# Statistical Analysis Plan

92616839, Version E

**MODULAR ATP Clinical Study**

**Effectiveness of the EMPOWER™ Modular Pacing System and EMBLEM™ Subcutaneous ICD to Communicate Antitachycardia Pacing**

C1907

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# Revision History

**Revision History**

| Revision Number/Release Date | Section | Change | Reason for Change |
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# TABLE OF CONTENTS

## PLANNED PROTOCOL ANALYSES

All information necessary to complete the required analyses for the MODULAR ATP study are contained within the MODULAR ATP protocol. Additional information is found in the following section. Note all sections referenced in the following section refer directly to those in the clinical study protocol.

# 1 ADDITIONAL INFORMATION

## 1.1 Sample Code for Adjusted Communication Success Rate

The following is sample code that will provide adjusted estimate of the communication success and 97.5% one-sided lower pointwise confidence limit:

where 'success' is an indicator of success for each communication test in all postures, 'subject' is the subject ID for all subjects that are evaluable for the endpoint, 'comm_success' is the adjusted communication success rate and 'lower_CL' is the 97.5% one-sided lower pointwise confidence limit.

## 1.2 Additional Information Regarding Secondary Effectiveness Endpoint

For a full description of this endpoint please refer to Section 11.1.5 of the MODULAR ATP Clinical Study Protocol.

Data used for the analysis of the Secondary Effectiveness Endpoint will be provided to the statistician performing the analysis as a validated dataset provided by the Boston Scientific engineering team with the normalized sensor-indicated rate and the normalized workload during the treadmill test.

The model for this endpoint is outlined in Section 11.1.5.3 of the MODULAR ATP Clinical Study Protocol. Subject-specific slopes from each test will be calculated by performing a general linear model with normalized sensor rate as the outcome and normalized workload as the predictor. For the purposes of evaluating the endpoint a zero-intercept model will be fit.

## 1.3 Ancillary Objectives

Additional information regarding the ancillary objectives outlined in Section 11.2 of the MODULAR ATP Clinical Study Protocol is found below:

- Summary of the mCRM Therapy System implant procedure characteristics:
    - Initial implant success rate of the EMPOWER PG – Number of implants out of all attempted implants
    - Initial implant success rate of the S-ICD (De Novo Implants) – Number of implants out of all attempted implants
    - Procedure Times (both EMPOWER PG and S-ICD)
    - Fluoro Time (both EMPOWER PG and S-ICD)
    - Implant position (both EMPOWER PG and S-ICD)
    - Number of EMPOWER PG repositions performed at implant
    - Summary of use of anticoagulation
    - Summary of use of antibiotics
    - Summary of use of antiplatelets
- Summary of pacing impedance and sensing amplitude at protocol-required follow ups
- Summary of ventricular tachycardia (VT)/ ventricular fibrillation (VF) S-ICD conversion and sensing interaction testing (Implant or Pre-Discharge)
    - Time to shock for induced episodes
    - Detected rhythm
    - Final Conversion Success Rate – successful conversion at ≤ 65J shock
- Summary of Communication Threshold Test at Implant, Pre-Discharge, 1-Month Visit and available Semi-Annual visits
- Summary of Communication Test results at available Semi-Annual visits
- Summary of incidence and threshold for Communication Muscle Stimulation at Implant
- Summary of number of postures with a successful communication test at the 6 Month Visit
- Summary of EMPOWER PG PCT at protocol-required follow ups
- Summary of spontaneous treated VT/ VF episodes
    - Initial Rhythm
    - Method of treatment (ATP, Shock, both)
    - Final Conversion Success – Any method
    - Time to first therapy (ATP or shock)
    - Summary of communication outcome between the S-ICD and EMPOWER MPS during treated spontaneous episodes, where

communication success will be reported as the number of qualified episodes with ATP delivered over the number of qualified episodes where ATP was requested

- Incidence of syncope related to treated and untreated spontaneous episodes of VT/ VF above the lowest programmed rate cutoff
- Incidence and appropriateness of post-shock demand pacing by the EMPOWER PG
- Summary of Inappropriate Therapy
    - Type of therapy delivered
    - Initial Rhythm
    - Arrythmia acceleration due to ATP delivery
    - Arrythmia induction due to ATP delivery
- Summary of Major EMPOWER MPS System- and Procedure-related Complications through both 6 and 12 months after the implant procedure
- Summary of mCRM Therapy System-related complications through both 6 and 12 months after the implant procedure*
- Summary of the EMPOWER PG performance from Holter Monitor recording
- Summary of EMPOWER PG battery charge remaining to End of Service (EOS) at protocol-required follow ups
- Summary of S-ICD PG remaining battery to Elective Replacement Indicator (ERI) per protocol-required follow ups (baseline adjusted to time of enrollment for S-ICD PGs implanted prior to enrollment in MODULAR ATP)

*S-ICD PG replacement due to normal battery depletion will not be included in this analysis

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### 1.4 Pooling Analysis

[redacted]

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### 1.5 Data Analysis for the DMC

Summaries of the AEs observed as part of the MODULAR ATP Clinical Study will be provided to the DMC in accordance to the timing outlined in the DMC Charter. These summaries will be performed by the MODULAR ATP statistician and he/she will attend the DMC meeting as requested by the DMC chair.