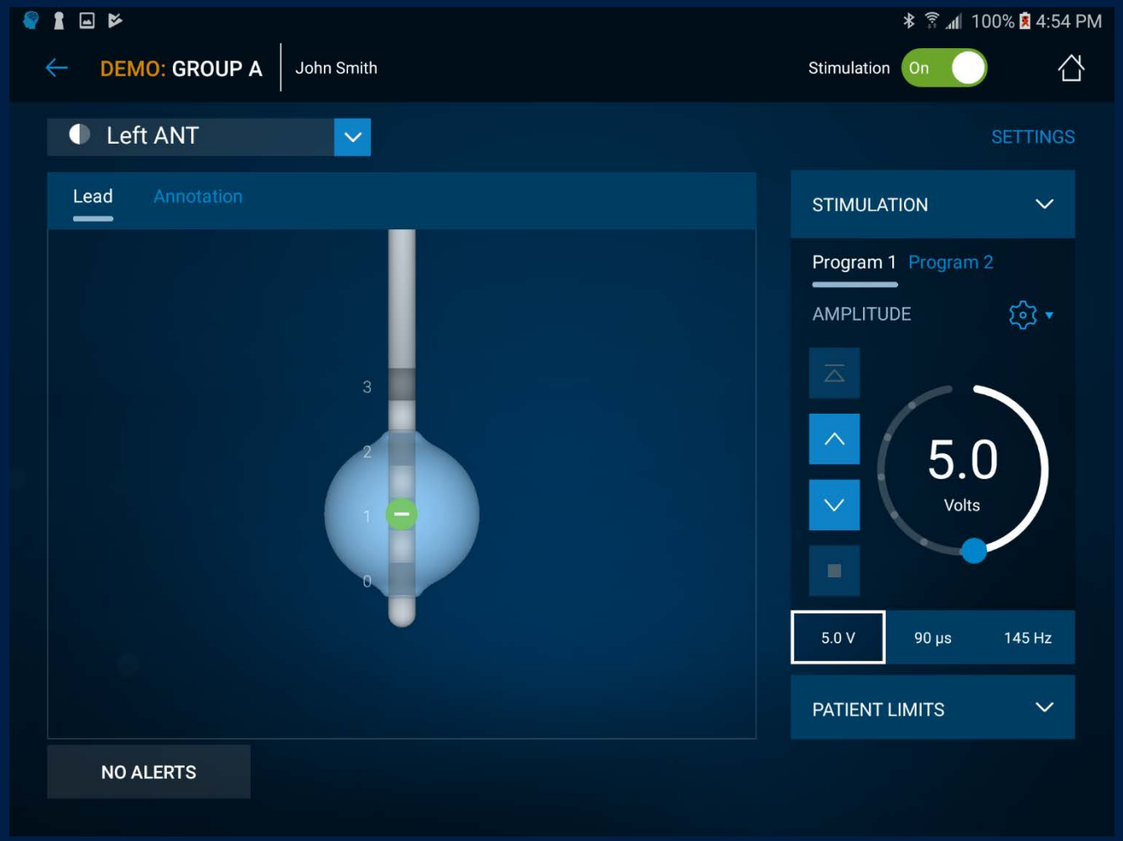
- Configure leads (completed in SET-UP)
- Verify system integrity (check electrode impedances)
- Program initial stimulation parameters
- Program the neurostimulator for patient control
- Provide patient and caregiver with instructions on use of patient programmer and tracking of seizures (count, type, severity)
- Emphasize adherence to AED regimen
- Verify tolerability of stimulation

SANTE STIMULATION PARAMETERS: EPILEPSY

Parameter	Typical Starting Value
Amplitude	5 V *In clinical practice clinicians may start at a lower amplitude and titrate up slower as they access patient response and tolerability.
Pulse Width	90 μs
Rate	145 Hz
Electrode Configuration	Unipolar Mode: Single electrode or two adjacent electrodes negative, case positive (all patients in the SANTE clinical trial were in unipolar mode)
Cycle of Therapy	Cycling mode ON: 1 minute on, 5 minutes off
SoftStart™Stop	programmed to 8 seconds

Tablet Clinician Programmer

Launched June 2018



Modern, usable interface.

Focus on control of stimulation and documentation of outcomes.

Intuitive patient management.

Medtronic

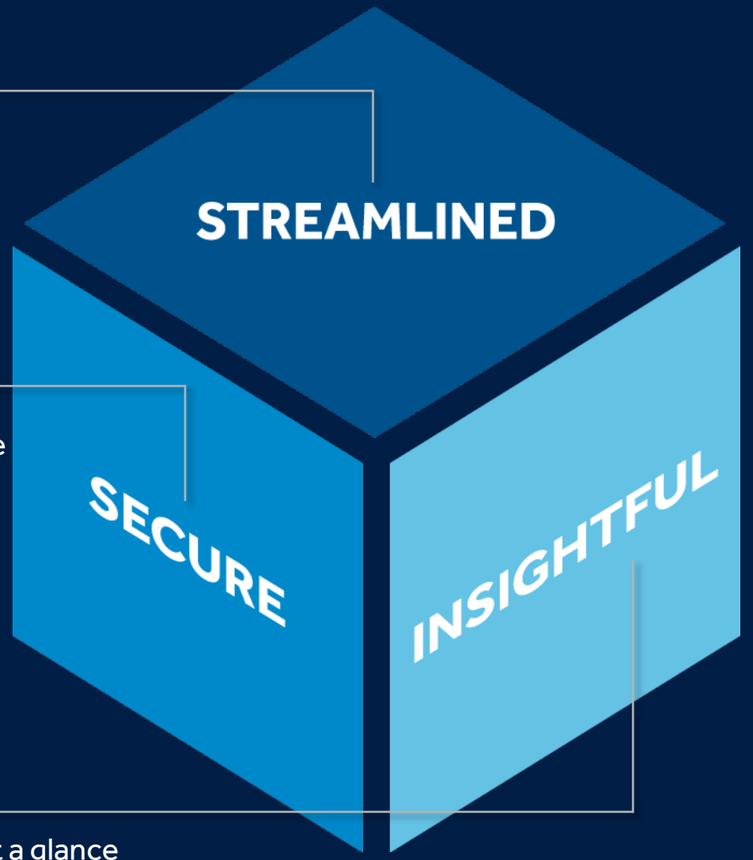
A SMARTER DBS JOURNEY
PLATFORM OVERVIEW

A new era of innovation from the only partner with **a 25-year DBS legacy, the Medtronic clinician programmer** offers easy navigation and an intuitive workflow over a safe and secure platform, so you can connect with patients with comfort and confidence.

STREAMLINING WORKFLOWS
Intuitive interface means more time focusing on your patient.

ENABLING SECURE PATIENT CONNECTIONS
Freedom to move with peace of mind.

INFORMATION MADE ACTIONABLE
Annotations and historical programming information at a glance that are saved in the patient's INS.



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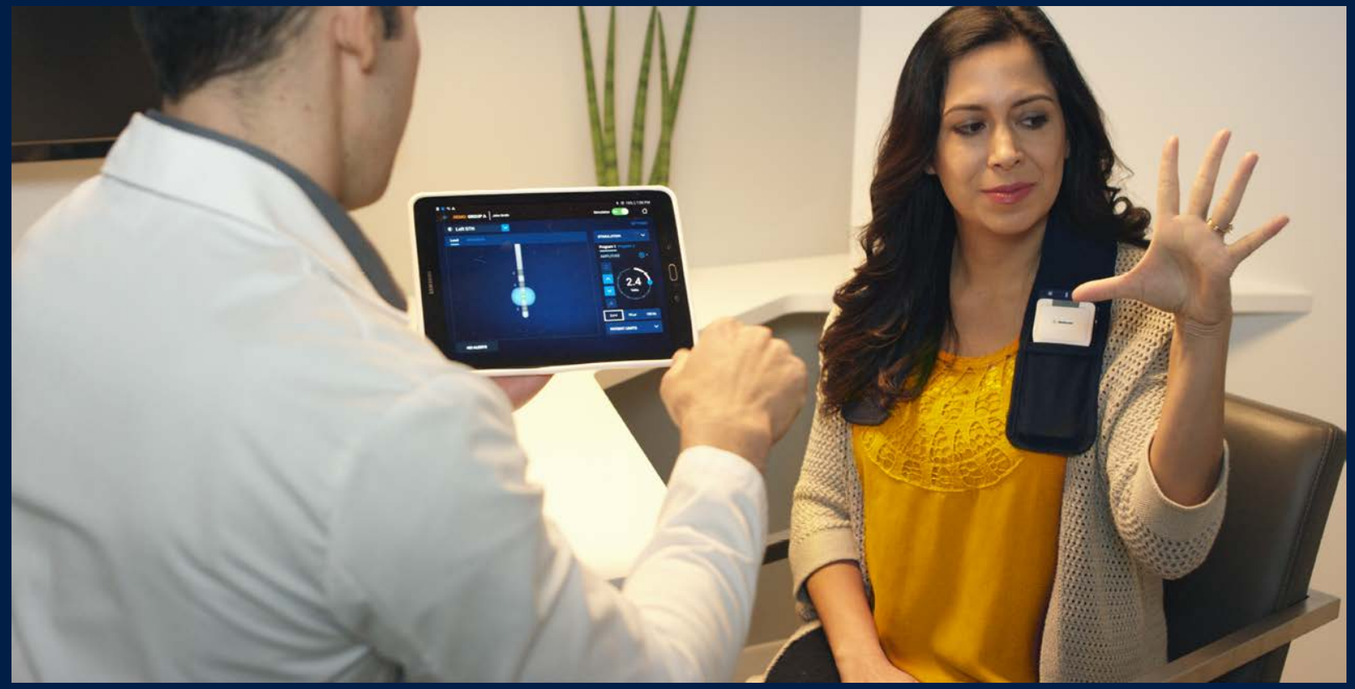
CLINICIAN PROGRAMMER & ACCESSORIES

COMMUNICATOR AND DRAPE



* Optional protective case and drape may be ordered from Medtronic

* *Activa App is NOT compatible with Soletra/Kinetra Neurostimulators

SYSTEM COMPONENTS

1.) TABLET *(with Activa App)

- Compatible with ALL Activa™ Family devices**

2.) COMMUNICATOR

- Encrypted Bluetooth connection from the programmer to the communicator
- Proprietary, proximal telemetry from the communicator to the implanted device

3.) DRAPE*

- Freedom of movement

INTENDED USE

-THIS DECK IS INTENDED TO BE USED TO TRAIN CLINICIANS ON THE MEDTRONIC CLINICIAN PROGRAMMER
-IT IS NOT INTENDED TO BE USED A SUBSTITUTE OR REPLACEMENT FOR THE LABELING
-INFORMATION CONTAINED HEREIN IS THE PROPERTY OF MEDTRONIC

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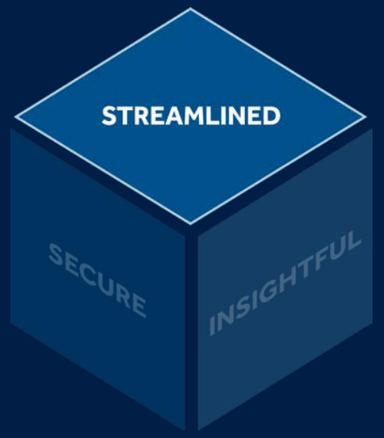
STREAMLINED

MODERN TECHNOLOGY UNLEASHED



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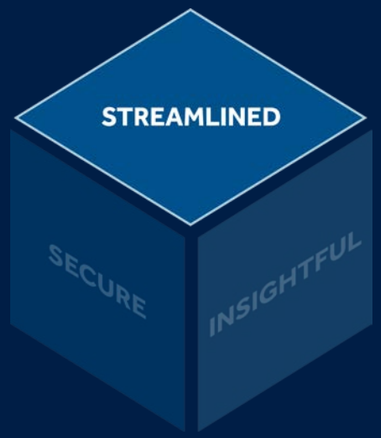
STREAMLINED

MODERN TECHNOLOGY
UNLEASHED



100% 9:02 AM

DEMO: CONNECT

SELECT DEVICE...

- Activa RC – new
- Activa RC
- Activa PC – new
- Activa PC
- Activa SC – new

CANCEL | RETRY | CONNECT

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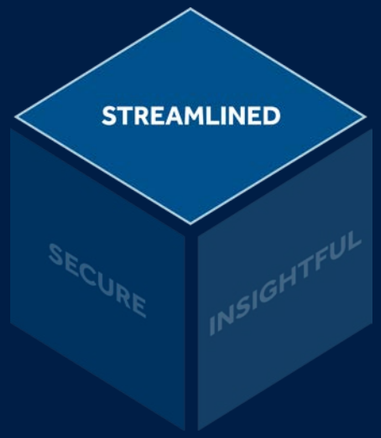
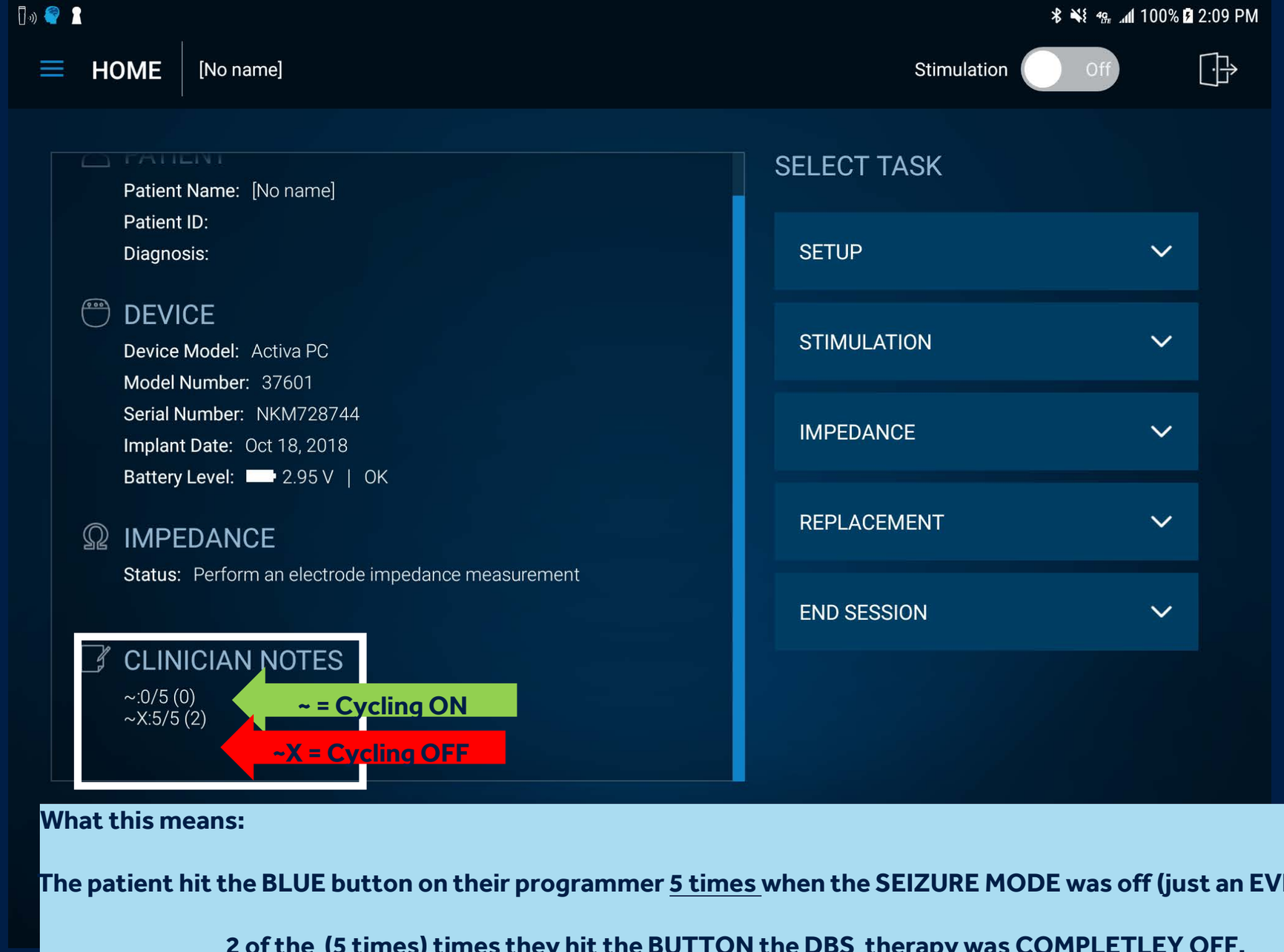
STREAMLINED

MODERN TECHNOLOGY
UNLEASHED

- ~:0/5- CYCLING ON
- ~X:5/5 – CYCLING OFF





What this means:

The patient hit the BLUE button on their programmer 5 times when the SEIZURE MODE was off (just an EVENT counter)

2 of the (5 times) times they hit the BUTTON the DBS therapy was COMPLETLEY OFF.
NUMBER in Brackets (2)

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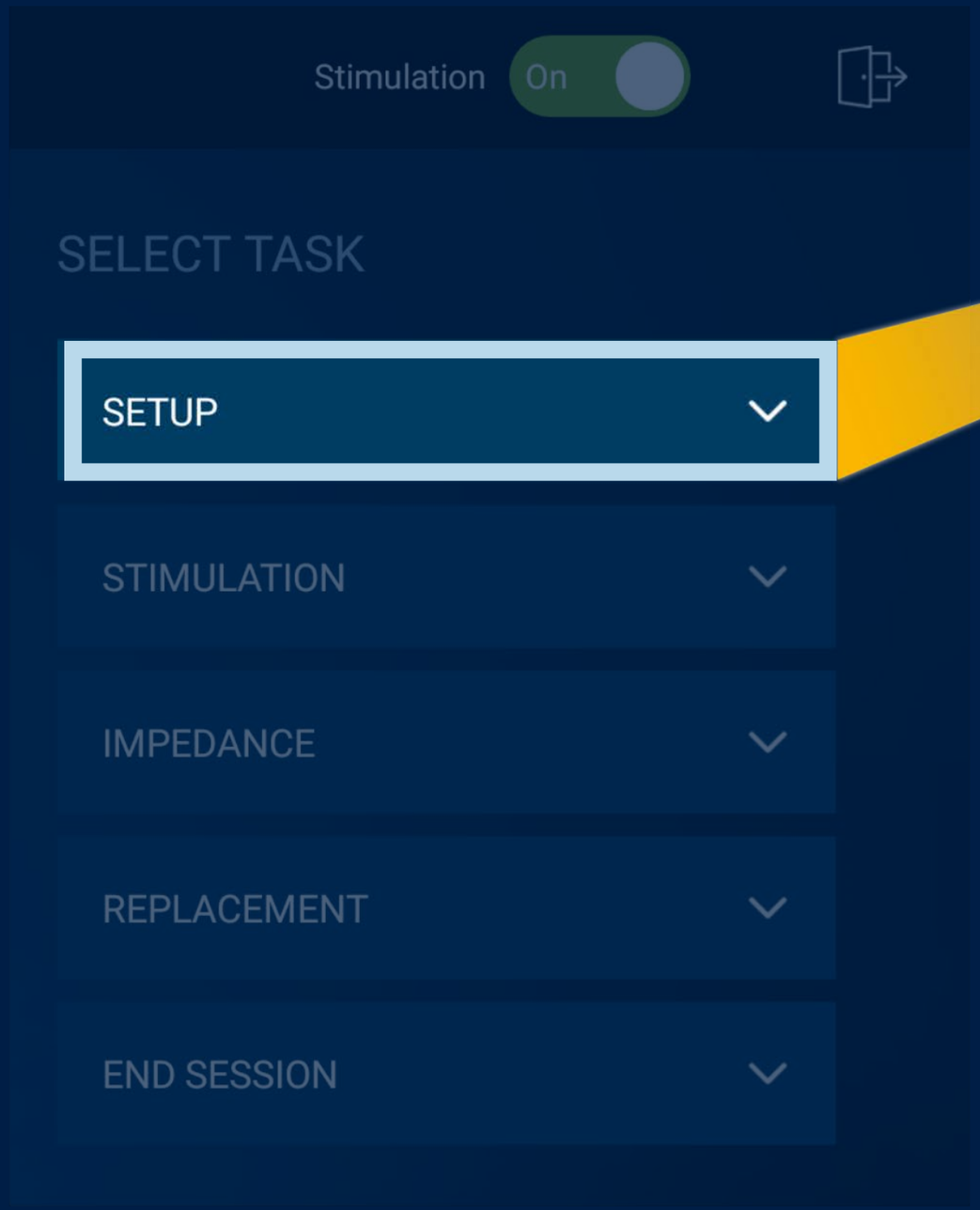
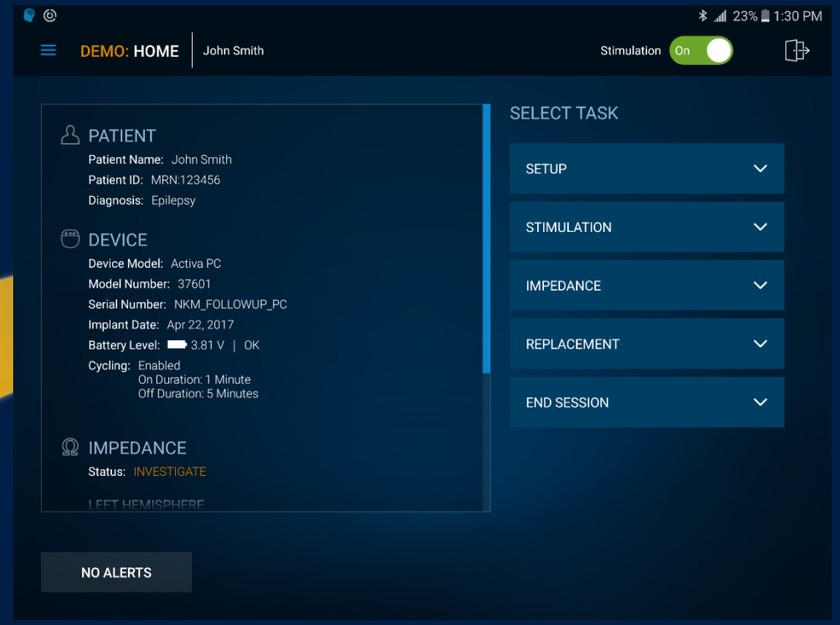
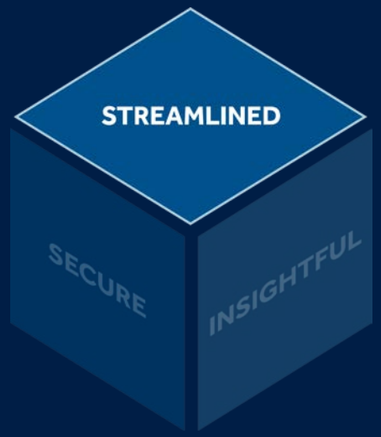
TASK BASED WORKFLOWS







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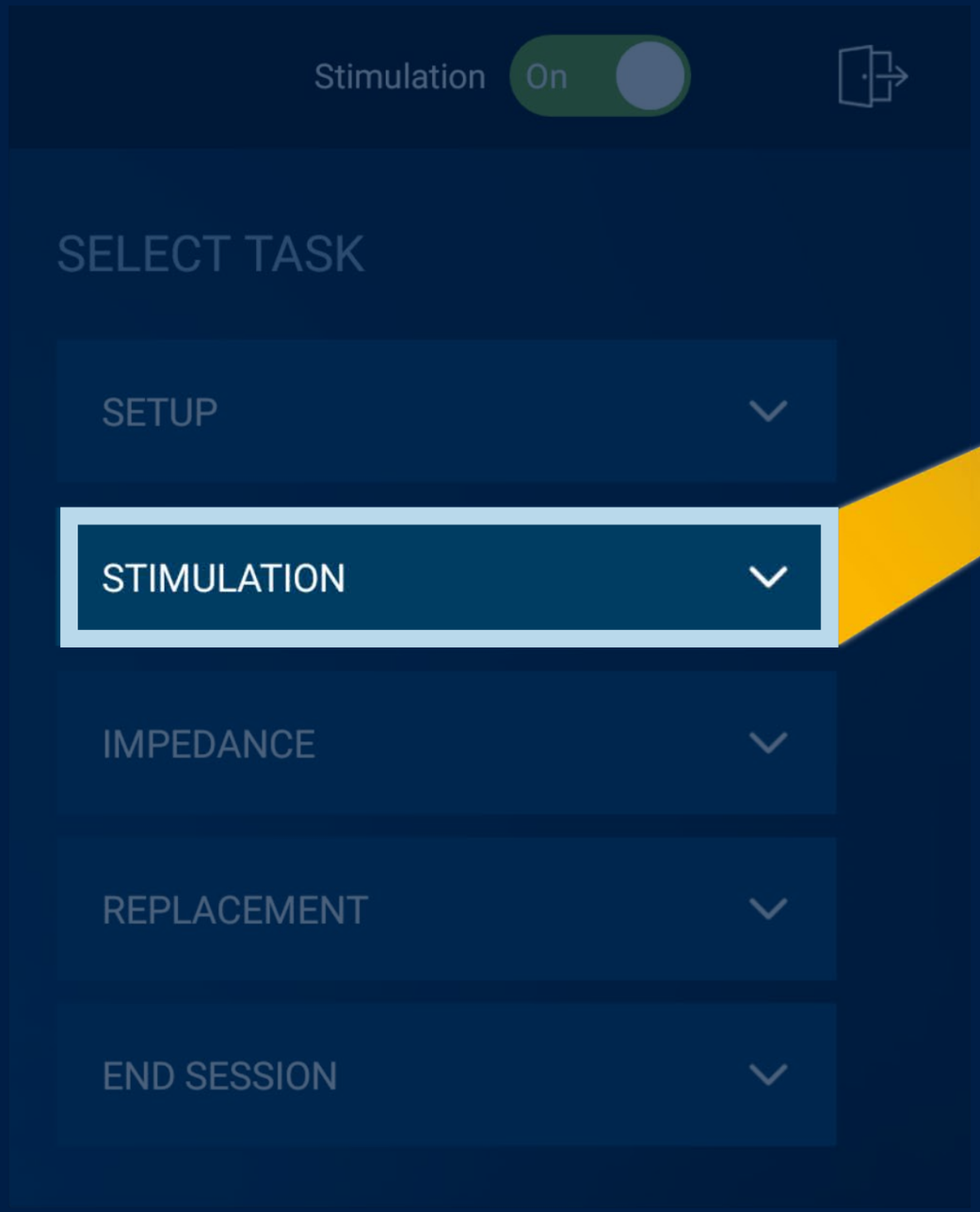
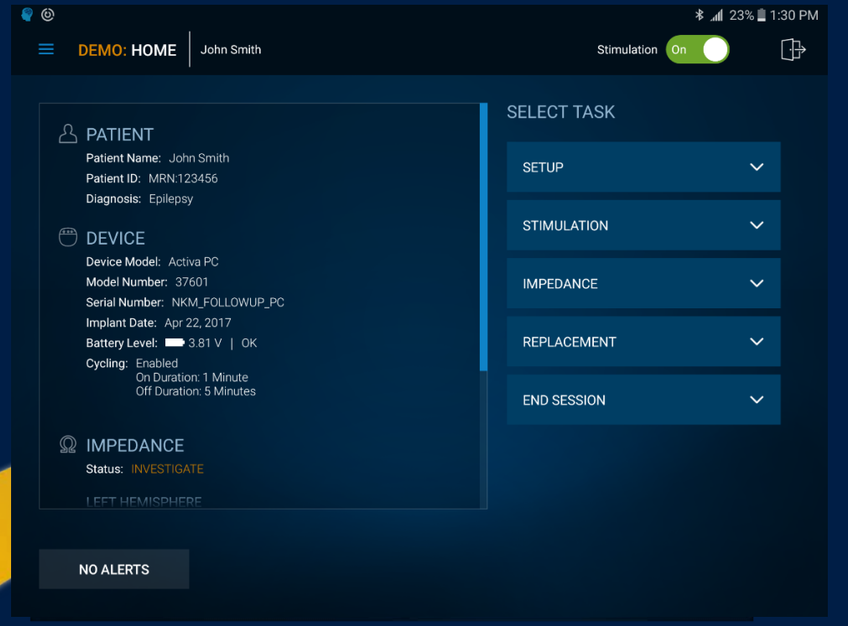
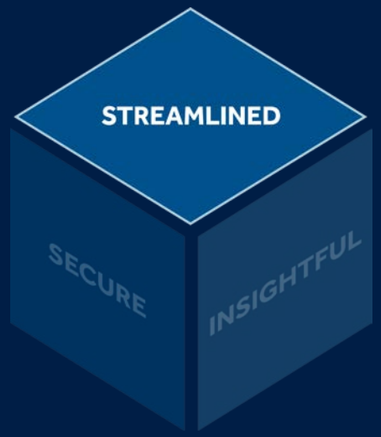
EASY TO NAVIGATE







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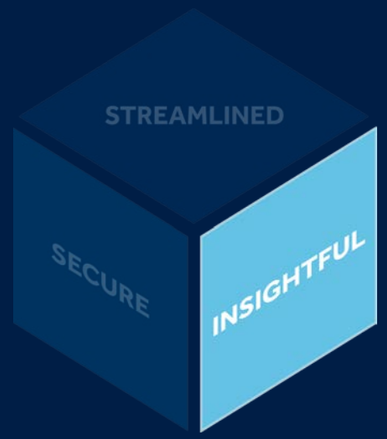
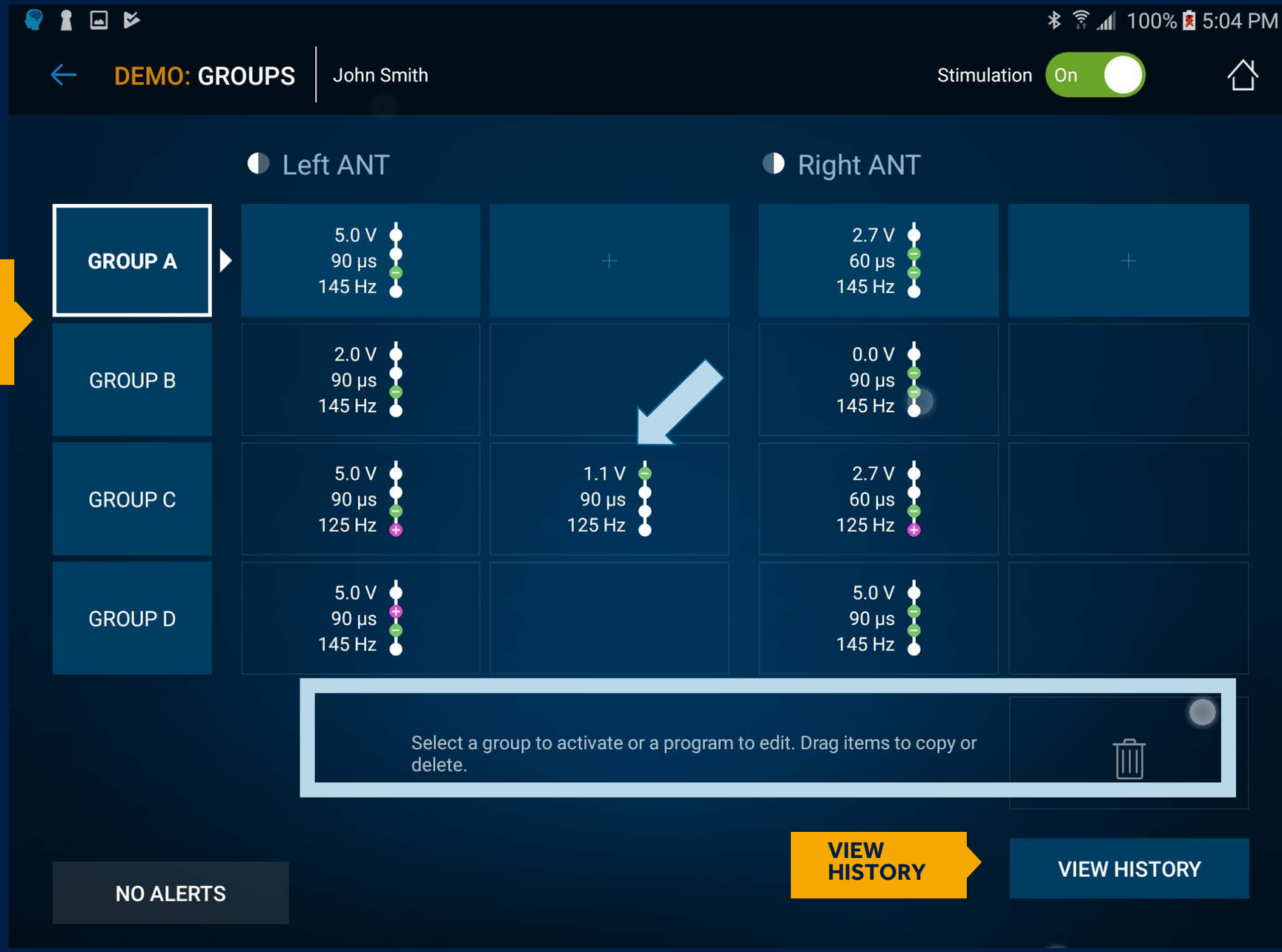
INSIGHTFUL

INFORMATION
YOU NEED

Group & Program
‘Management





DRAG AND DROP GROUPS

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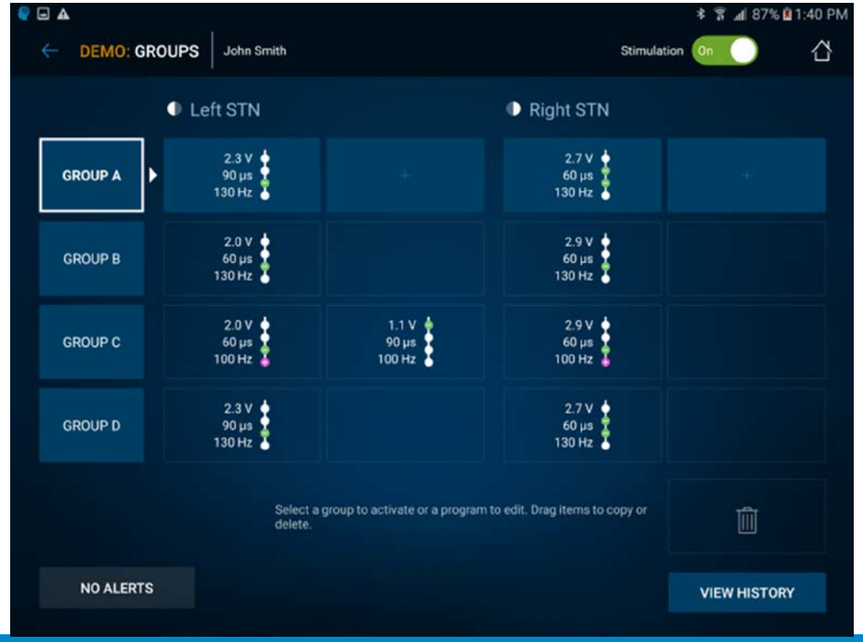
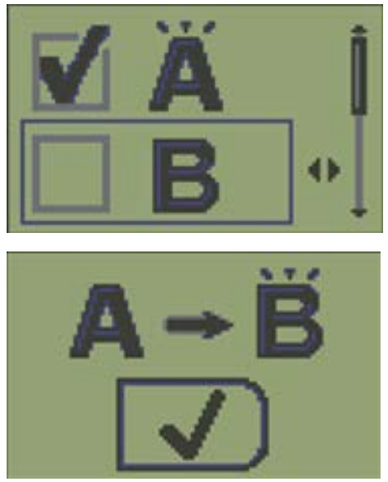
GROUPS

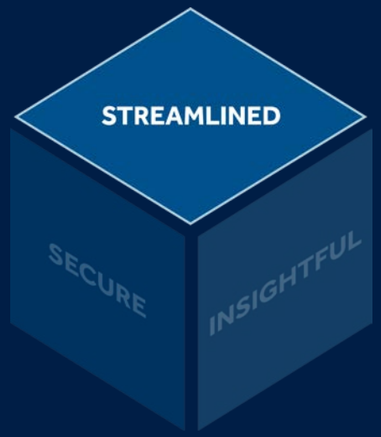
- “Packages” of therapy settings (electrode configurations, parameters, cycles)
- Clinicians may assign up to four groups using the clinician programmer (A, B, C, D) from which patients can select using their patient programmer
- A Group can be set in bipolar for MRI if conditions are met





STREAMLINED

SEE
BRIGHTER



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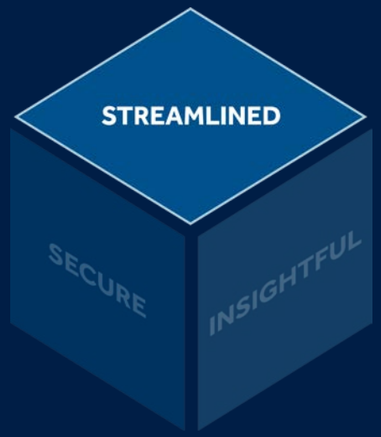
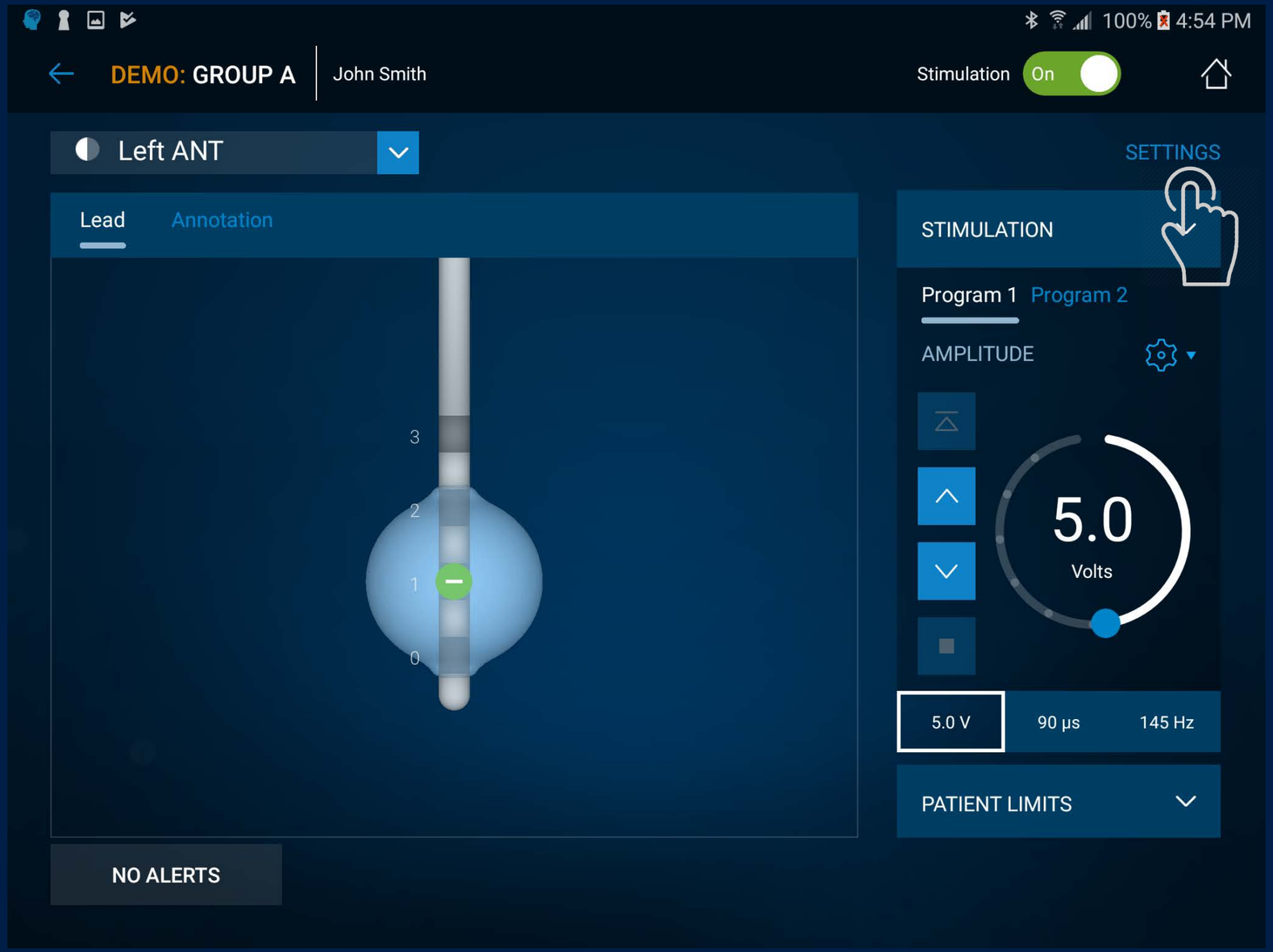
SETTINGS

ADVANCED PROGRAMMING FEATURES





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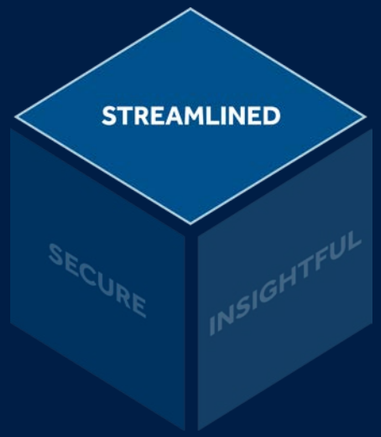
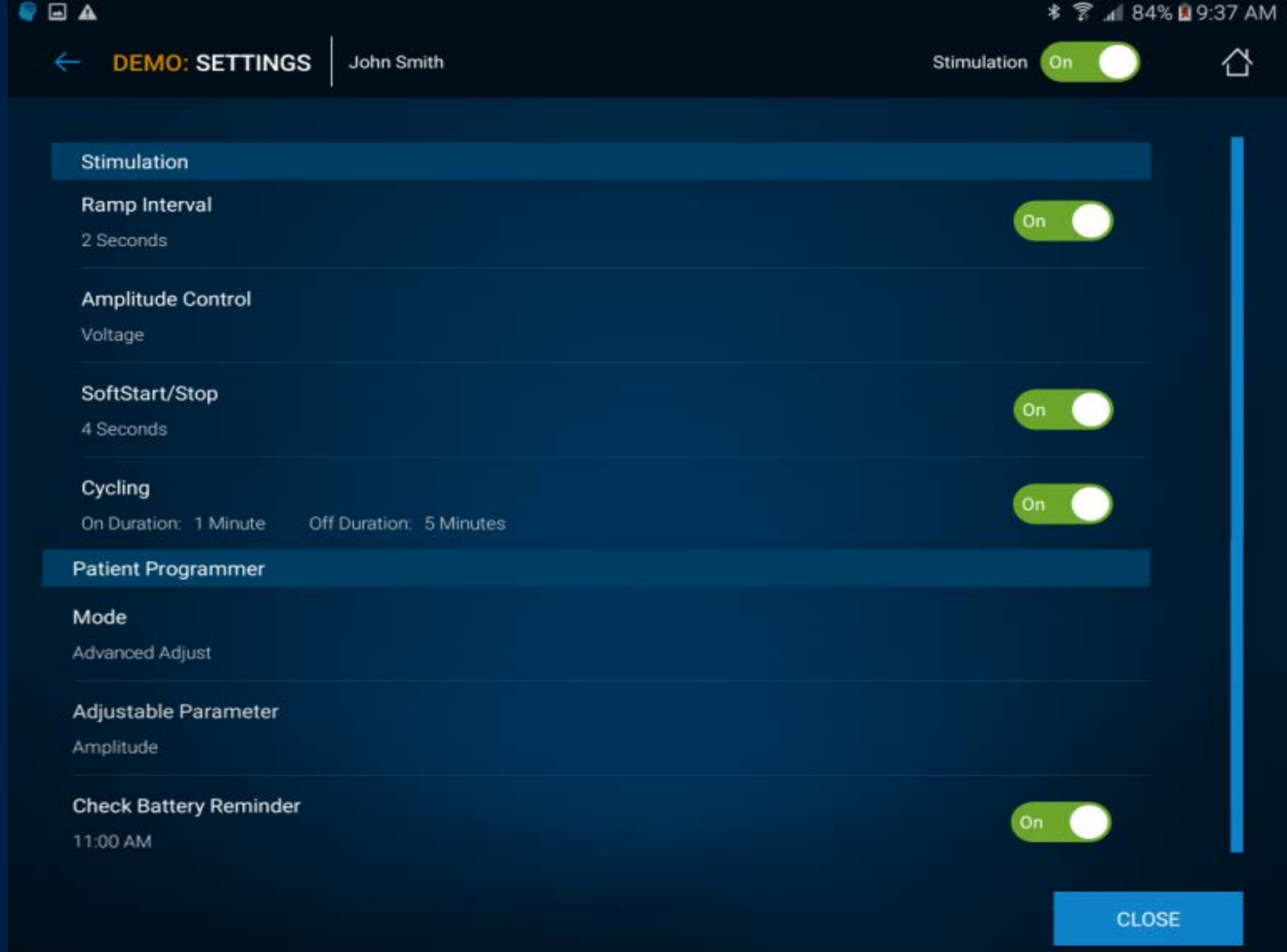
STREAMLINED

APP BASED
CONVENIENCE





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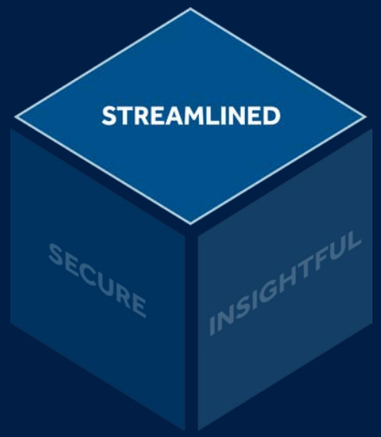
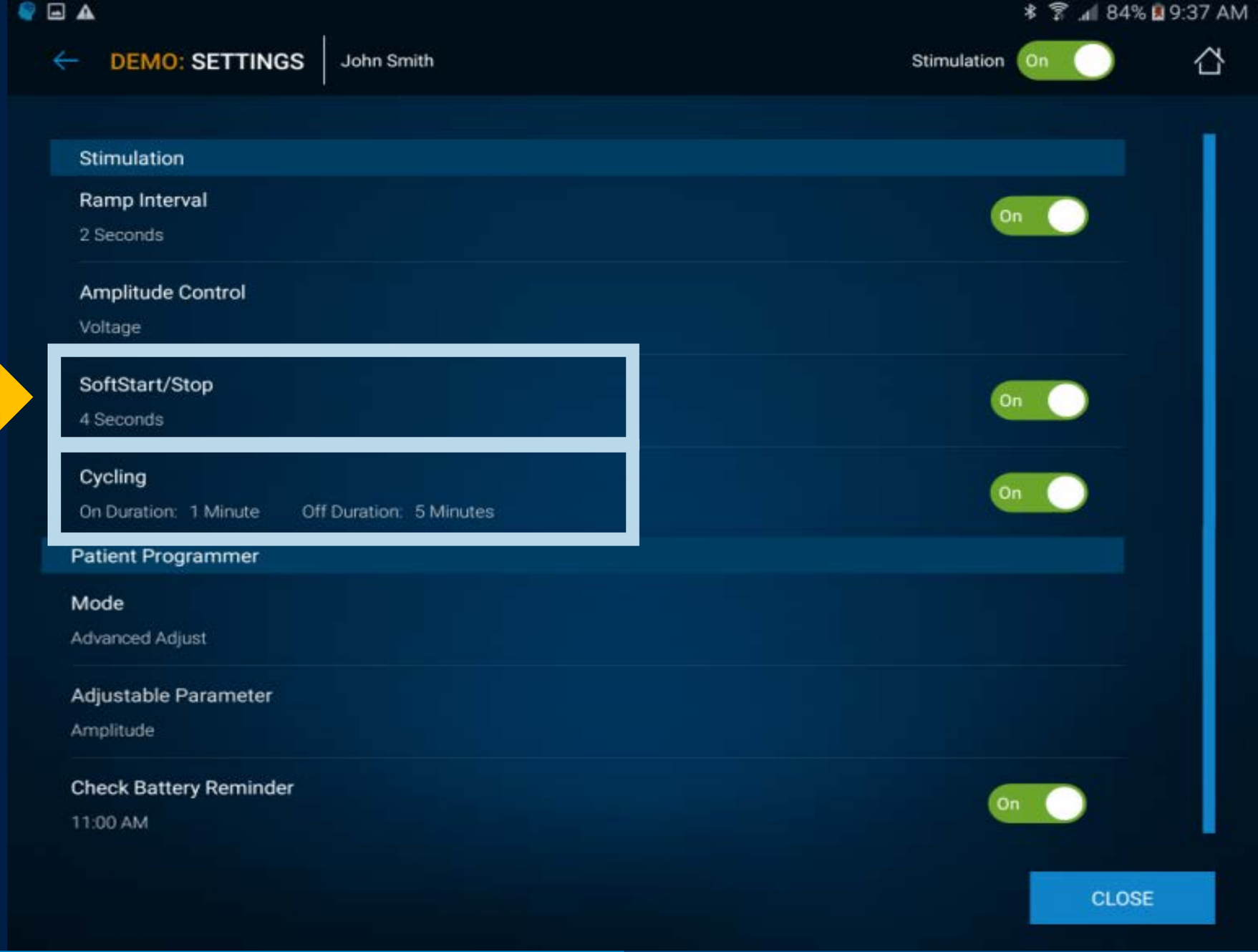
STREAMLINED

APP BASED
CONVENIENCE

8 seconds





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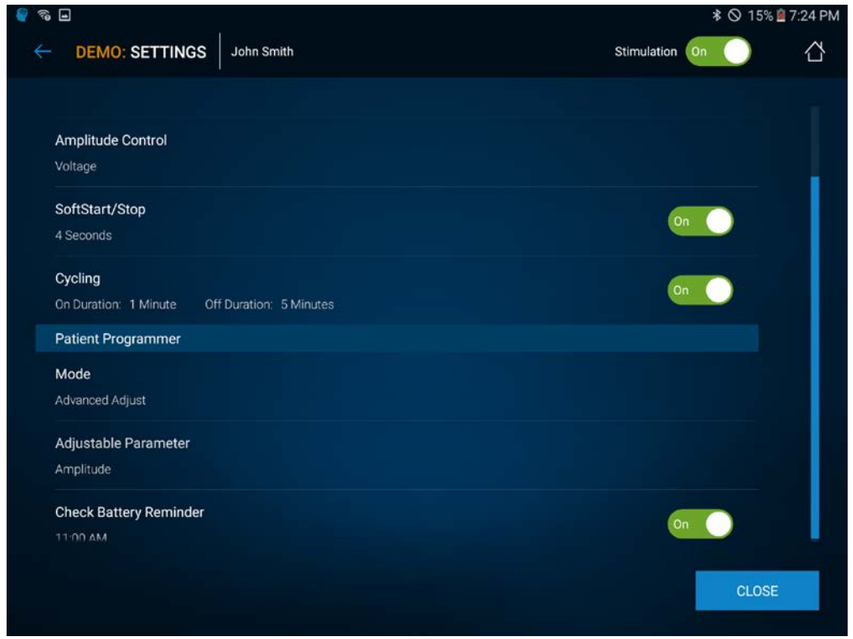
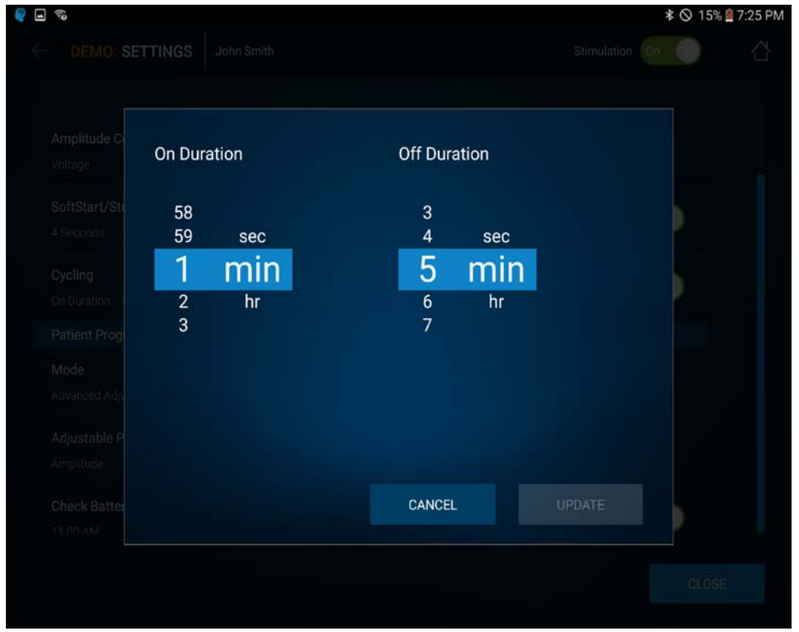
STIMULATION CYCLE OPTIONS
SETTING UP ON/OFF DURATION

- Minimum off or on time: 0.1sec
- Maximum off or on time: 24 hours
- SANTE Starting Parameters-Intervals:

1 min on 5 Minutes off



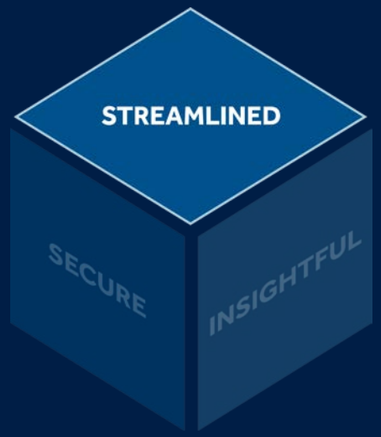


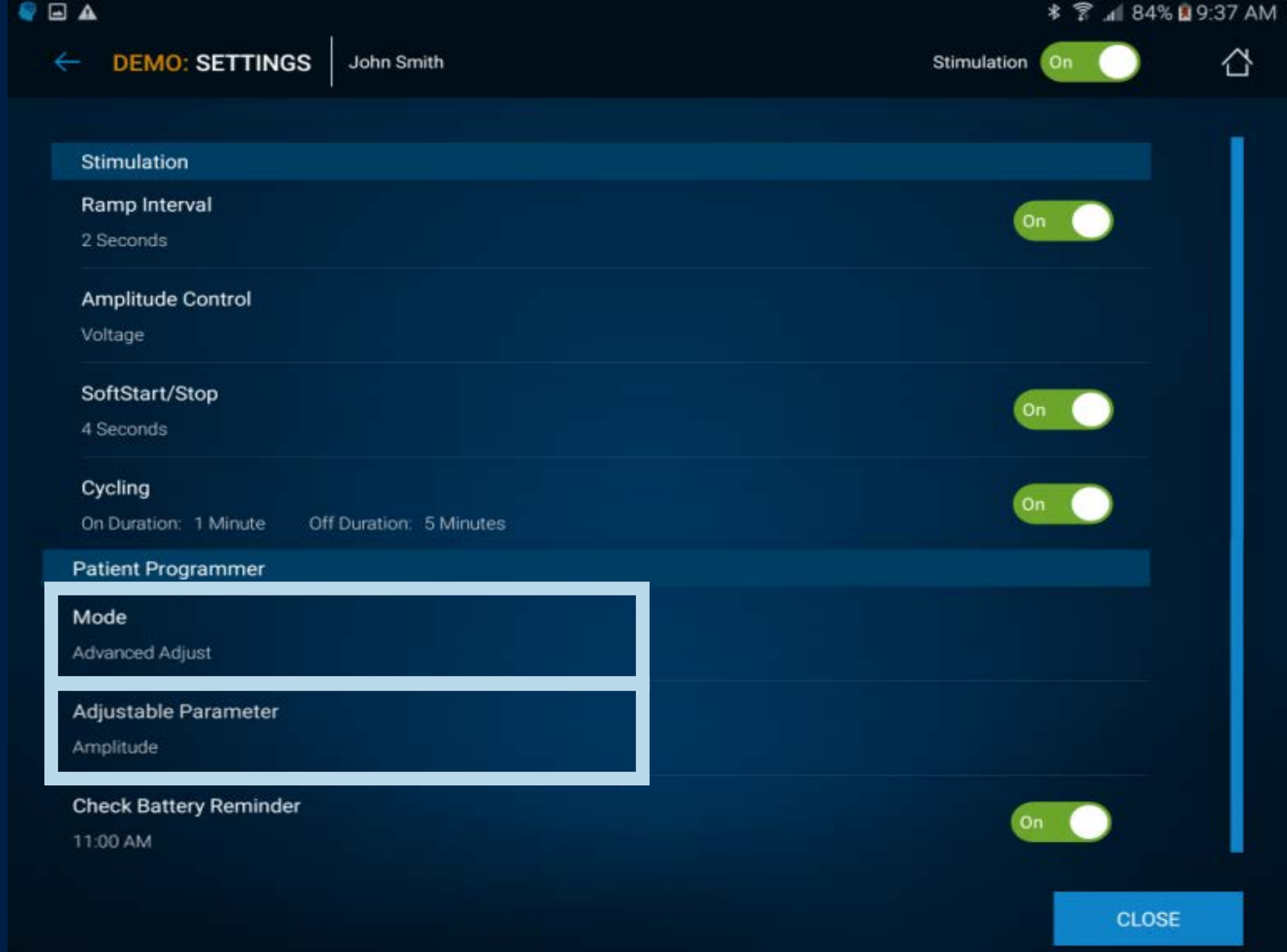
* Enabling cycling at certain parameter settings may decrease the device longevity of non-rechargeable devices.

STREAMLINED

APP BASED
CONVENIENCE

Setting Patient Limits





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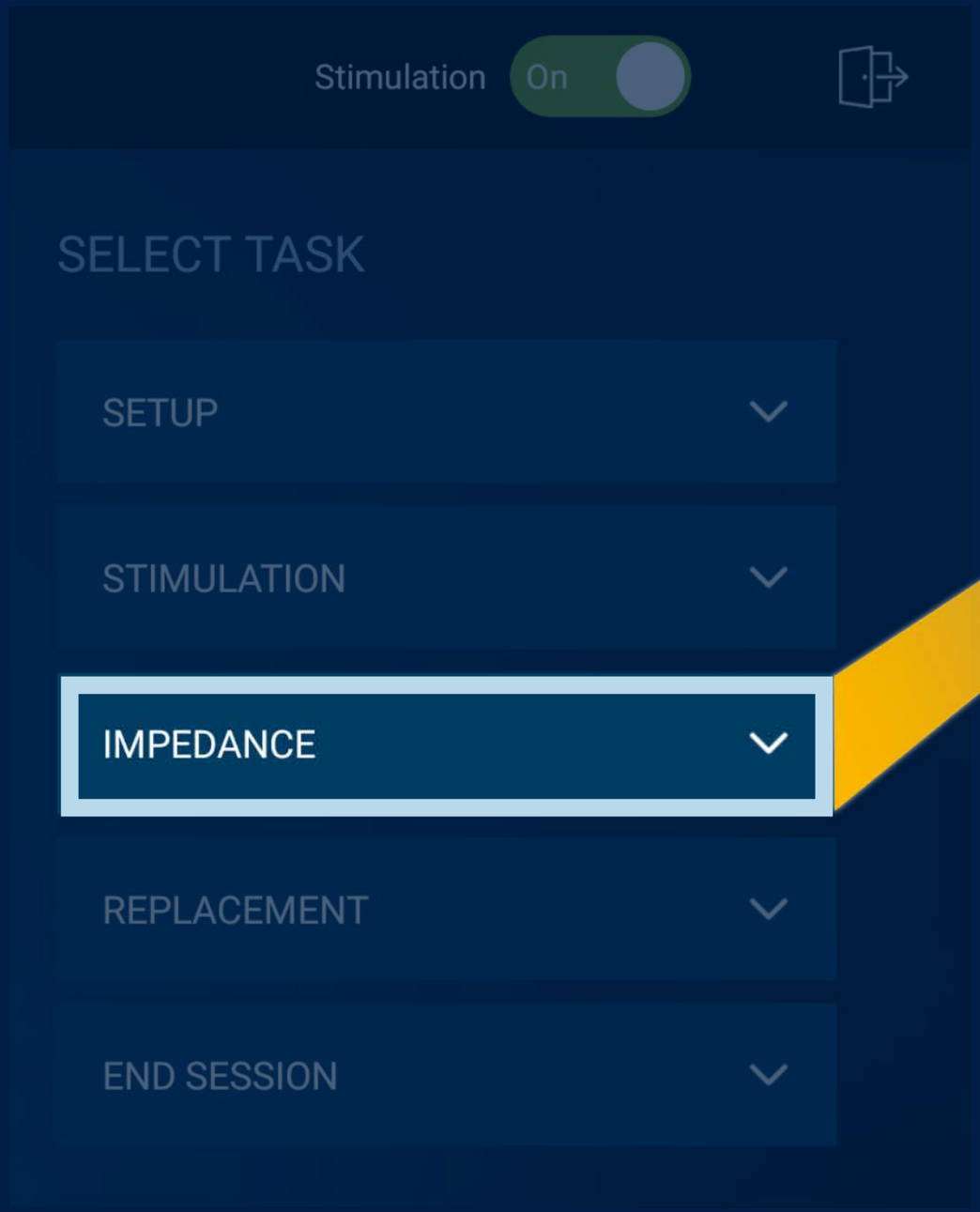
LETS PRACTICE SETTING UP A SAMPLE- PC- WORK IN DEMO MODE
NOT NEW – IF YOU HAVE ALL YOUR GROUPS FILLED DELETE THEM.

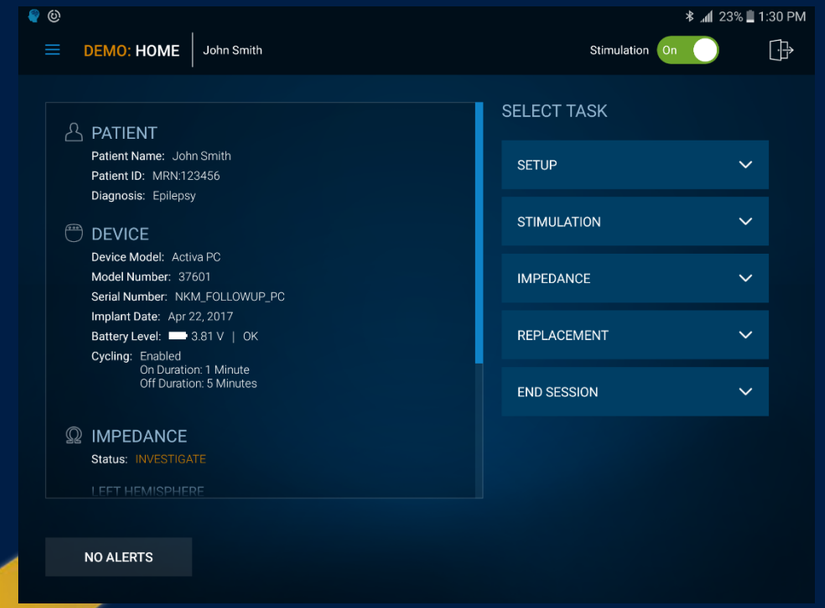
Parameter	Value
Amplitude	2.5 V
Pulse Width	90 μs
Rate	145 Hz
Electrode Configuration	2 (-) negative, case (+)
Cycle of Therapy	Cycling mode ON: 1 minute on, 5 minutes off
SoftStart™Stop	programmed to 8 seconds
Set up NEW for MRI	2(-) 3 (+) BIPOLAR so patient may be able to stay on during the MRI

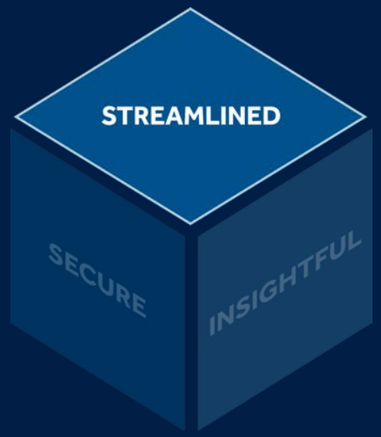
- Final task – What are the actions you want to take at the end of the session
- Be sure you end the session with the group you want the patient to leave the office on.

STREAMLINED

EASY TO NAVIGATE







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INSIGHTFUL INFORMATION
MADE
ACTIONABLE

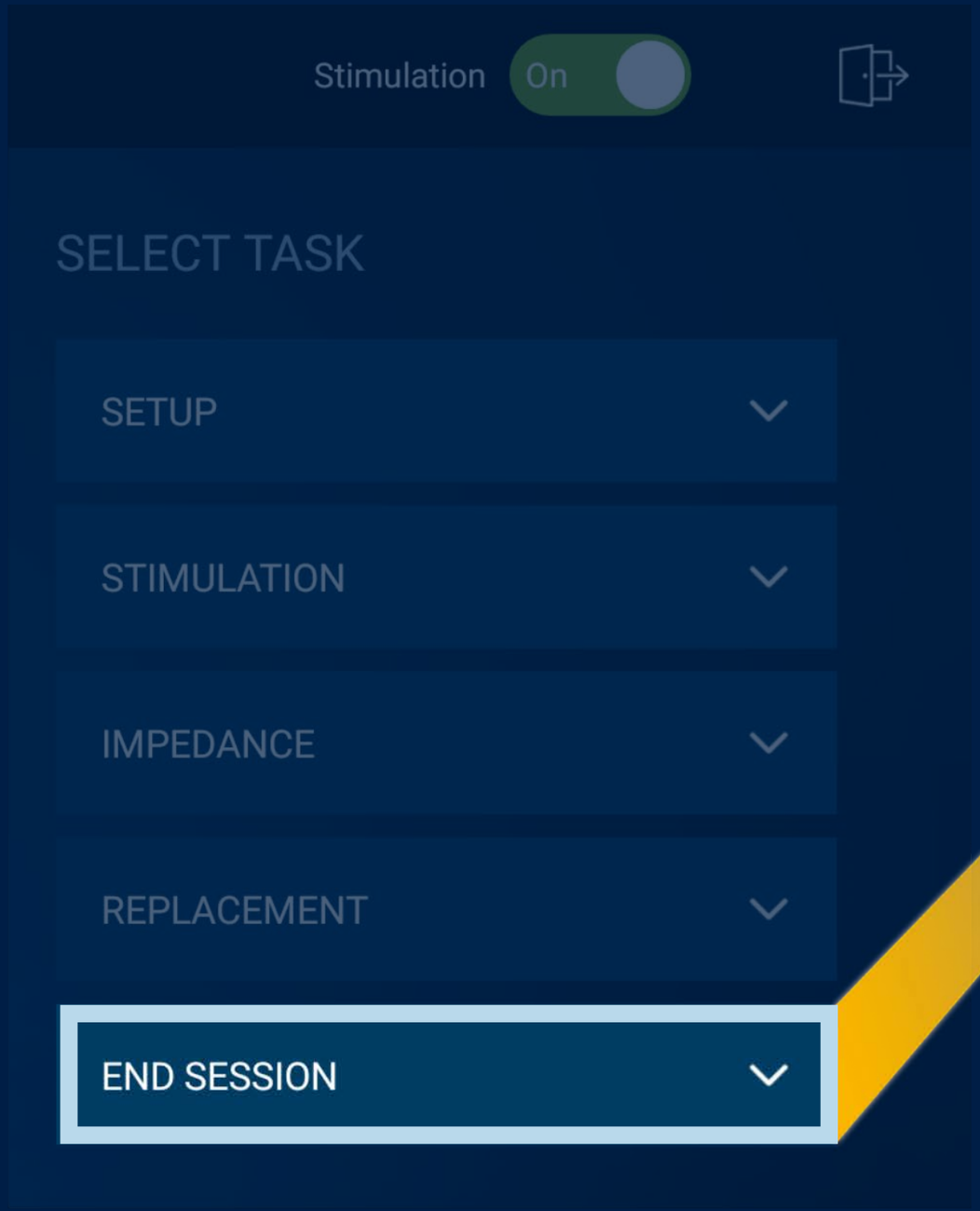
You can **select an automated impedance test or select a test amplitude for the electrode impedance measurement.**
If the automated selection is chosen the neurostimulator will automatically use the following combinations of stimulation parameters to measure impedance:

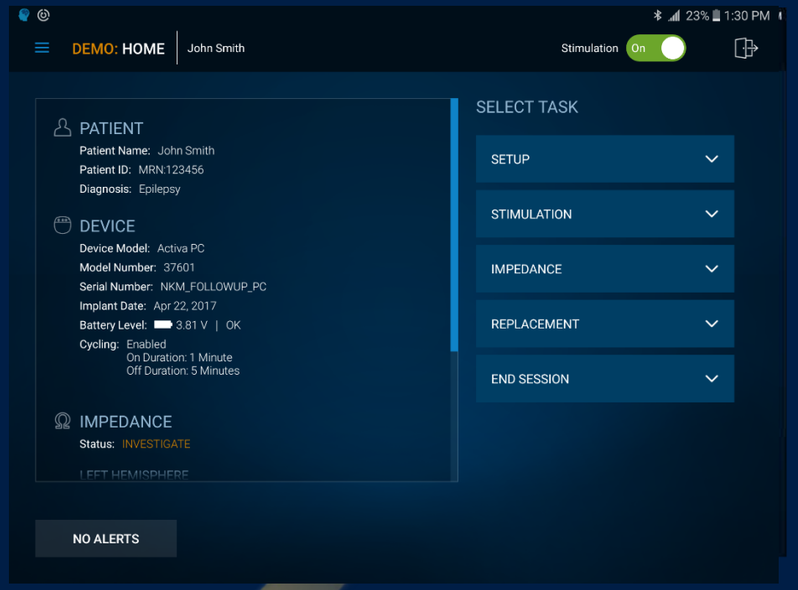
	Measurement Output (V) amplitude	PW	Rate	Measurement Range	Measurement At High Output
Meas 1	0.7	80µs	100 Hz	Up to 10,000 ohms	Value above 2,000
Meas 2	1.5	80µs	100 Hz	Up to 20,000 ohms	Value above 2,000
Meas 3	3.0	80µs	100 Hz	Up to 40,000 ohms	No prompt: highest range already achieved

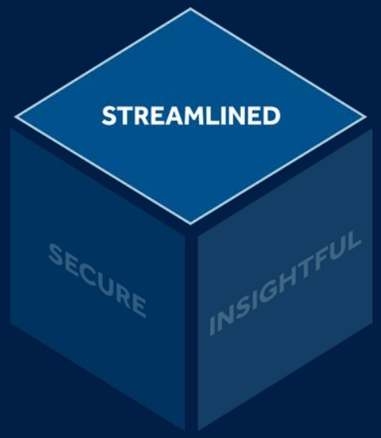
-The system takes the measurements in sequence. It is possible that the system will not need to take all three measurements.

STREAMLINED

EASY TO NAVIGATE







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REVIEWING FINAL SETTINGS AND ENDING A SESSION

Review Final Settings...

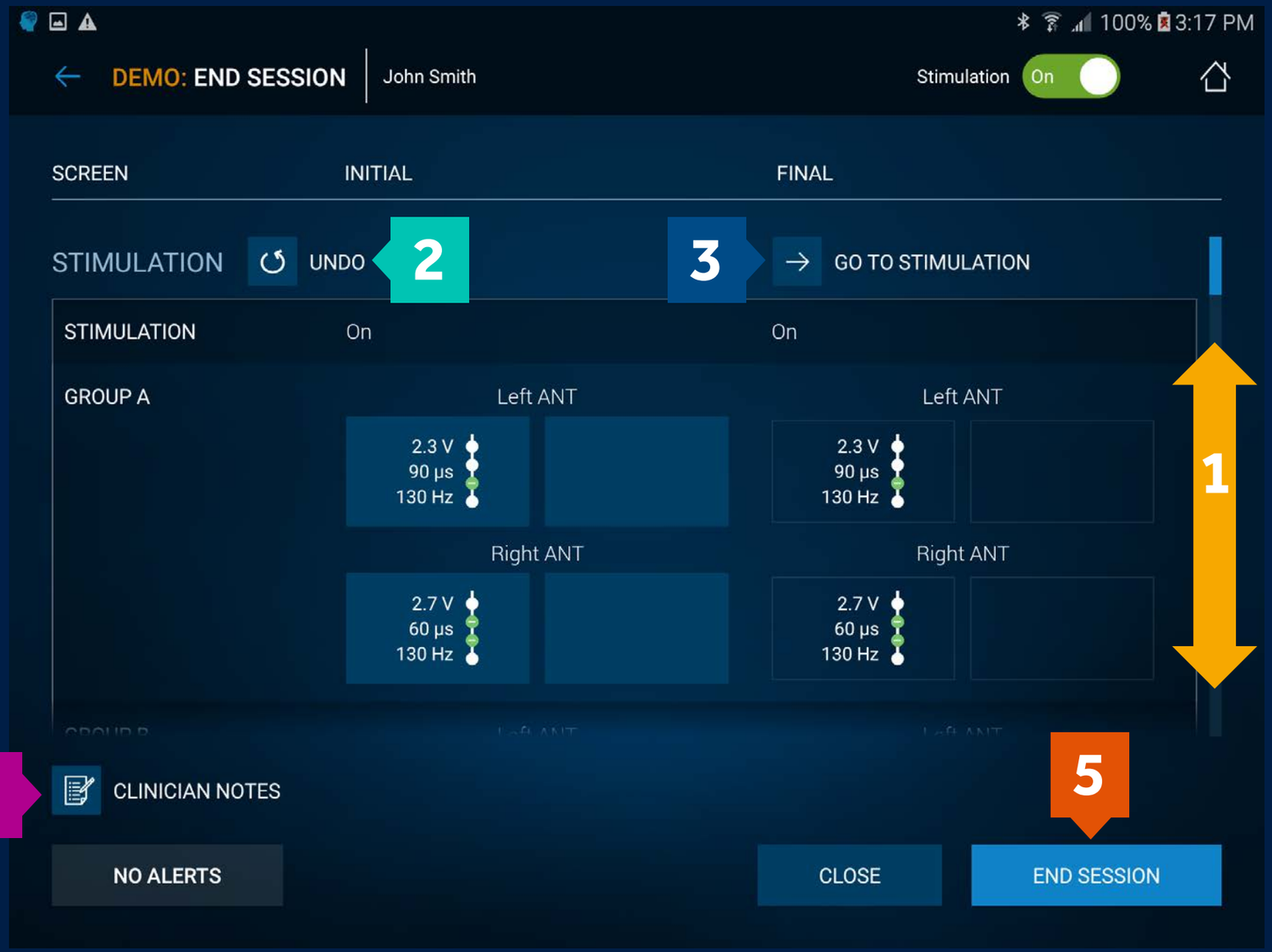
1
- Swipe up and down to scroll
- Left side = initial settings
- Right side = final settings

2
- Undo button = to undo programming changes made during programming session

3 **Go to Stimulation = go directly to Stimulation screen and adjust stimulation settings further**

4 **Clinician Notes = enter free-text notes**

5 **Tap End Session to complete programming session return to title screen**



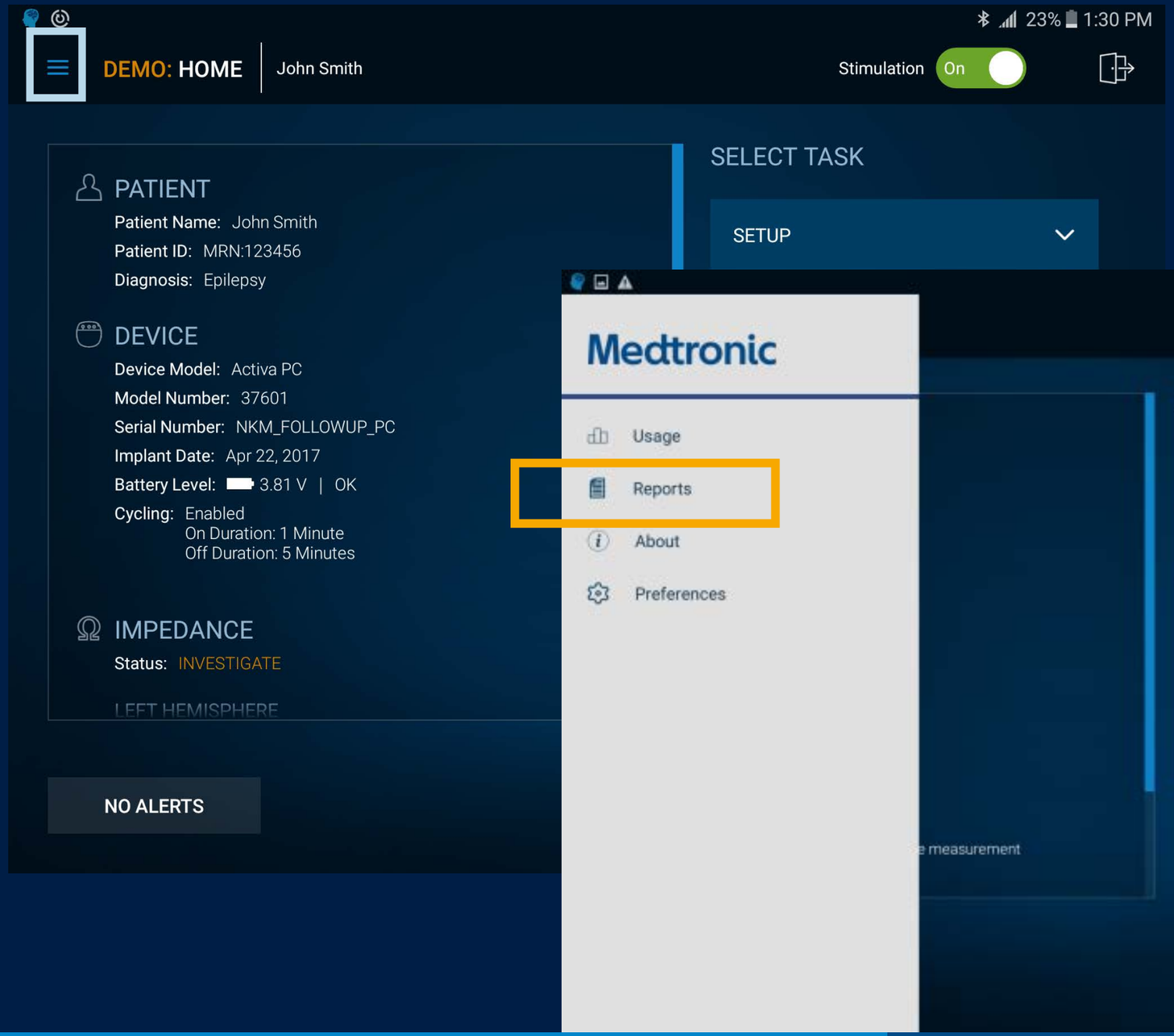
Medtronic

INSIGHTFUL

INFORMATION YOU NEED

Medtronic

MENU OPTIONS



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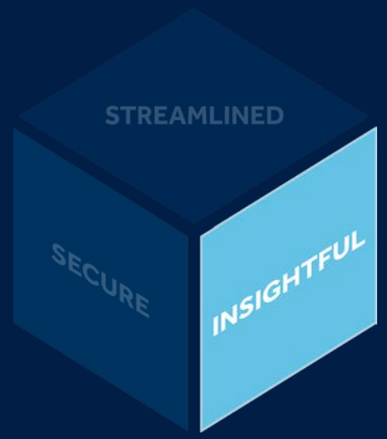
INSIGHTFUL
INFORMATION YOU NEED - REPORTS

Various report types



Session Report
[No name]
Activa PC NKM728744

Medtronic
Session Date:
Oct 24, 2018 1:35 PM

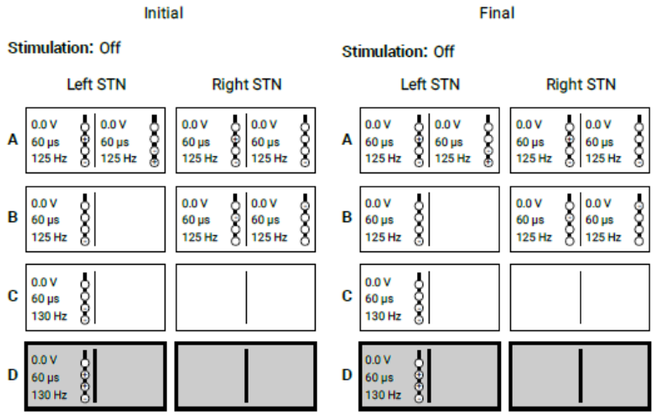
[No name]

Diagnosis:
Patient ID:

DEVICE

NEUROSTIMULATOR	Serial Number	Implanted
Activa PC	NKM728744	Oct 18, 2018
Model Number	**Firmware Version**	
37601	2.20	
Neurostimulator Location	**Battery Level**	
Chest Left	2.95 V | OK	

STIMULATION SETTINGS



Oct 24, 2018 1:37 PM from Programmer RF2H300D6AE Page 1

Session Report
[No name]
Activa PC NKM728744

Medtronic
Session Date:
Oct 24, 2018 1:35 PM

Clinician Notes

~:0/5 (0)
~X:5/5 (2)

A1 Session Date

	A	B	C	D	E	
1	Session Date	Patient Name	Patient ID	Diagnosis	INS Model	INS SN
2	Tue Oct 10 15:12:31 CDT 2017	John Smith	MRN:123456	Parkinson's Disease	37612	NKG_FOLLC

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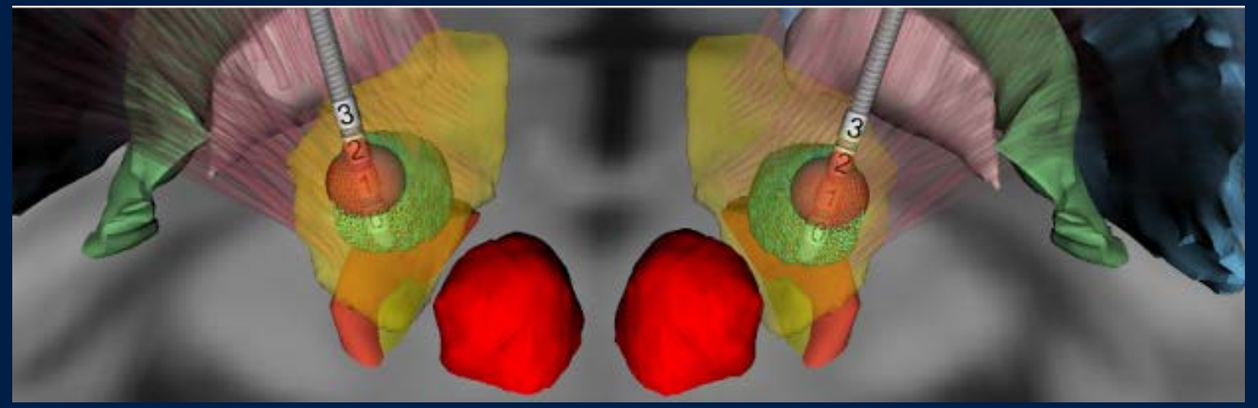
GOAL OF DBS PROGRAMMING

Deliver the therapy to the brain target of interest while minimizing stimulation of surrounding structures

- Using the lead electrode closest to the desired target provides maximal benefit and minimizes stimulation-induced adverse effects
- Setting appropriate stimulation parameters ensures that the desired brain target, but not adjacent structures, receives the stimulation



DBS PROGRAMMING ALGORITHM SAMPLE

INITIAL PROGRAMMING

Post-implant patient

Postpone initial programming 2-4 weeks to allow edema to subside

Maintain medication regimen

Establish Baseline Conditions

1. Assess surgical incisions
2. Assess patient seizure diary
3. Confirm leads
4. Review documentation of lead placement

Measure Impedance

Check and record impedance and current drain for each electrode

Initial Settings

1. SANTE Initial settings:
   a. Pulse width = 90µsec
   b. Rate = 145 Hz (maintain rate as invariable parameter)
   c. Amplitude = 5V

*In clinical practice clinicians may start at a lower amplitude and titrate up slower as they access patient response and tolerability.

2. Record effects

Subsequent Programming Visits

1. Remind patient to use patient programmer seizure key.
2. Remind patients to bring seizure diary to subsequent visits to assess therapy effectiveness

FOLLOW-UP PROGRAMMING VISITS

- **Review interim changes**
  - Seizure status (review event counter)
  - Medication changes
  - Adverse effects
    - ➢ Medication induced
    - ➢ Stimulation induced
- **Interrogate device**
- **Assess where the stimulation parameters are within the therapeutic range**
- **Formulate and implement management plan**
  - Adjust stimulation
  - Adjust medication
  - Make no adjustments
- **End session , then synchronize patient programmer to reset their seizure counter**

INS SETTINGS (HEAD-ONLY AND FULL-BODY SCAN)

PC with NO pocket Adaptor

PC WITH a pocket Adaptor

Full Body Eligible

Head Scan ONLY

Bipolar/Unipolar Defined

. Recommended neurostimulator settings (for all programs) for MRI

type	Settings
37 2, 37603, 37601 (no cket adaptor implanted)	Unipolar configuration[a] — Turn therapy off. Bipolar configuration[b] — Keep therapy on or turn therapy off.
3 37601 et adaptor implanted)	Turn therapy off.
376	Turn therapy off.
7428 **KINETRA**	Turn therapy off. Disable magnetic (reed) switch. Disable day cycling.
7426 **SOLETRA**	Turn therapy off. Set to bipolar configuration. Set amplitude to 0 volts.

[a] At least one electrode is negative and the case is positive, the other electrodes can be either negative or off.
[b] At least one electrode is positive, one electrode is negative, and the case is off.

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MRI ELIGIBILITY
ELIGIBILITY SHEET (HEAD-ONLY/FULL-BODY)

EN

MRI Eligibility Sheet

Completion of these sections is required prior to conducting an MRI scan on patients with a Medtronic Deep Brain Neurostimulator or implanted leads.

This form is for Medtronic DBS Systems only. Refer to the *MRI guidelines for Medtronic Deep Brain Stimulation Systems instructions for use* for complete safety information and instructions for conducting an MRI scan. The manual and the MRI eligibility sheet are available through www.medtronic.com/mri or by contacting Medtronic.

Complete or review the following sections to identify MRI scan-type eligibility (page 1) and to ensure that the DBS system is prepared for the MRI scan (page 2).

1. **Date eligibility was determined** _____

Patient name _____ **Date of birth** _____

DBS managing clinician _____ **Clinician phone number** _____

The MRI scan-type eligibility is based on the following combination of factors pertaining to the patient's DBS system:

- implantable neurostimulator model number
- presence of an implanted pocket adaptor
- lead implant status
- neurostimulation system integrity

2.

Medtronic DBS System types
☐ Implanted neurostimulation system
☐ Lead-only system

3. ☐ This section is not applicable because the patient does not have an implanted neurostimulation system.

Medtronic DBS Neurostimulators	
Head-only eligible	**Full-body eligible**
☐ Model 37602 (Activa® SC)	☐ Model 37612 (Activa® RC)
☐ Model 7428 (Kinetra®)	☐ Model 37603 (Activa® SC)
☐ Model 7426 (Soletra®)	☐ Model 37601 (Activa® PC)

4. ☐ This section is not applicable because the patient does not have an implanted neurostimulation system.

Pocket adaptors	
Head-only eligible	**Full-body eligible**
☐ Pocket adaptor(s) implanted (with Activa models 37612, 37603, and 37601 neurostimulators)	☐ No pocket adaptor
☐ No pocket adaptor (with Activa SC Model 37602, Soletra Model 7426 or Kinetra Model 7428 neurostimulator)	

5. ☐ This section is not applicable because the patient does not have a lead-only system.

Lead-only systems	
Head-only eligible	**Full-body eligible**
☐ Partially-implanted lead(s)	☐ Fully-implanted lead(s)

6. **Indicate the MRI scan-type eligibility based on the information provided. If more than one DBS system is implanted, MRI scan eligibility should be based on the most restrictive DBS system components.**

☐ **Head-only MRI scan** ☐ **Full-body MRI scan**

English

7. **Verified system integrity for all implanted neurostimulators by testing for open and short circuits using the clinician programmer to measure impedance.**

☐ This section is not applicable because the patient does not have an implanted neurostimulation system.
☐ System integrity verified. (No open or short circuits detected.)
☐ System is compromised. (Open or short circuit verified.) DO NOT perform the MRI.

8. **Neurostimulator programmed to the recommended settings listed below. Managing clinicians should document settings before changing to help ensure accurate re-programming after the MRI scan. Ensure that section 3 and section 4 have been completed on page 1 of this eligibility sheet. If the sections have not been completed, an MRI scan should not be performed.**

☐ This section is not applicable because the patient does not have an implanted neurostimulation system.

Recommended neurostimulator settings for MRI		
☐	37612, 37603, 37601 (no pocket adaptor implanted)	☐ Therapy off in unipolar or bipolar configuration. ☐ Therapy on in bipolar configuration.
☐	37612, 37603, 37601 (with pocket adaptor implanted)	Therapy off.
☐	37602	Therapy off.
☐	7428	Therapy off. Magnetic (reed) switch disabled. Day cycling disabled.
☐	7426	Therapy off. Bipolar configuration setting. Amplitude set to 0 volts.

☐ Neurostimulator has been programmed by clinician.
Radiology staff: Ask the patient if therapy settings have changed prior to the MRI appointment. If the patient has changed therapy settings, contact patient's clinician or Medtronic Technical Services.

☐ Neurostimulator will be programmed at MRI appointment by the patient or the clinician.
Radiology staff: Have the patient or clinician program the neurostimulator(s) now according to the recommended settings.

9. **For lead-only systems, partially-implanted or fully-implanted leads have been prepared by the clinician for the MRI scan. Ensure that section 5 has been completed on page 1 of the eligibility sheet. If that section has not been completed, an MRI scan should not be performed.**

☐ This section is not applicable because the patient does not have a lead-only system.
☐ Fully-implanted lead(s) has been capped and internalized.
☐ Partially-implanted lead(s) has been insulated, and the externalized portion of the lead is out-of-contact with the patient, is straight with no loops, and is centered in the head coil.

10. **DBS clinician signature** _____ **Date** _____

11.

FOR RADIOLOGY STAFF ONLY

This form reviewed by _____ _____
Print name **Signature**

☐ **MRI Technologist/Radiographer** ☐ **Radiologist** _____
Date

Assess other implanted medical devices before conducting an MRI scan.

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SUMMARY

POST-OPERATIVE MRI IN PATIENTS WITH BOTH DBS & VNS

Post-op MRI with both DBS and VNS implants ***may*** be possible provided all safety conditions are met. Several questions must be considered prior to scanning:

1. **Determine what model of DBS system** is implanted and if full-body or head-only MRI eligible

2. **Determine what brand/model of VNS system** is implanted

3. Determine if the VNS is complete, active or inactive, or partially excised

4. If the VNS system is complete (leads & IPG), determine if VNS IPG is to be excised or left in place prior to MRI scan

5. If the **VNS IPG has previously been removed**, determine:
    a. **If > 2 cm of VNS lead length remains, or**
    b. **If < 2 cm of VNS lead length remains**

For MRI compatibility questions about any implanted VNS system or partial system, <u>together with a DBS system</u>, Review **both sets of MRI instructions**, and to follow the more restrictive instructions.
Having answers to the questions above will facilitate this process.

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DISCUSSION QUESTIONS

- How can we predict responders?
- How can we best target the implant?
- Why does benefit increase over time?
- Which parameters are best?
- Where does DBS fit in with other therapies?

Discussion – Cases

BRIEF STATEMENT: MEDTRONIC DBS THERAPY FOR PARKINSON'S DISEASE, TREMOR, DYSTONIA AND EPILEPSY

Medtronic DBS Therapy for Parkinson's Disease, Tremor, Dystonia, and Epilepsy: Product labeling must be reviewed prior to use for detailed disclosure of risks.

Indications:
Medtronic DBS Therapy for Parkinson's Disease: Bilateral stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) using Medtronic DBS Therapy for Parkinson's Disease is indicated for adjunctive therapy in reducing some of the symptoms in individuals with levodopa-responsive Parkinson's disease of at least 4 years' duration that are not adequately controlled with medication, including motor complications of recent onset (from 4 months to 3 years) or motor complications of longer-standing duration.

Medtronic DBS Therapy for Tremor: Unilateral thalamic stimulation of the ventral intermediate nucleus (VIM) using Medtronic DBS Therapy for Tremor is indicated for the suppression of tremor in the upper extremity. The system is intended for use in patients who are diagnosed with essential tremor or parkinsonian tremor not adequately controlled by medications and where the tremor constitutes a significant functional disability.

Medtronic DBS Therapy for Dystonia: Unilateral or bilateral stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) using Medtronic DBS Therapy for Dystonia is indicated as an aid in the management of chronic, intractable (drug refractory) primary dystonia, including generalized and/or segmental dystonia, hemidystonia, and cervical dystonia (torticollis), in patients seven years of age or above.

Medtronic DBS Therapy for Epilepsy: Bilateral stimulation of the anterior nucleus of the thalamus (ANT) using the Medtronic DBS System for Epilepsy is indicated as an adjunctive therapy for reducing the frequency of seizures in individuals 18 years of age or older diagnosed with epilepsy characterized by partial-onset seizures, with or without secondary generalization, that are refractory to three or more antiepileptic medications.

The Medtronic DBS System for Epilepsy has demonstrated safety and effectiveness for patients who average six or more seizures per month over the three most recent months prior to implant of the DBS system (with no more than 30 days between seizures). The Medtronic DBS System for Epilepsy has not been evaluated in patients with less frequent seizures.

Contraindications: Medtronic DBS Therapy is contraindicated for patients who are unable to properly operate the neurostimulator and, for Parkinson's disease and Essential Tremor, patients for whom test stimulation is unsuccessful. The following procedures are contraindicated for patients with DBS systems: diathermy (e.g., shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy), which can cause neurostimulation system or tissue damage and can result in severe injury or death; Transcranial Magnetic Stimulation (TMS); and certain MRI procedures using a full body transmit radio-frequency (RF) coil, a receive-only head coil, or a head transmit coil that extends over the chest area if they have an implanted Soletra™ Model 7426 Neurostimulator, Kinetra™ Model 7428 Neurostimulator, Activa™ SC Model 37602 Neurostimulator, or Model 64001 or 64002 pocket adaptor.

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BRIEF STATEMENT: MEDTRONIC DBS THERAPY FOR PARKINSON'S DISEASE, TREMOR, DYSTONIA AND EPILEPSY

Warnings and Precautions: There is a potential risk of brain tissue damage using stimulation parameter settings of high amplitudes and wide pulse widths and, for Parkinson's disease and essential tremor, a potential risk to drive tremor using low frequency settings. Extreme care should be used with lead implantation in patients with an increased risk of intracranial hemorrhage. Sources of electromagnetic interference (EMI) may cause device damage or patient injury. Theft detectors and security screening devices may cause stimulation to switch ON or OFF and may cause some patients to experience a momentary increase in perceived stimulation. The DBS System may be affected by or adversely affect medical equipment such as cardiac pacemakers or therapies, cardioverter/ defibrillators, external defibrillators, ultrasonic equipment, electrocautery, or radiation therapy. MRI conditions that may cause excessive heating at the lead electrodes which can result in serious injury, including coma, paralysis, or death, or that may cause device damage, include: neurostimulator implant location other than pectoral and abdominal regions; unapproved MRI parameters; partial system explants ("abandoned systems"); misidentification of neurostimulator model numbers; and broken conductor wires (in the lead, extension or pocket adaptor). The safety of electroconvulsive therapy (ECT) in patients receiving DBS Therapy has not been established. Tunneling the extension too superficially or too deeply may result in nerve or vascular injury, or tunneling through unintended anatomy. The lead-extension connector should not be placed in the soft tissues of the neck due to an increased incidence of lead fracture. Abrupt cessation of stimulation should be avoided as it may cause a return of disease symptoms, in some cases with intensity greater than was experienced prior to system implant ("rebound" effect). Onset of status dystonicus, which may be life-threatening, may occur in dystonia patients during ongoing or loss of DBS therapy. For Epilepsy, cessation, reduction, or initiation of stimulation may potentially lead to an increase in seizure frequency, severity, and new types of seizures. For Epilepsy, symptoms may return with an intensity greater than was experienced prior to system implant, including the potential for status epilepticus. Patients using a rechargeable neurostimulator for Parkinson's disease or Essential Tremor should check for skin irritation or redness near the neurostimulator during or after recharging, and contact their physician if symptoms persist. Loss of coordination in activities such as swimming may occur. Depression, suicidal ideations and suicide have been reported in patients receiving Medtronic DBS Therapy for Movement Disorders and Epilepsy, although no direct cause-and-effect relationship has been established. For Epilepsy, preoperatively, assess patients for depression and carefully balance this risk with the potential clinical benefit. Postoperatively, monitor patients closely for new or changing symptoms of depression and manage these systems appropriately. Patients should be monitored for memory impairment. Memory impairment has been reported in patients receiving Medtronic DBS Therapy for Epilepsy, although no direct cause and effect relationship has been established. The consequences of failing to monitor patients are unknown. When stimulation is adjusted, monitor patients for new or increased seizures, tingling sensation, change in mood, or confusion.

Adverse Events: Adverse events related to the therapy, device, or procedure can include intracranial hemorrhage, cerebral infarction, CSF leak, pneumocephalus, seizures, surgical site complications (including pain, infection, dehiscence, erosion, seroma, and hematoma), meningitis, encephalitis, brain abscess, cerebral edema, aseptic cyst formation, device complications (including lead fracture and device migration) that may require revision or explant, extension fibrosis (tightening or bowstringing), new or exacerbation of neurological symptoms (including vision disorders, speech and swallowing disorders, motor coordination and balance disorders, sensory disturbances, cognitive impairment, and sleep disorders), psychiatric and behavioral disorders (including psychosis and abnormal thinking), cough, shocking or jolting sensation, ineffective therapy, and weight gain or loss.

Safety and effectiveness has not been established for patients with previous surgical ablation procedures, dementia, coagulopathies, or moderate to severe depression, or patients who are pregnant. Parkinson's disease and essential tremor: safety and effectiveness has not been established for patients under 18 years or patients with neurological disease other than idiopathic Parkinson's disease or Essential Tremor. Essential tremor: safety and effectiveness has not been established for bilateral stimulation or for patients over 80 years of age. Dystonia: age of implant is suggested to be that at which brain growth is approximately 90% complete or above. Epilepsy: the safety and effectiveness of this therapy has not been established for patients without partial-onset seizures, patients who are pregnant or nursing, patients under the age of 18 years, patients with coagulopathies, and patients older than 65 years.

Humanitarian Device (Dystonia): Authorized by Federal Law as an aid in the management of chronic, intractable (drug refractory) primary dystonia, including generalized and/or segmental dystonia, hemidystonia, and cervical dystonia (torticollis), in patients seven years of age or above. The effectiveness of the devices for treating these conditions has not been demonstrated.

USA Rx only Rev 08/18

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THANK YOU