Clinical Investigation Plan
Study Title

A Prospective Evaluation of Surveillance Monitoring as an Alternative to Telemetry in Patients Scheduled for Telemetry without AHA Indication

Document Revision
E

Document date
09Aug2017

Medtronic **Clinical Investigation Plan**	
Clinical Investigation Plan/Study Title	A Prospective Evaluation of Surveillance Monitoring as an Alternative to Telemetry in Patients Scheduled for Telemetry without AHA Indication
Clinical Investigation Plan Identifier	COVMOPO0561
Study Product Name	Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform BioModule™ BH3-M2 sensor
Sponsor/Local Sponsor	Medtronic MITG, Patient Monitoring & Recovery Health Informatics & Monitoring 6135 Gunbarrel Ave Boulder, CO, 80301 USA
Document Revision	Revision E
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1. Revision History

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2. Investigator Statement

Study Product Name	Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform BioModule™ BH3-M2 sensor
Sponsor	Medtronic MITG, Patient Monitoring & Recovery Health Informatics & Monitoring
Clinical Investigation Plan Identifier	COVMOPO0561
Revision/Date	Revision E / 09AUG2017

I have read the protocol, including all appendices, and I agree that it contains all necessary details for me and my staff to conduct this study as described. I will conduct this study as outlined herein and will make a reasonable effort to complete the study within the time designated.

I agree that this clinical study will be conducted in compliance with 21 CFR 803, laws and regulations of the countries in which the clinical study is conducted, including data protection laws, the Clinical Investigation Agreement, and the Clinical Investigation Plan. I agree to ensure that the confidential information contained in this document will not be used for any purpose other than the evaluation and conduct of the clinical investigation without the prior written consent of Medtronic.

I will provide all study personnel under my supervision copies of the protocol and access to all information provided by Medtronic. I will discuss this material with them to ensure that they are fully informed about the products and the study.

Investigator's Signature:	
Investigator's Name:	
Institution:	
Date:	

Table of Contents

1. Revision History 2
2. Investigator Statement 4
Table of Contents 5
3. Glossary 8
4. Synopsis 12
5. Introduction 14
5.1. Background 14
5.2. Purpose 15
6. Objectives and Endpoints 16
6.1. Objectives 16
6.1.1. Primary Objective 16
6.1.2. Secondary Healthcare Economic and Resource Utilization Objectives 16
6.1.3. Secondary Clinical and Qualitative Objectives 16
6.2. Endpoints 17
6.2.1. Definition of Primary Endpoint 17
6.2.2. Definition of Secondary Healthcare Economic and Resource Utilization Endpoints 17
6.2.3. Definition of Clinical and Qualitative Endpoints 18
7. Study Design 19
7.1. Duration 19
7.2. Rationale 19
8. Product Description 19
8.1. Surveillance Monitoring System 19
8.1.1. Vital Sync™ Informatics Manager (IM) & Virtual Patient Monitoring Platform (VPMP) 19
8.1.2. Wearable Physiological Monitor 20
8.2. Packaging 21
8.3. Intended Population 21
8.4. Product Use 21
8.5. Product Training Requirements 22
8.6. Product Receipt and Tracking 22
8.7. Product Return 22
8.8. Product Storage and Accountability 22
8.9. Recalls 22
9. Selection of Subjects 23
9.1. Study Population 23
9.2. Subject Enrollment 23

9.3. Inclusion Criteria 23
9.4. Exclusion Criteria 23
9.5. Childbearing Potential and Pregnancy Testing 24

10. Study Procedures 24
10.1. Monitoring Group Assignment 24
10.2. Data Collection and Schedule of Events 27
10.2.1. Screening/Enrollment Visit 29
10.2.2. Inpatient Data Collection 29
10.2.3. End of Study Visit 30
10.2.4. Clinician Focused Qualitative Assessments 30
10.3. Subject Screening 31
10.4. Subject Consent 32
10.5. Blinding 32
10.6. Randomization 32
10.7. Assessment of Safety 32
10.8. Recording Data 32
10.9. Deviation Handling 33
10.10. Subject Withdrawal or Discontinuation 34
10.11. Role of Sponsors Representatives 34

11. Risks and Benefits 34
11.1. Potential Risks 34
11.2. Potential Benefits 36
11.3. Risk-Benefit Rationale 36

12. Adverse Event Assessments 36
12.1. Anticipated Adverse Events 37
12.2. Definitions/Classifications 37
12.3. Recording and Reporting Adverse Events and Device Deficiencies 38
12.3.1. Product Complaint Reporting 38
12.3.2. Emergency Contact Information in case of SAE/SADE 39

13. Statistical Design and Methods 39
13.1. Sample Size Justification 39
13.2. Hypotheses and Endpoints 39
13.3. Statistical Analysis 40

14. Ethics 41
14.1. Statements of Compliance 41
14.2. Subject Compensation 41

15. Study Administration 41
15.1. Monitoring 41
15.2. Data Management 42
15.3. Accessibility of Investigation Site Staff and Study Materials 43
15.4. Audits and Investigation Site Inspections 43
15.5. Confidentiality 43
15.6. IRB Approval 43

15.7. CIP Amendments 44
15.8. Reporting Requirements and Record Retention 44
15.9. Publication and Use of Information 47
15.10. Suspension or Early Termination 47

16. Advisory Committees 47
16.1. Data Monitoring Committee 47

17. References 48

3. Glossary

Term	Abbreviation	Definition
Adverse Event	AE	Any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the medical device. NOTE 1: This definition includes events related to the medical device or the comparator. NOTE 2: This definition includes events related to the procedures involved. NOTE 3: For users or other persons, this definition is restricted to events related to the medical devices.
American Heart Association	AHA	A non-profit organization in the United States that fosters appropriate cardiac care in an effort to reduce disability and deaths caused by cardiovascular disease and stroke. The AHA published guidelines in 2003 for telemetry monitoring that are still applicable and being used currently.
Adverse Device Effect	ADE	Adverse event related to the use of a medical device.
Clinical Investigation Plan	CIP	The present document describing the study protocol.
CIP Deviation	CIP Deviation	An event when the investigator or site personnel did not conduct the study according to the CIP or the clinical trial agreement. Medtronic's term for protocol deviation.
Case Report Forms / Electronic CRF	CRF/eCRF	Forms where the clinical data are collected. eCRF is the electronic version of the CRF.
Device Deficiency	DD	Inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety or performance. NOTE 1: This definition includes adverse events resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, or operation, or any malfunction of the medical device. NOTE 2: This definition includes any event resulting from use error or from intentional misuse of the medical device
Electrocardiogram	ECG	A clinical technique measuring transthoracic electrical activity of

Term	Abbreviation	Definition
		the heart over time.
Electronic Data Capture	EDC	Electronic system where the data are collected through the eCRF (Oracle Clinical). May also be referred to as RDC (Remote Data Capture).
Emergency Department	ED	Medical treatment facility specializing in emergency medicine, the acute care of patients who present without prior appointment; either by their own means or by that of an ambulance.
Electronic Medical Record	eMR	Digital version of a patient's medical record within a single facility.
Food and Drug Administration	FDA	Federal agency of the United States Department of Health and Human Services; regulates medical devices.
Heart Rate	HR	A unit of measure that indicates speed of heartbeat in beats per minute.
Intensive Care Unit	ICU	A hospital unit with concentrated special equipment and specially trained personnel for the care of seriously ill patients requiring immediate and continuous attention
Informatics Manager	IM	A type of software that is intended to route and store medical device data and device diagnostic information from supported devices to the VPMP, 3rd Party Annunciation Systems, Electronic Medical Record (eMR) and Clinical Information System (CIS).
Institutional Review Board	IRB	An independent body in US, consisting of healthcare professionals and non-medical members, whose responsibility is to protect rights, safety and well-being of human subjects involved in a clinical trial and to provide public assurance of that protection, by, among other things, expressing an opinion on the clinical trial protocol, the suitability of the investigators involved in the trial and the adequacy of facilities, and on the methods and documents to be used to inform trial subjects and obtain their informed consent.
Investigator Site File	ISF	Regulatory binder supplied by the sponsor.
Length of stay	LOS	The overall hospital length of stay, time of admission to discharge.
Post-anesthesia care unit	PACU	Hospital until typically attached to an operating suite that provide care to patients recovering from anesthesia
Product Accountability Log	PAL	A log maintained by investigative site personnel to document that the study product (s) have been used according to the protocol, and to document the final accounting of study product(s) received at the site, dispensed to subjects, returned by the subjects, and returned to the sponsor.

Term	Abbreviation	Definition
Patient-controlled analgesia	PCA	A drug-delivery system that dispenses a preset intravascular dose of a narcotic analgesic when the patient pushes a switch on an electric cord.
Rapid Response Team	RRT	A team of health care providers that responds to hospitalized patients with early signs of clinical deterioration on non-intensive care units to prevent respiratory or cardiac arrest.
Respiration Rate	RR	A unit of measure that indicates rate of breathing in breaths per minute.
Serious Adverse Event	SAE	Adverse event that 1. led to death, 2. led to serious deterioration in the health of the subject, that either resulted in a. a life-threatening illness or injury, or b. a permanent impairment of a body structure or a body function, or c. in-patient or prolonged hospitalization, or d. medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function, 3. led to fetal distress, fetal death or a congenital abnormality or birth defect Note: Planned hospitalization for a pre-existing condition, or a procedure required by the protocol, without serious deterioration in health, is not considered a serious adverse event.
Serious Adverse Device Effect	SADE	Adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event.
Surveillance Monitoring	SM	The SM group will serve as the group who will be monitored by the study device for the duration of study enrollment on a medical-surgical unit(s).
Standard Operating Procedures	SOP	Medtronic Quality Standard Operating Procedures
Telemetry Monitoring	TM	The TM group will serve as the control group in this study and will be monitored via the site's standard of care telemetry practice/protocol.
Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform	Vital Sync™ IM & VPMP	A software only device that provides mobile and centralized remote monitoring.
Virtual Patient Monitoring Platform	VPMP	A display system that provides visual and audible renderings of physiologic data, waveforms, alarms and alerts routed through the Vital Sync™ IM from supported devices. The Vital Sync™

Term	Abbreviation	Definition
		VPMP displays information received from the IM on any web-enabled device.

4. Synopsis

Title	A Prospective Evaluation of Surveillance Monitoring as an Alternative to Telemetry in Patients Scheduled for Telemetry without AHA Indication
Clinical Study Type	Post-market
Product Name	Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform (Vital Sync™ IM & VPMP) BioModule™ BH3-M2 sensor
Sponsor	Medtronic
Investigation Purpose	The purpose of the study is to evaluate the impact of surveillance monitoring versus telemetry monitoring on clinical, healthcare economics, resource utilization, and qualitative outcomes.
Product Status	Vital Sync™ IM & VPMP [redacted] and the BioModule™ BH3-M2 sensor are Class II devices and 510(k) cleared by the FDA.
Primary Objective	The primary objective of this study is to compare hospital length of stay (LOS) between the surveillance monitoring (SM) and telemetry monitoring (TM) period on patients without AHA telemetry indication.
Secondary Objectives	<u>Healthcare Economic and Resource Utilization Objectives</u> 1. Compare telemetry bed, emergency department (ED) bed, and intensive care unit (ICU) bed availability between monitoring periods 2. Compare associated health care costs between monitoring periods 3. Compare the number of ICU, ED, post-anesthesia care unit (PACU), and telemetry delays in transfer between monitoring periods 4. Compare the number of hospital unit transfers between monitoring groups 5. Compare the number of unplanned ICU transfers between monitoring groups 6. Compare ICU LOS for subjects having unplanned transfers to the ICU between monitoring groups 7. Compare the number of unnecessary diagnostic tests and therapeutic procedures generated by artifacts and/or misdiagnosis between monitoring groups <u>Clinical and Qualitative Objectives</u> 1. Compare the number of Rapid Response Team (RRT) interventions between monitoring groups 2. Compare survival rates post RRT interventions between monitoring groups

	3. Compare code blue rates between monitoring groups 4. Compare unplanned intubations between monitoring groups 5. Compare time of RRT activation to time of threshold notifications from SM system following clinical deterioration events 6. Assess clinical team satisfaction with surveillance monitoring and study product 7. Assess patient satisfaction with surveillance monitoring and study product 8. Assess perceptions of clinicians who prescribe telemetry to patients without AHA indication 9. Assess clinicians' perceptions on telemetry utilization and impact on hospital resource utilization and patient flow
Study Design	This will be single-center, prospective, pilot, pre/post implementation study to collect post-market data on hospitalized subjects monitored via telemetry monitoring and surveillance monitoring. The planned duration of the study is greater than or equal to six months. The TM (control) group will complete enrollment first over an estimated three month period, followed by an estimated three month enrollment period for the SM group. Subject participation will last less than or equal to the duration of the hospital stay. Each subject will be followed in the hospital for a maximum period of 30 days (± 2 days) from the start of enrollment. No follow-up will occur after subjects are discharged from the hospital.
Sample Size	The subject population will include up to a total of 440 subjects with up to 220 subjects in each monitoring group.
Inclusion/Exclusion Criteria	**Inclusion Criteria:** Each subject must meet the following criteria to be enrolled in the study: 1. Signed and dated informed consent by subject 2. Male or female 18 years of age or older 3. Expected hospitalized admission on the general care floor or medical surgical unit for at least one overnight stay and/or >12 hours 4. Scheduled for telemetry monitoring 5. Diagnosis indicates AHA telemetry Class III or none and therefore not indicated for telemetry monitoring 6. For SM group subjects, treating provider who scheduled subject for telemetry agrees to alternative monitoring plan of surveillance monitoring 7. Willingness to have study devices attached and hair shaved at sensor location as needed during study participation 8. Willingness to participate in all aspects of the study **Exclusion Criteria:** Subjects who meet any of the following criteria will be excluded from the study: 1. Implanted pacemaker or automatic defibrillator 2. Allergy or sensitivity to ECG leads or adhesives that are similar to ECG leads 3. Current AHA Class I or II indication/prescription for telemetry monitoring 4. Prescription for other continuous condition monitoring such as capnography or pulse oximetry

	5. Ongoing opioid therapy by PCA, by epidural or intrathecal infusions or by intravenous analgesia, per Investigator discretion 6. Ventilated or intubated patients at the time of enrollment 7. Female subject is pregnant, lactating, trying to get pregnant, or has a positive pregnancy test for women with childbearing potential 8. Condition that, in the opinion of the investigator, may prevent completion of the study or protocol requirements 9. Subject is considered as being morbidly obese (defined as BMI >50.0)
Study Procedures and Assessments	Subjects who meet all of the inclusion criteria and none of the exclusion criteria will be assigned to either one of the monitoring groups and then followed for the duration of their hospital stay. The monitoring groups will be enrolled in two prospective phases: telemetry monitoring (TM) OR surveillance monitoring. Enrollment of the TM group will occur first. After TM enrollment is complete, the enrollment phase of SM will initiate. The TM group will serve as the control group and will be monitored via the site's standard of care telemetry practice/protocol. Subjects will continue to be enrolled in the study if subjects are transferred to medical-surgical unit after initial period of TM. No additional monitoring will be used for duration of study enrollment. The SM group will undergo placement of the study device following study enrollment and hospital staff will implement the SM strategy for the duration of study enrollment. A dedicated medical-surgical unit(s) will be utilized for the SM phase. Study procedures during the hospital stay will involve assessing eligibility, collecting baseline information, documenting clinical data from the eMR, unit transfers, discharges, and evaluating changes in health status. All study related subject data will be documented and entered into the subjects' eCRF. All treatment will be standard of care per institutional practice.
Safety Assessments	Subjects will be monitored for Serious Adverse Events and Device-Related Adverse Events as noted in Section 12.
Statistics	Baseline and study outcomes will be summarized using descriptive statistics. One-way analysis of variance will be used to compare continuous variables (e.g., age, length of study) and Chi-square or Fisher's exact test will be used for categorical variables. Multivariate regression will be used to assess impacts of potential confounders. A P-value <0.05 is considered statistically significant unless otherwise specified.

5. Introduction

5.1. Background

Continuous ECG monitoring (telemetry) is indicated and highly valuable for monitoring patients at risk for cardiac events. The use of telemetry has gradually expanded to lower-risk patients for whom such monitoring may not provide substantial clinical benefit. Moreover, clinicians often use telemetry with the intent to provide enhanced vigilance over patients' clinical status, even when that patient does not have a

significant underlying cardiac risk (1,2). The American Heart Association (AHA) has published a guideline indicating that low-risk patients do not require telemetry, as outcomes of these patients are not affected by telemetry monitoring (3,4). Despite these recommendations and evidence, one study reported that three of the top diagnoses of patients admitted to telemetry units are not clinically indicated, per AHA guidelines (4) and other studies report non-indicated monitoring may account for ~35% of patient telemetry days (5,6).

Telemetry in non-indicated patients has been shown to have limited clinical benefit. In lower-risk patients, clinically significant telemetry-monitored events are rare. The use of telemetry in these patients does not often change clinical management. In a retrospective analysis of 501 patients on telemetry, Benjamin and colleagues reported the incidence of arrhythmias on non-indicated days to be low (3.1 per 100 non-indicated days) as compared to indicated days (20.7 per 100 indicated days) (5). Dressler et al redesigned their cardiac telemetry sets and reduced telemetry use by 70% with no change in code blue, mortality, or rapid response team activation rates (7).

Overuse of telemetry in lower-risk patients can overburden the hospital system and was highlighted by the Choosing Wisely campaign as one of five "opportunities for improved healthcare value (8)." As such, the authors stated that telemetry overuse "can be linked to increased length of stay, boarding in the emergency department, reduced hospital throughput, increased ambulance diversion, increased operation costs," and "lead to a false sense of security and alarm fatigue (8)." In addition to the direct costs of telemetry, there are indirect costs related to Emergency Department (ED) backlog and hospital overcrowding. One study estimated that a delay in the ED of more than three hours before admission to a telemetry bed results in an opportunity cost in lost revenue of about $204 per patient (9). Other studies estimate savings ranging from $250,000 – $4.8 million annually through adherence to the AHA recommendations for telemetry use (5,7).

Overall, available data indicate that reducing the incidence of unnecessary telemetry could increase bed availability, shorten length of stay, and decrease the cost of care with relatively low clinical risk. Recent advances in monitoring technology may allow for cost-effective monitoring alternatives of key vital signs, provide for the early detection of patients who warrant increased attention, aid in ED triage, and improve overall caregiver workflow. These newer technologies have the ability to monitor multiple variables at once, including single-lead ECG and respiratory rate, and thus allow for the pre-programming of 'smart-alerts' better designed to detect clinically significant changes in patient condition. In these patients where physiologic monitoring is desired yet clinical diagnoses do not meet the AHA criteria for cardiac telemetry, such alternative surveillance monitoring strategies may provide acceptable clinical benefit while reducing hospital burden. This may be enabled through the provision of monitoring and enhanced vigilance within the general medical/surgical floor without requiring patient transfer to a dedicated telemetry bed.

While these newer monitoring technologies are novel, prospective evidence to support surveillance monitoring is limited. This study is designed to address the gap in evidence to compare surveillance monitoring to telemetry monitoring.

5.2. Purpose

The purpose of the study is to evaluate the impact of surveillance monitoring versus telemetry monitoring on clinical, healthcare economics, resource utilization, and qualitative outcomes.

6. Objectives and Endpoints

6.1. Objectives

6.1.1. Primary Objective

The primary objective of this study is to compare hospital length of stay (LOS) between the surveillance monitoring and telemetry monitoring period on patients without AHA telemetry indication.

6.1.2. Secondary Healthcare Economic and Resource Utilization Objectives

1. Compare telemetry bed, emergency department (ED) bed, and intensive care unit (ICU) bed availability between monitoring periods
2. Compare associated health care costs between monitoring periods
3. Compare the number of ICU, ED, PACU, and telemetry delays in transfer between monitoring periods
4. Compare the number of hospital unit transfers between monitoring groups
5. Compare the number of unplanned ICU transfers between monitoring groups
6. Compare ICU LOS for subjects having unplanned transfers to the ICU between monitoring groups
7. Compare the number of unnecessary diagnostic tests and therapeutic procedures generated by artifacts and/or misdiagnosis between monitoring groups

6.1.3. Secondary Clinical and Qualitative Objectives

1. Compare the number of Rapid Response Team (RRT) interventions between monitoring groups
2. Compare survival rates post RRT interventions between monitoring groups
3. Compare code blue rates between monitoring groups
4. Compare unplanned intubations between monitoring groups
5. Compare time of RRT activation to time of threshold notifications from SM system following clinical deterioration events
6. Assess clinical team satisfaction with surveillance monitoring and study product
7. Assess patient satisfaction with surveillance monitoring and study product
8. Assess perceptions of clinicians who prescribe telemetry to patients without AHA indication
9. Assess clinicians' perceptions on telemetry utilization and impact on hospital resource utilization and patient flow

6.2. Endpoints

6.2.1. Definition of Primary Endpoint

1. Length of stay

   Definition: The overall hospital LOS; time(in minutes) of admission to discharge during indexed hospitalization.

6.2.2. Definition of Secondary Healthcare Economic and Resource Utilization Endpoints

1. Telemetry bed, ED, and ICU bed availability

   Definition: Daily available number of beds available in both telemetry ED, and the ICU measured daily in hours from 12:00 AM to 11:59 PM.

2. Associated health care costs

   Definition: Costs attributable to the primary and secondary clinical and resource utilization endpoints.

3. ICU, ED, PACU, and telemetry delays in transfer

   Definition: Number of patients delayed admission to the ICU, ED, PACU, and to a telemetry bed.

4. Hospital unit transfers

   Definition: Number of inpatient transfers from one unit to another unit during course of hospital stay.

5. Unplanned ICU transfers

   Definition: Direct transfers from either study monitoring group to the ICU where the transfer was not planned during the hospital stay. For example, a transfer may be planned in advance of certain procedures for high risk patient as a preventative measure. The study team will determine if transfer were considered planned versus unplanned by review of the medical record.

6. LOS for ICU transfers

   Definition: The LOS (time in minutes) in the ICU for subjects who have an unplanned transfer to the ICU.

7. Diagnostic tests and therapeutic procedures generated by artifacts and/or misdiagnosis

   Definition: Any diagnostic test or therapeutic procedure that was performed because of an ECG artifact or misdiagnosis made by clinician using monitoring technology

6.2.3. Definition of Clinical and Qualitative Endpoints

1. RRT interventions

   Definition: RRT's that are activated due to clinical deterioration as reported by the hospital or subject's medical record.

2. Survival rates post RRT interventions

   Definition: Survival at discharge or study completion following RRT activation.

3. Code blue rates

   Definition: Code blue teams that are initiated due to cardiopulmonary arrest as reported by the hospital or subject's medical record.

4. Unplanned intubations

   Definition: An intubation and mechanical ventilation that was not planned during the course of the hospital stay.

5. Time of RRT activation to time of a threshold notification(s) from the SM system following clinical deterioration events

   Definition: Time of RRT activation is the time that a clinician called or initiated the RRT team. Time of a threshold notification(s) is the time when the SM system alerts or alarms when a hospital protocol-defined threshold is exceeded.

6. Clinical team satisfaction with surveillance monitoring and study product

   Definition: Clinical team (nurse or physician) who treated at least one study subject will be asked to take a qualitative survey on satisfaction and confidence.

7. Patient satisfaction with surveillance monitoring and study product

   Definition: Each subject will be asked to take a qualitative survey on satisfaction and comfort and the end of enrollment.

8. Perceptions of clinicians who prescribe telemetry to patients without AHA indication

   Definition: Each eligible clinician will be asked to take a qualitative survey focused on the AHA guidelines and the monitoring modalities of the study.

9. Clinicians' perceptions on telemetry utilization and impact on hospital resource utilization and patient flow

Definition: Each eligible clinician will be asked to take a qualitative survey focused on telemetry utilization and the monitoring modalities of the study.

7. Study Design

This will be single-center, prospective, pilot, pre/post implementation study to collect post-market data on hospitalized subjects monitored via telemetry and surveillance monitoring.

Subjects who meet all of the inclusion criteria and none of the exclusion criteria will be assigned to either one of the monitoring groups and then followed for the duration of their hospital stay.

The subject population will include up to a total of 440 subjects with up to 220 subjects in each monitoring group.

7.1. Duration

The planned duration of the study is greater than or equal to six months. The control (TM) group will complete enrollment first over an estimated three month period, followed by an estimated three month enrollment period for the SM group.

Subject participation will last less than or equal to the duration of the hospital stay. Each subject will be followed in the hospital for a maximum period of 30 days (± 2 days) from the start of enrollment.

No follow-up will occur after subjects are discharged from the hospital.

7.2. Rationale

The rationale for the study is fueled by: 1) reported widespread overuse of telemetry in US hospitals; 2) recommendations from the Choose Wisely campaign to reduce overutilization of resources; 3) recent advances in monitoring technology alternatives; 4) lack of prospective clinical evidence to support surveillance monitoring as an alternative to telemetry.

8. Product Description

8.1. Surveillance Monitoring System

8.1.1. Vital Sync™ Informatics Manager (IM) & Virtual Patient Monitoring Platform (VPMP)

The Vital Sync™ Informatics Manager (IM) & Virtual Patient Monitoring Platform (VPMP) [redacted] (Medtronic, Boulder) is a software only device that provides mobile and centralized remote monitoring. The Vital Sync™ IM is intended to route and store medical device data from connected medical devices to the electronic medical record (eMR), clinical information system (CIS) and/or the VPMP. The Vital Sync™ VPMP displays information received from the IM on any web-enabled device. The product is a Class II device and 510(k) cleared by the FDA.

The Vital Sync™ IM & VPMP routes and displays parameters, waveforms and alarms for the connected medical devices in near-real time. The Vital Sync™ IM & VPMP allows users to set up a new default alarm priority across device types and allows for institutions to modify alarm priorities per their internal protocols. The Vital Sync™ IM & VPMP provides for the setting or adjusting of thresholds on supported

devices where this capability is not available on the device itself; the platform can also act as the primary display for patient data and alerts where this capability is not available or enabled on the device itself. Vital Sync™ IM & VPMP includes Turn Time functionality which allows position and posture of the patient to be monitored. The Vital Sync™ IM & VPMP allows the user the capability, via the software, to perform simple calculations from processed parameters, or from manual input by the user.

The Vital Sync™ IM & VPMP will receive and display vital sign data from the BioModule wearable physiological monitor (see Section 8.1.2).

The indications for use are as follows:

The Vital Sync™ IM is software that is intended to route and store medical device data and device diagnostic information from supported devices to the VPMP, 3rd Party Annunciation Systems, Electronic Medical Record (eMR) and Clinical Information System (CIS).

The Vital Sync™ VPMP is a display system that provides visual and audible renderings of physiologic data, waveforms, alarms and alerts routed through the Vital Sync™ IM from supported devices. The Vital Sync™ VPMP is intended to be used by healthcare professionals in a hospital or hospital-type facility for the following purposes:

- To remotely view and review patient data, waveforms, alerts and alarm information from supported devices and clinical information systems to facilitate clinical management.
- To facilitate remote collaboration with other healthcare professionals regarding patient data from supported devices.
- To access additional processed parameters to facilitate patient monitoring, assessment and clinical management.
- To set and adjust alert thresholds on supported devices where this capability is not available on the device itself.
- To access data, waveforms and alerts from supported devices where these capabilities are not enabled or available on the device itself.

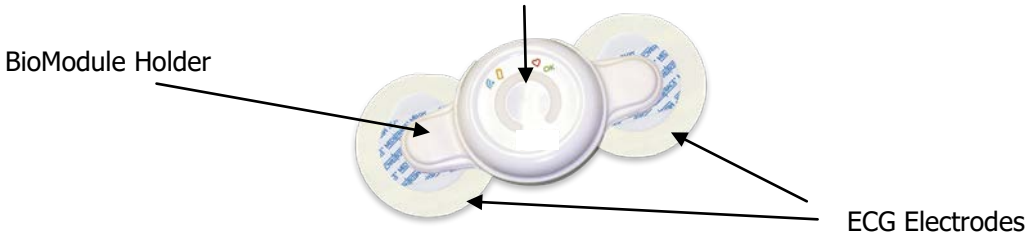
WARNING: The Vital Sync™ IM & VPMP is a notification system and is not a replacement for direct patient observation, patient assessment or clinical judgment.

8.1.2. Wearable Physiological Monitor

The BioModule™ BH3-M2 sensor is a wearable physiological monitoring device intended for monitoring adults in hospitals and alternate care settings. When combined with the BioModule Holder and snap ECG electrodes, it becomes the BioPatch™ wireless device. It continuously collects a patient's physiologic data including ECG, HR, RR, body orientation, and activity and transmits data to the Vital Sync™ VPMP every [redacted]. The BioModule™ sensor provides a [redacted], single-lead ECG that records either automatically or on demand when a patient's heart or respiration rate crosses clinician-assigned thresholds.

The BioModule™ sensor is a Class II device and 510(k) cleared by the FDA.

BioModule™



[redacted]

8.2. Packaging

Research conducted for this study will utilize devices cleared through the 510(k) regulatory process. FDA cleared devices do not require special labeling. Labeling and package for all products used in this study will follow the local and regional regulatory requirements. Labeling, user guides, and instructions for use will be provided to the site.

8.3. Intended Population

The intended study population is adult patients hospitalized and scheduled for telemetry monitoring but do not meet AHA criteria for telemetry monitoring.

8.4. Product Use

The Vital Sync™ IM & VPMP will be used to allow clinicians to remotely view patient information collected from the BioModule and enable clinicians to be notified of clinical distress via color coded alarms and audible alerts. The BioModule will be attached to each subject and placed on the lower section of the sternum via two electrodes.

User guides and instructions for use of the Vital Sync™ IM & VPMP and BioModule™ will be provided to the study team prior to or at the Site Initiation Visit.

8.5. Product Training Requirements

Prior to investigation site activation or subsequent involvement in clinical study activities, Medtronic will provide product and clinical study training relevant and pertinent to the involvement of personnel conducting clinical study activities and investigator responsibilities.

As a minimum, Investigators and coordinators will be trained on their responsibilities, on the CIP, on the use of data collection tools as well as applicable local regulations. Study-specific training will be documented prior to investigation site activation. Hospital staff will be trained on the surveillance monitoring system prior to start of the SM phase of the study.

The support and training of the hospital units using the study product will be performed by employees of Medtronic.

8.6. Product Receipt and Tracking

The following records will be maintained at minimum for product delivery, receipt and tracking at the site: dates, quantities received, lot/serial numbers, and expiration dates, as applicable. Traceability of devices will be achieved during and after the clinical investigation by means of recording lot numbers, batch numbers or serial numbers, as applicable, on the Product Accountability Log (PAL). There are no investigational devices/supplies being utilized in this study. All non-investigational devices/supplies associated with Vital Sync™ IM & VPMP and the BioModule will be maintained on the PAL as instructed during the Site Initiation Visit training.

8.7. Product Return

The investigator will return used and unused study supplies and maintain documentation of return as instructed during the Site Initiation Visit training. Study supplies should be returned to: [redacted]

8.8. Product Storage and Accountability

The investigator will store the study product per the instructions for use and product manual. The storage area should be locked/secure with access limited only to approved hospital and study staff. Devices should be stored in a way that they will not be mixed with standard clinical inventory.

Use of the study devices by each participant will be recorded on the PAL as instructed during the Site Initiation Visit training.

8.9. Recalls

In the event of a recall, Medtronic will immediately inform investigator to cease the use of the product or other study equipment and make arrangements for the return/disposition of the recalled product.

Medtronic will notify the FDA and all reviewing IRBs/ECs, within 30 working days after the request is made to cease the use of the device, as applicable.

9. Selection of Subjects

9.1. Study Population

The target population consists of hospitalized patients aged ≥18 who are scheduled for admission to telemetry but do not meet AHA criteria for telemetry.

9.2. Subject Enrollment

Subject is considered enrolled once they sign the informed consent form. Subject will be considered a screen failure and immediately exited from the study if:

- The subject signs the informed consent form but fails to meet study inclusion/exclusion criteria.
- The subject signs the informed consent form, meets the study inclusion/exclusion criteria but does not start telemetry or surveillance monitoring for any reason.

The investigator will maintain a log of all subjects enrolled in the clinical investigation called the Subject Identification Log for internal use to track subject identification numbers, subject names, and contact information. This log will be kept updated in real time during enrollment and stored in the ISF.

A Screening and Enrollment Log described in Section 10.3 will also be maintained by the investigator.

Individual subject enrollment will be complete when the subject is discharged from the hospital, completes 30 days (± 2 days) of enrollment, or is withdrawn from the study, whichever comes first.

9.3. Inclusion Criteria

Each subject must meet the following criteria to be enrolled in the study:

1. Signed and dated informed consent by subject
2. Male or female 18 years of age or older
3. Expected hospitalized admission on the general care floor or medical surgical unit for at least one overnight stay and/or > 12 hours
4. Scheduled for telemetry monitoring
5. Diagnosis indicates AHA telemetry Class III or none and therefore not indicated for telemetry monitoring
6. For SM group subjects, treating provider who scheduled subject for telemetry agrees to alternative monitoring plan of surveillance monitoring
7. Willingness to have study devices attached and hair shaved at sensor location as needed during study participation
8. Willingness to participate in all aspects of the study

9.4. Exclusion Criteria

Subjects who meet any of the following criteria will be excluded from the study:

1. Implanted pacemaker or automatic defibrillator
2. Allergy or sensitivity to ECG leads or adhesives that are similar to ECG leads
3. Current AHA Class I or II indication/prescription for telemetry monitoring
4. Prescription for other continuous condition monitoring such as capnography or pulse oximetry
5. Ongoing opioid therapy by PCA, by epidural or intrathecal infusions or by intravenous analgesia, per Investigator discretion
6. Ventilated or intubated patients at the time of enrollment
7. Female subject is pregnant, lactating, trying to get pregnant, or has a positive pregnancy test for women with childbearing potential (**see Section 9.5**)

8. Condition that, in the opinion of the investigator, may prevent completion of the study or protocol requirements
9. Subject is considered as being morbidly obese (defined as BMI >50.0)

9.5. Childbearing Potential and Pregnancy Testing

Pregnancy testing will only be performed in women with childbearing potential. Women of nonchildbearing potential are defined of self report of any female who meets one of the following condition.

- Postmenopausal defined as amenorrhea for at least 2 years.
- Surgically sterile (have had a hysterectomy or bilateral oophorectomy, tubal ligation, or otherwise be incapable of pregnancy)
- Abstinent (at the discretion of the investigator)
- Having other congenital or medical condition that prevents subject from becoming pregnant

Women of childbearing potential must have a negative serum β-human chorionic gonadotropin (β-hCG) pregnancy test or a negative urine pregnancy test prior to placement of any monitoring devices.

10. Study Procedures

Each enrolled subject will be assigned to one of two types of monitoring arms: telemetry monitoring (TM) OR surveillance monitoring (SM) and then followed for the duration of their hospital stay up to 30 days (± 2 days). The monitoring groups described in Section 10.1 will be enrolled in two prospective phases. The enrollment phase of the TM group will occur first. After TM subjects have completed study participation, the SM phase will initiate.

The SM phase will begin with a tuning period to educate the hospital staff so they can obtain experience using the SM system within their workflow. No subjects will be enrolled in the study during this time as hospital staff will be able to pilot the SM system within hospitalized patients.

Study flowchart is reported in Figure 1.

10.1. Monitoring Group Assignment

Telemetry Monitoring (TM) Group, Control
The TM group will serve as the control group and will be monitored via the site's standard of care telemetry practice/protocol. Subjects will continue to be enrolled in the study if subjects are transferred to medical-surgical unit after initial period of TM. Subjects will be tracked daily to confirm continuing eligibility for the study. Temporary alternate monitoring modalities will be allowed per the discretion of the Investigator. If subject no longer meets eligibility criteria, the subject should be withdrawn and study completion date will be the date the subject became ineligible not the date the study team discovered the ineligibility.

If a subject is transferred to another hospital unit or telemetry is discontinued, subject will continue to be enrolled in the study.

If subject is transferred to ICU, there will be an exception to the requirement of tracking daily continuing eligibility. It is expected for additional care and monitoring to be administered during the ICU stay and AHA indication to change. Once subject is transferred from the ICU back to a lower acuity unit, eligibility criteria will be reassessed and documented. If subject no longer meets eligibility criteria upon return to

lower acuity unit, the subject should be withdrawn from the study. If subject meets eligibility criteria daily, subject will resume SM procedures and daily tracking of eligibility criteria

Surveillance Monitoring (SM) Group
Subjects in the SM group will alternatively be admitted to a medical surgical unit and placed with the study device following study enrollment. Hospital staff will utilize SM for the duration of study enrollment.

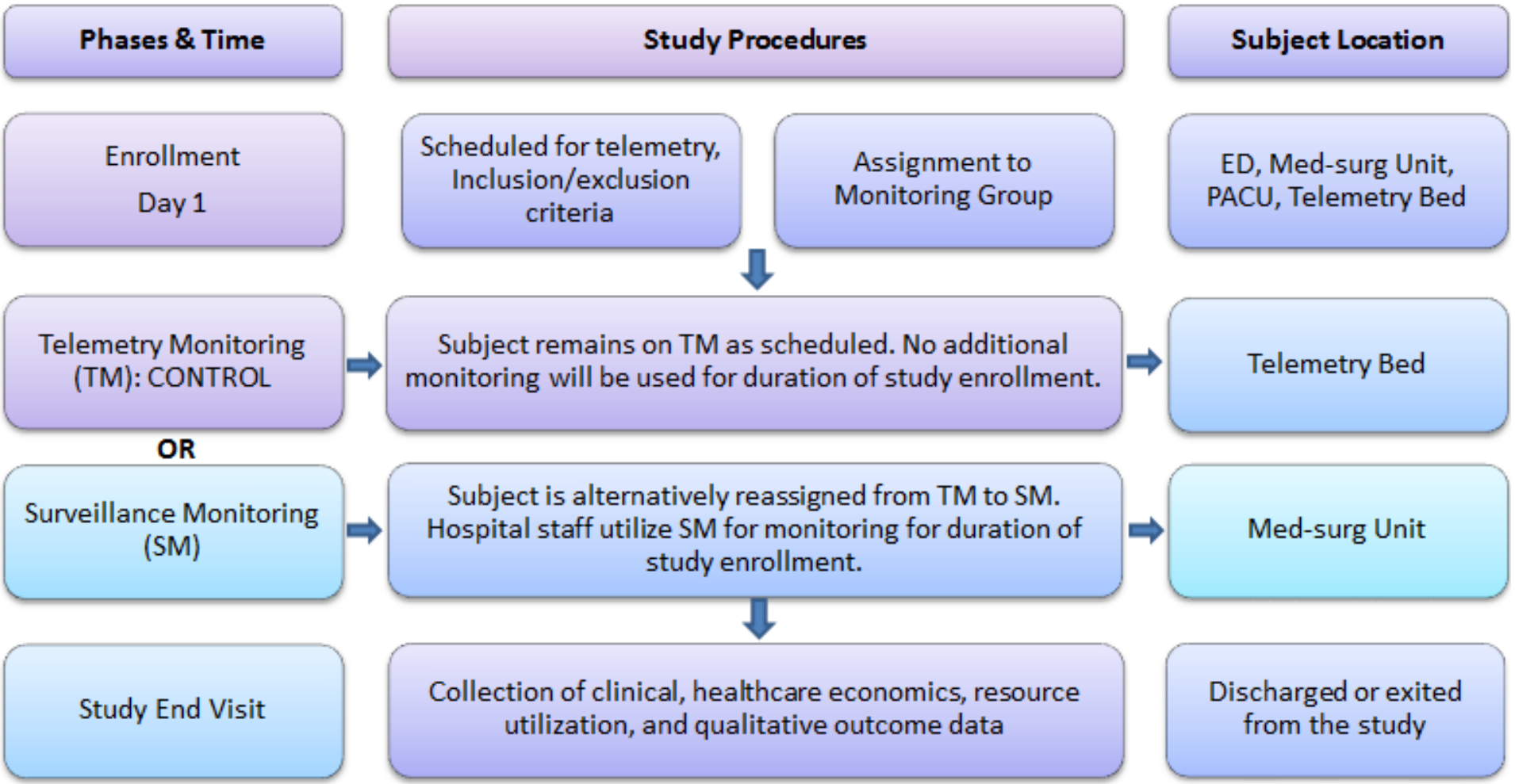
The sponsor and investigator will collaborate to implement the SM strategy. This implementation could include a variety of strategies based on the site's facilities, staffing resources, and IT infrastructure. The Vital Sync™ IM & VPMP conveys physiologic data, waveforms, and will provide visual alerts and annunciation alarms. Alert and alarm thresholds will be customized as needed to align with the hospital's protocols. Data from the remote monitoring platform will be accessed at a central workstation, a workstation on wheels, a bedside tablet, and/or smartphones/tablets.

Subjects will be tracked daily to confirm continuing eligibility for the study. Temporary alternate monitoring modalities will be allowed per the discretion of the Investigator. If subject no longer meets eligibility criteria, the subject should be withdrawn and study completion date will be the date the subject became ineligible not the date the study team discovered the ineligibility.

If a subject is transferred to another hospital unit, subject will continue to be enrolled in the study. However, the subject will be removed from SM during the transfer including placement of BioModule. When the subject transfers back to the medical-surgical unit, SM should resume as soon as reasonably possible per discretion of the Investigator until discharge from the hospital or end of study enrollment.

If subject is transferred to ICU, there will be an exception to the requirement of tracking daily continuing eligibility. It is expected for additional care and monitoring to be administered during the ICU stay and AHA indication to change. Once subject is transferred from the ICU back to a lower acuity unit, eligibility criteria will be reassessed and documented. If subject no longer meets eligibility criteria upon return to lower acuity unit, the subject should be withdrawn from the study. If subject meets eligibility criteria daily, subject will resume SM procedures and daily tracking of eligibility criteria.

Figure 1. Study Flowchart.



10.2. Data Collection and Schedule of Events

The Schedule of Events (Table 1) summarizes the intervals and data collection procedures. Table 1 outlines the events that occur during both study phases and events that occur during only the TM and SM phase.

Applicable clinical data will be collected from the eMR or source documentation and entered into the eCRF. Clinical data will be entered electronically through two different secure systems:

- (EDC, Oracle Clinical): Enrollment, Baseline Assessments, Monitoring Group Assignment, Hospital History, Patient and HCP satisfaction, Adverse Events, Protocol Deviations, Device Deficiencies, will be collected through eCRF.
- Vital Sync™ IM & VPMP : Raw vital sign data from the SM system may be utilized to determine the time that the SM system detected a protocol defined activation threshold and thus activated an alarm notification. This will occur post-completion of each subject's enrollment and will occur only in subjects who had a RRT intervention and/or code blue. Alternately, alarm notifications generated by the Vital Sync™ IM & VPMP system may be utilized to determine changes in patient data relative to protocol defined thresholds and associated timing for those changes. Raw de-identified vital sign data will be collected throughout the duration of the study. All data may be used for future product development.

Healthcare economic and resource utilization data will be collected separately via hospital and billing records.

Table 1. Schedule of Events

Event/Activity to Occur Across All Phases			
Event/Activity	**Screening/ Enrollment**	**Inpatient Days**	**End of Study**
Informed Consent	X		
Inclusion/Exclusion Criteria • Pregnancy test, if applicable	X	X	
Baseline Assessments • Demographics • Medical history • Primary diagnosis • Hospital admission data • Pregnancy test, if applicable	X		
Monitoring Group Assignment	X		
Inpatient Tracking Form (daily eligibility)		X	
Hospital History data			X
Healthcare Economic data			X
Resource Utilization data			X
Adverse Events		X	X
Protocol Deviations		X	X
Device Deficiencies		X	X
eCRF Data Entry	X	X	X
Event/Activity to Occur During TM Phase Only			
Event/Activity	**Screening/ Enrollment**	**Inpatient Days**	**End of Study**
Telemetry Utilization Questionnaire for Clinicians (PRE)	X		
Perception Questionnaire for Prescribing Clinicians (PRE)	X		
Event/Activity to Occur During SM Phase Only			
Event/Activity	**Screening/ Enrollment**	**Inpatient Days**	**End of Study**
BioModule Placement	X		
BioModule Replacement (~every 24 hrs)		X	
Patient Satisfaction Questionnaire			X
Clinical Team Satisfaction Questionnaire			X
Telemetry Utilization Questionnaire for Clinicians (POST)			X
Perception Questionnaire for Prescribing Clinicians (POST)			X

10.2.1. Screening/Enrollment Visit

The first visit is the screening and enrollment visit. Patients considered potential candidates for the study based on pre-screening will sign informed consent form prior to participating in any study activities.

The following procedures and assessments will be performed **during both phases of the study** on the day of study enrollment and the results will be recorded on the subject eCRFs.

- Signed and dated informed consent
- Pregnancy test if applicable
- Verify that the subject meets all inclusion/exclusion criteria and collect the following:
    - Demographics
    - Medical history
    - Hospital admission data
- Assignment to monitoring group
- Assignment of study number
    - SM group will be a consecutive number beginning with 1001
    - TM group will be a consecutive number beginning with 2001
- Verify data and enter into eCRF within 5 preferred business days of collection

During the TM Phase only, the following procedures and assessments will be performed.

- Eligible clinicians complete Telemetry Utilization Questionnaire for Clinicians (PRE)
- Eligible clinicians complete Perception Questionnaire for Prescribing Clinicians (PRE)

During the SM Phase only, the following procedures and assessments will be performed.

- Attach BioModule to subject according to user manual instructions and keep device attached to subject for the duration of the evaluation or until fully charged BioModule is needed
- Link subject to BioModule using the Vital Sync™ VPMP
- Confirm that BioModule is communicating to Vital Sync™ VPMP by observing flashing green light on BioModule AND that HR, RR, and activity parameters are displayed on the central station

10.2.2. Inpatient Data Collection

Data collected during the course of the hospital stay will be limited to daily reviews of the subject status to assess continuing eligibility and to assess for AEs/SAEs, protocol deviations, and device deficiencies as applicable per Section 12.

The following procedures and assessments will be performed **during both phases of the study** on inpatient days and the results will be recorded on the subject eCRFs.

- Complete inpatient tracking form to confirm continuing eligibility for the study
- Check and record daily AEs/SAEs and protocol deviations
- Verify data and enter into eCRF within 5 preferred business days of collection

During the SM Phase only, the following procedures and assessments will be performed.

- Change-out BioModule as battery limits are reached, return the BioModule to the charging station
- Apply a new fully charged BioModule to the subject and link subject to new BioModule using the Vital Sync™ VPMP
- Clean reusable BioModule and return to the charging station
- Perform daily checks to confirm BioModule and the Vital Sync™ VPMP are communicating and operating properly
- Assess for and document any device deficiencies

10.2.3. End of Study Visit

The last visit will be on the day the subject is discharged from the hospital or at day 30 (± 2 days) of hospital admission. Subject participation ends at this visit or if the subject is withdrawn from the study for any reason. The following procedures and assessments will be performed **during both phases of the study** at the end of the study and will be recorded on the subject eCRFs.

- Check and record AEs/SAEs and protocol deviations
- Collect the following from the medical and billing records (UB04):
    - Hospital History data
    - Healthcare Economic data
    - Resource Utilization data
- Verify data and enter into eCRF within 5 preferred business days of collection

During the SM Phase only, the following procedures and assessments will be performed.

- Remove BioModule, BioModule holder and electrodes. Discard disposable BioModule holder and electrodes.
- Clean reusable BioModule and return to the charging station
- Assess for and document any device deficiencies
- Subject complete Patient Satisfaction Questionnaire
- Eligible clinicians complete Clinical Team Satisfaction Questionnaire
- Eligible clinicians complete Telemetry Utilization Questionnaire for Clinicians (POST)
- Eligible clinicians complete Perception Questionnaire for Prescribing Clinicians (POST)

10.2.4. Clinician Focused Qualitative Assessments

A series of questionnaires will be administered to the clinicians involved in the care of study participants across the hospital. Each questionnaire will be focused on a subset of clinicians. It is likely that the same clinician may provide care for multiple study participants over the course of the study. Eligible clinicians should complete the focused questionnaire(s) only once if they provide care to more than one study participant. If the questionnaire has a Pre/Post component, both the Pre and the Post should be completed only one by each eligible clinician.

Eligible clinicians will be provided with the clinical team questionnaire information sheet during the informed consent process. If the clinician is willing to consider participation, the clinician will provide consent by completing the questionnaire and returning to the study team. A Clinician Participant Log will be used to capture clinicians who participated in the clinician focused qualitative assessments.

Perception Questionnaire for Prescribing Clinicians (PRE)
Eligible clinicians will be any clinician who ordered telemetry monitoring for the study participant. The questionnaire should be administered to the clinician after enrollment of the subject, but if the clinician is not available at the time of enrollment it is acceptable to administer the questionnaire during the inpatient period.

Perception Questionnaire for Prescribing Clinicians (POST)
Eligible clinicians will be any clinician who ordered telemetry monitoring for the study participant. The POST questionnaire should be administered at the end of the SM phase after all subjects have completed study participation.

Telemetry Utilization Questionnaire for Clinicians (PRE)
Eligible clinicians will be any telemetry clinician who provides inpatient care for the study participant. Other eligible clinicians who may not provide direct care to participants but have visibility into hospital resource utilization impacting the flow of patients during the study period will be eligible. Examples clinicians include ED physicians/nurses, intensivists, critical care nurses, and hospitalists. The PRE questionnaire should be administered to the clinician after enrollment of the subject, but if the clinician is not available at the time of enrollment it is acceptable to administer the questionnaire during the inpatient period.

Telemetry Utilization Questionnaire for Clinicians (POST)
Eligible clinicians will be any telemetry clinician who provides inpatient care for the study participant. Other eligible clinicians who may not provide direct care to participants but have visibility into hospital resource utilization impacting the flow of patients during the study period will be eligible. Examples clinicians include ED physicians/nurses, intensivists, critical care nurses, and hospitalists. The POST questionnaire should be administered at the end of the SM phase after all subjects have completed study participation.

Clinical Team Satisfaction Questionnaire
Eligible clinicians will be any clinician who provides inpatient care to the study subject participating during the SM phase of the study and interacts with the study devices, the Vital Sync™ IM & VPMP and the BioModule. The satisfaction questionnaire should be administered to clinicians at the end of the SM phase after all subjects have completed study participation.

10.3. Subject Screening

Subjects who have an order placed for telemetry monitoring at the study site will be pre-screened as potential subjects for the study. In order to do so, only the existing information obtained per standard routine medical procedures will be used. No study-specific screening procedures, activities or questionnaires will be performed during the pre-screening. The Screening and Enrollment Log will capture both pre-screened and screened subjects. The log will also capture reasons why eligible pre-screened subjects did not participate in the study.

Potentially eligible subjects will be provided with detailed information about the study during the informed consent process. If the subject is willing to consider participation, written informed consent must be obtained.

After informed consent, if a subject does not meet the inclusion/exclusion criteria, the subject will be considered a screening failure and may not participate in the study. If the subject is determined to be ineligible for the study, the reason will be documented on the Screening and Enrollment Log.

10.4. Subject Consent

Informed consent must be obtained before a subject is enrolled in the study and/or before any study-specific procedures are initiated.

Potential subjects expressing an interest in participating in the study will be given written and oral information about the study, their rights as a subject in a research project, as well as a copy of the subject informed consent form. The potential subject will be encouraged to discuss participation in the study with their support network (family, friends, ordering physician). Any study-related questions posed by the potential subject will be answered. Potential subjects are given adequate time to consider their participation.

Potential subjects who then wish to participate and who appear to meet the inclusion/exclusion criteria will be asked to sign and personally date the Informed Consent Form. The investigator and or an authorized designee will also sign and personally date the Informed Consent Form The signed original informed consent is maintained in the investigator's records, and a copy given to the subject.

The Informed Consent Form should cover all essential information per the protocol, Good Clinical Practices (GCP), release of hospital billing data, and the applicable regulatory requirements.

If the Informed Consent Form is amended/updated throughout the life-cycle of the study, study subjects may be asked to re-consent by reviewing, signing and personally dating the updated Informed Consent Form. A copy of the amended/updated Informed Consent Form will be provided to the subject.

10.5. Blinding

No blinding will occur during the course of the study.

10.6. Randomization

No randomization will be used during the course of the study. Assignment to a monitoring arm will be determined by the phase status of the study. During the TM phase, all subjects will be assigned to the TM group. During the SM phase, all subjects will be assigned to the SM group.

10.7. Assessment of Safety

Methods and timing for assessing, recording, and analyzing safety parameters, including adverse events are described in section 12.

10.8. Recording Data

The investigator will clearly mark the clinical records to indicate that the subject is enrolled in this clinical study.

Subject's medical record will be used as source documents. Additional source worksheets will serve as supplemental source documentation when a data field is not in the subject's medical record.

The investigator will allow inspections of the study site and documentation by Clinical Research and audit personnel from Medtronic or designee, IRB, external auditors, or representatives of regulatory authorities. The purpose of these inspections is to verify and corroborate the data collected on the eCRFs. In order to do this, direct and secure access to medical or clinical records and billing databases will be necessary.

The investigator must ensure accuracy, completeness and timeliness of the data reported in the eCRFs and in all other required reports. Data reported on the eCRFs which are derived from source documents, such as patient medical records, must be consistent with the source documents or the discrepancies need to be justified in a documented rationale, signed and dated by the Principal Investigator, to be filed in the subject file. All baseline and medical history data must be derived from source documents. Only authorized persons can complete eCRFs and record observation. Training will be provided to site personnel on the use of data collection tools, as described in section 8.5. A final version of eCRFs will be provided to the investigation site when the investigational site has been declared ready for the study.

Sponsor study personnel will review collected data and create data queries for missing data that impacts data analysis. Queries will be sent to the investigator or appropriate support staff for resolution within a preferred 5 business day period. Where copies of the original source document as well as print outs of original electronic source documents are retained, these shall be signed and dated by a member of the investigation site team with a statement that it is a true reproduction of the original source document.

10.9. Deviation Handling

The investigator is required to conduct this study in accordance with the CIP, IRB requirements and applicable regulations.

A CIP deviation is defined as an event when the investigator or site personnel did not conduct the study according to the CIP or the clinical trial agreement. Thorough documentation of all deviations in source documents and transcription to eCRF is required, along with notification to your sponsor contact. Additionally, the site must complete the Deviation Log found in the ISF.

Major deviations are associated with subject safety or data integrity. They are defined as deviations with respect to:

- Patient informed consent procedure
- Patient eligibility criteria at the time of initial screening/enrollment
    - Deviations of daily tracking of eligibility procedures are not a major deviation
- Study data collection and reporting
- SADE reporting

All deviations and reasons to deviate from the study protocol must be reported prior to deviation when planned or promptly after occurrence when unplanned to the sponsor regardless of whether medically justifiable, pre-approved by the sponsor, or taken to protect the subject in an emergency.

10.10. Subject Withdrawal or Discontinuation

During the course of this study, subjects may elect to be or may be withdrawn from further treatment for any of the following reasons:

- The subject may withdraw from the study for any reason without prejudice
- The clinician or investigator may terminate the study at their discretion
- Subject is prescribed additional continuous monitoring after enrollment
- Within the first 12 hours of study participation, subject is discharged from hospital or removed from the study for any reason
- Subject no longer meet study inclusion/exclusion criteria
- Technical issues that prevent continuous data collection from the Vital Sync™ IM & VPMP
- Sponsor terminates the study
- Other

Subjects may withdraw from the study at any time and for any reason. If a subject officially withdraws from the study, the investigator will document the reason and collect final outcomes data from the subject's medical record. No additional follow-up will occur for withdrawn subjects.

Subjects may only be replaced if the they are a screen failure OR are withdrawn from the study during the first 12 hours of enrollment for any reason.

Withdrawal or discontinuation from the study will not affect the subject's regular care/hospitalization in any way.

10.11. Role of Sponsors Representatives

Sponsor's representatives may provide support as required for the clinical study, including technical support or training staff in the different hospital units. The sponsor will collaborate with investigator to implement the SM strategy which may include a sponsor implementation team to assist the site with adopting the SM strategy into their clinical workflow.

11. Risks and Benefits

11.1. Potential Risks

Risks under this protocol relate to both study devices and study procedures. The devices in this study are non-invasive, post-market products with FDA clearance, and will be used in accordance with their labeling. The clinical protocol design is minimal risk to the subject.

Following is a list detailing potential risks from the Vital Sync™ IM & VPMP, the BioModule, and the clinical study protocol.

Risk associated with the Vital Sync™ IM & VPMP

- Use errors could cause delay in treatment or incorrect treatment. Potential use errors include manually entering incorrect parameter values, adjusting the alarm priority for the incorrect alarm, or an unauthorized user disassociating devices from patients. Multiple design mitigations such as

data validation, administrator account, and user interface acknowledgement messages have been implemented to reduce the possibility of hazardous situations arising from use errors.

- Use of the Vital Sync™ IM & VPMP by clinicians remotely viewing patient data in a non-secure environment presents potential risk of breaches of patient confidential data from clinicians remotely viewing patient data. Mitigations for patient privacy risks include security on the software server architecture, providing instructions for users on how to lock down the bedside displays' operating system, and instructing users to utilize a secure network for remote viewing of patient data.

- Environmental risks could cause delay in treatment. Potential environmental risks includes radio interference, patient being out of range, and network failure. This would result in delay in treatment since the patient would experience a loss of monitoring, sending stale data over the network, or having the clinician unable to receive the alert notification. Environmental risk mitigations include an aged data indicator, message time stamps, disconnect and performance notifications.

[redacted]

Risks associated with clinical study protocol:
There are no known risks associated specifically with the clinical study protocol.

Inclusion and exclusion criteria have been described to recruit only appropriate subjects into the study. Potential subjects who may be at increased risk from the devices will not be enrolled. For example, subjects with implanted pacemaker or defibrillator will not be included. If there is any question of the subject meeting inclusion/exclusion for enrollment, Medtronic should be contacted to discuss first.

11.2. Potential Benefits

Subjects' participation in this study may offer no additional benefit in respect to the same monitoring provided outside of the study.

Possible benefits for participating in this study include the following (although others are possible):

- Subjects in SM arm may benefit from the alternative surveillance monitoring strategy via detection of clinical deterioration during the course of hospital stay.

There is, however, the potential for benefiting future patients should this study lead to the development of safer, more accurate, more cost-effective, and easier-to-use medical monitoring devices.

Since this is not a treatment study, the alternative is to not participate in the study.

11.3. Risk-Benefit Rationale

Medtronic believes that the potential risks associated with the conduct of this trial are minimal using nonsignificant risk, non-invasive study devices for the following reasons:

- All the devices used in the study are cleared by FDA and available in the hospitals and used within their intended use.
- Surveillance monitoring will be performed in addition to standard patient "spot-check" monitoring performed by hospital staff.
- The "Instructions for Use" and product labeling for the devices which will be provided to investigator prominently include statements that clearly advise users about how to properly use the system and interpret the output. Thus, users will clearly be instructed how to avoid and prevent many of these risks.
- The expected likelihood that any of these failure modes could occur during conceivable use of the BioModule on a patient is very small. The likelihood that an actual injury would occur if a rare failure mode of the BioModule occurs simultaneously is vanishingly small. This analysis is based upon clinical experience as well as a wide body of published knowledge on the magnitude and impact of changes in physiology of low acuity patients possibly monitored with the BioModule.
- Risk of injury is further mitigated because routine clinical observation is frequently deployed in addition to any monitoring. Based on the results of the risk benefit analysis, the benefits outweigh the risks for basic physiologic monitoring.

12. Adverse Event Assessments

Only the following adverse events will be collected for this study:

- Any adverse events noting mild or moderate physiological deterioration
- Any adverse event whose relationship to the study device is: possible, probable, definite, or unknown/ impossible to determine, regardless of what the event may be.
- All SAEs, of any relationship, meeting definition in section 12.2 of the CIP must be reported.

The recording of adverse events for all enrolled subjects begin after the study devices are attached and ends with the subject's completes study enrollment. Completion is defined by when a subject is discharged from the hospital, completes 30 day (± 2 days) enrollment period, or if the subject is withdrawn from the study for any reason.

12.1. Anticipated Adverse Events

Types of anticipated clinical signs, symptoms or conditions that could occur during this study, include the following:

- Redness of skin
- Skin burn
- Allergic reaction to ECG lead adhesives

12.2. Definitions/Classifications

For the purposes of the clinical report, the sponsor will classify each adverse.

- **Adverse Events (AE):** Any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the medical device.
  NOTE 1: This definition includes events related to the investigational medical device or the comparator.
  NOTE 2: This definition includes events related to the procedures involved.
  NOTE 3: For users or other persons, this definition is restricted to events related to investigational medical devices.

- **Adverse Device Effect (ADE):** Adverse event related to the use of a medical device.
  NOTE 1: This definition includes adverse events resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, or operation, or any malfunction of the investigational medical device.
  NOTE 2: This definition includes any event resulting from use error or from intentional misuse of the investigational medical device

- **Serious Adverse Event (SAE):** Adverse event that
  1. led to death,
  2. led to serious deterioration in the health of the subject, that either resulted in
     a. a life-threatening illness or injury, or
     b. a permanent impairment of a body structure or a body function, or
     c. in-patient or prolonged hospitalization, or
     d. medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,
  3. led to fetal distress, fetal death or a congenital abnormality or birth defect

NOTE: Planned hospitalization for a pre-existing condition, or a procedure required by the protocol, without serious deterioration in health, is not considered a serious adverse event.

- **Serious Adverse Device Effect (SADE):** Adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event.

- **Device Deficiency:** Inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety or performance. Device deficiencies include malfunctions, use errors, and inadequate labelling.

12.3. Recording and Reporting Adverse Events and Device Deficiencies

Adverse Event and Device Deficiency information will be collected throughout the study on the source, eCRF, AE log, or the Device Deficiency form located in the Investigator Site File (ISF).

Information reported on the CRF will include:

- Adverse Event diagnosis term to be determined by investigator
- A detailed description of the event
- The date of event onset
- The relatedness of the event to the device to be determined by investigator
- The relatedness of the event to the procedure to be determined by investigator
- Severity to be determined by investigator
- Actions taken as a result of the event per investigator
- The outcome of the event
- The date the event was first noticed by the investigator
- For device deficiency, determine if it could have led to a SADE

The investigator must report any SADE/SAE to the sponsor and IRB as soon as possible, but no later than 10 working days after the investigator learns of the effect.

Medtronic will conduct an evaluation of any SADE/SAE after first receiving notice of the event and report the results to all reviewing IRBs, the participating investigator and, if the effect is determined to be device-related, to the FDA.

12.3.1. Product Complaint Reporting

In geographies where devices are market-released, product complaint reporting is applicable. This includes when an AE is related to a market-released device during the study. The reporting of product complaints is not part of the clinical study and should be done in addition to the AE reporting requirements. Refer to local regulations for reporting requirements.

Product Complaint: Any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness or performance of a medical device that has been placed on the market.

It is the responsibility of the investigator to report all product complaint(s) associated with a medical device distributed by Medtronic, regardless whether they are related to intended use, misuse or abuse of

the product. Any complaints should be reported to Medtronic via written, electronic, or oral reporting method in a timely manner to your Medtronic contact. Medtronic will notify the regulatory authorities (e.g. FDA, Competent Authority) for applicable incidents immediately upon learning of them.

12.3.2. Emergency Contact Information in case of SAE/SADE

[redacted]

13. Statistical Design and Methods

13.1. Sample Size Justification

The study sample size is based on the primary non-inferiority objective of comparing hospital length of stay (LOS) between the surveillance monitoring (SM) and telemetry monitoring (TM) period on subjects without AHA telemetry indication. From similar study data published in the literature, we assume a similar LOS distribution for both monitoring groups with a common coefficients of variation of 0.65. With a pre-specified non-inferiority margin of 0.2 for the mean ratio, a sample size of 132 in each group will provide more than 80% power to assess the objective at the significance level of 0.05. Assuming at least 30% attrition from withdrawals and screen failures, up to 220 recruited subjects in each monitoring group will be used for this study.

13.2. Hypotheses and Endpoints

The primary study endpoint is hospital of length of study (LOS), which is calculated from date of admission and discharge. The primary objective is to demonstrate that LOS of the SM group is similar (non-inferior) to the TM group.

[redacted]

Additionally, if the non-inferiority objective is met, superiority will also be assessed (without statistical penalty) to further understand the effectiveness of SM versus TM. The corresponding superiority hypothesis [redacted] e., SM has shorter LOS duration than TM).

Secondary clinical and qualitative endpoints include:

- number of RRT interventions between monitoring groups
- survival rates post RRT interventions between monitoring groups
- Time of RRT activation to time of threshold notifications from SM system following clinical deterioration events
- code blue rates between monitoring groups
- unplanned intubations between monitoring groups
- clinical team satisfaction with surveillance monitoring and study product
- patient satisfaction with surveillance monitoring and study product
- perceptions of clinicians who prescribe telemetry to patients without AHA indication
- Clinicians' perceptions on telemetry utilization and impact on hospital resource utilization and patient flow

Additionally, healthcare economic and resource utilization data will be collected to evaluate:

- telemetry bed, ED, and ICU bed availability between monitoring periods
- associated health care costs between monitoring periods
- the number of ICU, ED, PACU, and telemetry delays in transfer between monitoring periods
- the number of hospital unit transfers between monitoring groups
- the number of unplanned ICU transfers between monitoring groups
- ICU LOS for subjects who have an unplanned transfer to the ICU between monitoring groups
- the number of unnecessary diagnostic tests and therapeutic procedures generated by artifacts and/or misdiagnosis between monitoring groups

13.3. Statistical Analysis

In general, descriptive statistics will be used to summarize baseline and study outcomes. For continuous variables, number of available observations, mean, standard deviation, median, minimum and maximum values will be provided. For categorical variables, frequency and percentage will be used. Unless otherwise specified, statistical assessments will be based on 2-sided tests at an alpha level of 0.05, which include Student-t or Wilcoxon rank-sum or ANOVA test for continuous variables, and Chi-square or Fisher's exact test for categorical variables. Multivariate regression models will be used to assess impacts of potential confounding variable. [redacted].

The primary effectiveness analysis will be based on all evaluable data from this study. A per protocol analysis will be performed based on all subjects who are compliant with the study protocol, i.e. who provide valid informed consents.

For safety assessments, adverse events (AEs) will be summarized using frequency counts and percentages. Descriptive statistics will be provided by monitoring group and by severity and relationship. Additionally, differences between the two monitoring groups will be summarized along with 95% confidence intervals. Individual listings of adverse events, including event type, start date, duration,

severity, and device-relatedness will be provided as appropriate. The safety analysis will be based on all patients participated in the study.

Further, a health economic analysis will be performed based on healthcare economic and resource utilization data collected in this study. A separate health economic data collection plan will be developed outside of this CIP. Monitoring effectiveness, QoL in the form of Quality-Adjusted Life-Years (QALYs), life-years gained and other data collected in this study may be used as inputs to the model.

Any deviations from the original statistical plan will be justified and documented appropriately.

14. Ethics

14.1. Statements of Compliance

This clinical study will be conducted in compliance with 21 CFR 803, laws and regulations of the countries in which the clinical study is conducted, including data protection laws, the Clinical Investigation Agreement, and the Clinical Investigation Plan.

All principles of the Declaration of Helsinki have been implemented in this clinical study by means of the informed consent process, IRB approval, and clinical study training.

If the regulatory authority imposes any additional requirements (e.g. safety reports, progress reports etc.), Medtronic will prepare the required documents and send them to the respective authority.

Patient Monitoring & Recovery is a business unit of Covidien LP, an indirect wholly owned subsidiary of Medtronic plc, which as the parent company of such entity maintains appropriate clinical study liability insurance coverage as required under applicable laws and regulations and will comply with applicable law and customs concerning specific insurance coverage. If required, a Clinical Trial Insurance statement/certificate will be provided to the IRB.

14.2. Subject Compensation

[redacted]

15. Study Administration

15.1. Monitoring

It is the responsibility of Medtronic to ensure proper monitoring of the study per regulations. Appropriately trained Medtronic personnel or delegates appointed by Medtronic will perform study monitoring at the study center in order to ensure that the study is conducted in accordance with the Clinical Investigation Plan (CIP), the Clinical Trial Agreement, and applicable regulatory requirements. Medtronic must therefore be allowed access to the subject's clinic and hospital records when so requested as per the Informed Consent Form and Clinical Trial Agreement.

Monitoring visits will be conducted at the start, during and at the closure of the clinical study in accordance with Medtronic internal SOPs and the Monitoring Plan. An interim monitoring visit may be combined with the closing monitoring visit.

Frequency of monitoring visits will occur based on subject enrollment, duration of the study, study compliance, findings from previous monitoring visits and any suspected inconsistency in data that requires investigation. Regulatory documents (e.g., Informed Consent Form, IRB approval letters and Clinical Trial Agreements, etc.) will be reviewed at the study center.

Monitoring visits will be conducted periodically to assess site study progress, the investigator's adherence to the CIP, regulatory compliance including but not limited to IRB review and approval of the study, maintenance of records and reports, and review of source documents against subject eCRFs. Monitors facilitate site regulatory and study compliance by identifying findings of non-compliance and communicating those findings along with recommendations for preventative/corrective actions to site personnel. This may be done in collaboration with the study management and the local field personnel, if available. Communication with the site personnel occurs during the visit and following the visit via a written follow-up letter. Monitors may work with study personnel to determine appropriate corrective action recommendations and to identify trends within the study or at a particular center. Study closure visits will be conducted via telephone, letter, or on site at the enrolling study center.

15.2. Data Management

The investigator must ensure accuracy, completeness, and timeliness of the data reported in the CRFs and in all other required reports. Data reported on the eCRFs which are derived from source documents must be consistent with the source documents and discrepancies need to be justified in a documented rationale, signed and dated by the Principal Investigator, and filed in the subject medical file.

Only authorized persons can complete eCRFs. eCRFs shall be signed by the investigator (physicians only) as specified on the Delegated Tasks List included in the Investigator Site File.

The Electronic Data Capture (EDC) system maintains an audit trail on entries, changes or corrections in eCRFs. If a person is only authorized to complete eCRFs or make changes to an already signed eCRF, the investigator shall re-sign this eCRF.

The following data will be recorded directly on the eCRF and is considered as source data:

- Patient hospital billing data
- Hospital resource utilization data

Reports generated by Vital Sync™ IM & VPMP and raw data from the BioModule will be the source to determine the time of when a subject crossed protocol defined activation thresholds for clinical deterioration.

It is preferred that eCRFs will be completed within 5 business days from the performed visit or as soon as source documents are available, except for Serious Adverse Events that require immediate reporting and for Protocol Deviation requiring pre-approval. A delayed completion of the eCRF will not be considered a Protocol Deviation.

Data management will be done according to Medtronic SOPs that will be made available on request.

All collected data will be reviewed for completeness, correctness and consistency. In case of issues, queries will be sent to the investigator or appropriate support staff to complete, correct or comment on the data. Corrections are preferred within 5 business days.

15.3. Accessibility of Investigation Site Staff and Study Materials

The principal investigator(s), his/her delegate(s) and the study coordinator(s) shall be accessible to Medtronic field personnel and the Clinical Study Manager. This accessibility is of particular importance for reviewing data in the eCRF. Individual, secure, and direct access to patient medical files for source data verification (if applicable) will need to be granted and prepared prior to any monitoring visits.

15.4. Audits and Investigation Site Inspections

In addition to regular monitoring visits, Medtronic may conduct audits at the participating investigation site. The purpose of an audit is to verify the adequate performance of the clinical study related activities independent of the employees involved in the clinical study. Regulatory authorities may also perform inspections at the participating investigation site. Any regulatory authority inspection announcements shall be forwarded immediately to Clinical Study Manager.

The investigator and/or institution shall permit Medtronic and regulatory bodies direct access to source data and documents, taking into account any restrictions due to local law, to perform clinical study related monitoring, audits, IRB review (if applicable), and regulatory inspections.

15.5. Confidentiality

Access to subject's records is restricted to the clinical investigator and clinical site support staff, to the sponsor and to other researchers involved. Regulatory authorities and IRB may also be granted direct access to the medical records/ study files in order to comply with legal and regulatory requirements. Physical study documents will be stored in secure, access-controlled locations at the clinical site.

Study results reported by the investigator or the sponsor will be in aggregate form with individual identities not publicly disclosed. It is possible that legal authorities may request detailed clinical information regarding specific subjects. In these situations, information will be provided by study identification number.

15.6. IRB Approval

Prior to enrolling subjects in this clinical study, the investigation site's IRB will be required to approve the current Clinical Investigation Plan, the Patient Information and Informed Consent form, including any other written information to be provided to the subjects and materials used to recruit subjects. IRB approval of the clinical study must be received in the form of a letter and provided to Medtronic before commencement of the clinical study at an investigation site. The approval letter must contain enough information to identify the version or date of the documents approved. If this information is not contained in the approval letter, it must be retrievable from the corresponding submission letter. In addition, the approval letter needs to be accompanied by an IRB roster or letter of compliance, to allow verification that the investigator, other investigation site personnel, and/or Medtronic personnel are not members of the IRB. If they are members of the IRB, written documentation is required stating that he/she did not participate in the approval process. If the IRB imposes any additional requirements (e.g. safety reports, progress reports etc.), Medtronic will prepare the required documents and send them to the investigator

for reporting to the IRB. The investigator must inform Medtronic of any change in status of IRB approval once the investigation site has started enrollment. If any action is taken by an IRB with respect to the investigation, that information will be forwarded to Medtronic by the respective investigator

15.7. CIP Amendments

The investigator will propose any appropriate modification(s) of the Clinical Investigation Plan. Medtronic will review this proposal and decide whether the modification(s) will be implemented.

Medtronic will submit any significant amendment to the Clinical Investigation Plan, including a justification for this amendment, to the appropriate regulatory authorities and to the investigator to obtain approval from their IRB, if applicable. Administrative amendments to the Clinical Investigation Plan will be submitted to the IRB and appropriate regulatory authorities for notification, if applicable.

15.8. Reporting Requirements and Record Retention

Investigator records

At a minimum, the following records must be kept by the investigator:

- Clinical Investigation Plan and, if applicable, any amendments
- Medtronic and IRB approved Informed Consent
- Regulatory Authority approval or notification, if applicable
- Fully signed clinical investigation agreement and confidentiality agreement (if not included in the clinical investigation agreement)
- Financial disclosures, if applicable
- Insurance certificates
- Completed Delegated Task List and Curriculum Vitae of Primary Investigator
- Training documentation of all investigation site personnel
- Relevant communications
- Screening and Enrollment Log
- Subject Identification Log
- Product Accountability Log
- Clinician Participant Log
- Signed, dated and fully executed informed consent forms
- Fully executed CRFs and corrections

Investigator reporting responsibilities

Report	Submitted to	Description
Adverse Events	Sponsor, IRB, and local regulatory authority, where applicable	Refer to section 12.3 for reporting requirements.
Withdrawal of IRB approval	Sponsor	Investigator will inform Medtronic in case IRB approval is withdrawn.

Report	Submitted to	Description
Final Clinical Study Report	IRB	A copy of the Final Clinical Study Report will be provided to the IRB.
Deviations from Investigational Plan		
Emergency Use	Sponsor, IRB, regulatory authority	Investigator will report deviation as soon as possible to the sponsor and IRB.
Planned deviation	Sponsor, IRB, regulatory authority	Prior approval from Medtronic must always be obtained from Medtronic. If the deviation affects scientific soundness of the clinical study or the rights, safety, or welfare of the subject and is not an emergency, prior approval must be obtained from the IRB and regulatory authority.
Other Deviations	Sponsor	Deviations that are beyond the control of the investigator or deviations that do not affect the scientific soundness of the clinical study or the rights, safety, or welfare of the subject and are not an emergency, should be submitted as they are identified by the investigation site or Medtronic staff.

Sponsor records

At a minimum, the sponsor will keep the following records:

- All essential study documents and correspondence that pertains to the clinical study
- CIP and, if applicable, any amendments
- Curriculum vitae of Primary investigator Delegated Task Lists and training records of investigators and site staff
- IRB approvals/notifications and regulatory approvals/notifications
- Signed Clinical Investigation Agreements and signed agreements with third parties
- Insurance certificates
- Medtronic and IRB approved Informed Consents
- Site selection reports, site initiation reports and monitoring visit reports
- Adverse event reports
- Financial disclosures, if applicable
- Fully executed CRFs and corrections

Sponsor reporting responsibilities

Report	Submit to	Description
Adverse Events	IRB, Investigator, and regulatory authorities, where applicable	Medtronic will report adverse events as required and in compliance with local regulatory requirements, as applicable.
Withdrawal of IRB approval	IRB, Investigator, and regulatory authorities, where applicable	In case of withdrawal of IRB approval Medtronic will suspend the clinical study as described below.
Premature termination or suspension of study	IRB, Investigator, and regulatory authorities, where applicable	Medtronic will provide prompt notification of termination or suspension and reason(s) to investigator and where required to IRB and regulatory authorities.
Final Report	Investigator, and regulatory authorities, where applicable	Medtronic will provide the investigator with a copy of the Final Clinical Study Report of the clinical study. IRBs and regulatory authorities will be informed when required.
Emergency Deviations from Investigational Plan	Regulatory authorities, where applicable	If required, Medtronic will inform regulatory authorities as soon as possible about any emergency deviations that affect scientific soundness of the clinical study or the rights, safety, or welfare of the subject.

Study related documents must be maintained for a minimum of two years after latter of the following two dates in a limited access location: The date on which the study is terminated or completed, or the date that the records are no longer required for the purposed of supporting a premarket approval application or a notice of completion of a product development protocol. Prior to the destruction of the study related data, the investigator should notify the sponsor.

The investigator should take measures to prevent accidental or early destruction of the clinical study related materials.

15.9. Publication and Use of Information

The results of this clinical study are planned for publication. Publication/Presentation statement will be included in the clinical trial agreement between Medtronic and the site.

The study will be recorded on www.clinicaltrials.gov by Medtronic before the first enrollment.

15.10. Suspension or Early Termination

Medtronic or Regulatory Authority may decide to suspend or prematurely terminate the clinical study (e.g. if information becomes available that the risk to study subject is higher than initially indicated). If the clinical study is terminated prematurely or suspended, Medtronic shall promptly inform the clinical investigator of the termination or suspension and the reason(s) for this. The investigator shall then promptly inform the reviewing IRB and the study subjects or their legal representative.

Medtronic, IRB or Regulatory Authority may decide to suspend or prematurely terminate an investigation site (e.g. in case of expiring approval of the reviewing IRB, non-compliance to the Clinical Investigation Plan, or lack of enrollment). If an investigation site is suspended or prematurely terminated, Medtronic shall promptly inform the investigator(s) of the termination or suspension and the reason(s) for this. The investigator shall then promptly inform the reviewing IRB, if required, the study subjects or their legal representative.

When the risks are found to outweigh the potential benefits or when there is conclusive proof of definite outcomes, the investigator must assess whether to continue, modify or immediately stop the clinical study in
the respective investigation site and immediately inform the sponsor and IRB, if applicable.

In case of early investigation site suspension or termination subjects will be followed-up as per standard of care.

In case of close out, the investigator will be notified and notification/report to Medtronic and Regulatory Authority will be done, if required.

16. Advisory Committees

16.1. Data Monitoring Committee

A Data Monitoring Committee (DMC) will not be utilized for this clinical study as no interventions intended to prolong life or reduce risk of a major adverse health outcome (e.g., cardiovascular events) are evaluated, for which favorable or unfavorable study results suggest study termination. Additionally, there are no safety concerns suggesting the need for a DMC. This study is considered non-significant risk for study participants, thus the need for additional safety oversight beyond Medtronic's already rigorous safety monitoring processes is not required. Finally, this study does not have a pre-specified interim analysis.

17. References

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