

STUDY NAME:

*EvaluatIng normal values for traditional anorectal fUnction paraMeters with aIr charged aNd
solid state HRAM catheters
("ILLUMINATE" study)*

NCT Number:

Not Applicable

Date of Document:

16SEP2025

SPONSOR:

Laborie Medical Technologies Corporation

180 International Drive

Portsmouth, NH 03801

USA

Status CURRENT Effective 6/19/2025

CLINICAL STUDY STATISTICAL ANALYSIS PLAN

DEVICE:

Solar™ Anorectal Manometry Catheter and Solar™ Anorectal Manometry Charger
(Herein referred to as “Solar catheter”)

And

UNITIP™ Solid State High Resolution Anorectal Manometry Catheter
(Herein referred to as “UNITIP catheter”)

STUDY NUMBER:

Solar-01





STUDY NAME:

Evaluating normal values for traditional anorectal function parameters with air charged and solid state HRAM catheters
(“ILLUMINATE” study)

Revision History

[REDACTED]		
[REDACTED]	[REDACTED]	[REDACTED]

Contents

1	Introduction and Purpose	4
2	Abbreviations	4
3	Objectives and Endpoints	4
3.1	ILLUMINATE Clinical Study Objectives	4
3.2	Study Endpoints	5
3.3	Procedure Related Terminologies	6
4	Study Design.....	7
4.1	Randomization/Blinding	7
4.2	Sample Size Determination.....	7
5	Statistical Analysis.....	8
5.1	General Considerations.....	8
5.2	Analysis population.....	8
5.3	Handling of Missing Data	8
5.4	Demographics and Baseline Characteristics	8
5.5	Analysis of Study Endpoints.....	8
5.6	Adverse Events (AEs).....	8

ILLUMINATE Clinical Study Statistical Analysis Plan

1 Introduction and Purpose

This statistical analysis plan (SAP) describes the statistical methods for the “Evaluating normal values for traditional anorectal function parameters with air charged and solid state HRAM catheters (known as the “ILLUMINATE” study for short)” clinical study. The SAP describes the planned statistical methods to be used during the analysis and reporting of data that will be collected during the ILLUMINATE study under the clinical investigation plan (CIP): [REDACTED] ILLUMINATE Clinical Study Protocol. This SAP should be read in conjunction with the CIP and associated case report forms (CRFs).

The purpose of the SAP is to provide clarification about the statistical considerations and methods to be implemented for the analysis of data. The statistical analysis plan has been reviewed by an independent statistician with no access to or knowledge of accumulating trial data. It is based on version B of the CIP [REDACTED]. Any revisions to this SAP will be made prior to database lock and reasons for such revisions will be described in the final clinical study report.

2 Abbreviations

Abbreviation or Acronym	Term/Meaning
ADE	adverse device effect
AE	adverse event
ASADE	anticipated serious adverse device effect
CRF	case report form
CIP	clinical investigation plan
DD	device deficiency
EC	ethics committee
SADE	serious adverse device effect
SAE	serious adverse event
USADE	unanticipated serious adverse device effect

3 Objectives and Endpoints

3.1 ILLUMINATE Clinical Study Objectives

The ILLUMINATE Clinical Study has a primary and a secondary objectives.

3.1.1 Primary objective:

- Obtain normative datasets for traditional measures of anorectal function with an air charged HRAM catheter in healthy subjects using the IAPWG standardized testing protocol and London classification for ARM measurement

ILLUMINATE Clinical Study Statistical Analysis Plan

3.1.2 Secondary objective:

- Qualitatively compare the performance of air charged and solid state HRAM catheters in determining normative values for traditional measures of anorectal function in a subset of study subjects using the IAPWG standardized testing protocol and London classification for ARM measurement.

3.2 Study Endpoints

3.2.1 Primary endpoints:

Each subject will undergo a standard ARM procedure using the Solar Catheter in accordance with standard of care, device IFU and the IAPWG standardized testing protocol and London classification for ARM measurement where, at minimum, the following parameters are collected:

- Functional anal canal length, cm
- Anal resting pressure, mmHg
- Anal squeeze pressure, mmHg
- Push pressure, mmHg
- Cough pressure, mmHg

Additionally, the following parameters may be collected:

- Rectal pressure increase, mmHg
- Anal pressure decrease, mmHg
- First constant sensation
- Defecatory desire volume, ml
- Maximum tolerated volume, ml

3.2.2 Secondary endpoints:

Will be measured by recording specific anorectal pressure parameters in each healthy individual using SolarTM air charged catheter and UniTipTM solid state catheter. The goal is to compare the readings recorded for each parameter by both catheters in the same healthy individual. The parameters to be recorded for comparison include, at minimum, the following:

- Functional anal canal length, cm
- Anal resting pressure, mmHg
- Anal squeeze pressure, mmHg
- Push pressure, mmHg
- Cough pressure, mmHg

Additionally, the following parameters may be collected:

- Rectal pressure increase, mmHg
- Anal pressure decrease, mmHg
- First constant sensation
- Defecatory desire volume, ml
- Maximum tolerated volume, ml

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

- [REDACTED]
- [REDACTED]
- [REDACTED]

[REDACTED]
[REDACTED]

Safety:

Collection and characterization of all reported adverse events from the start of study to study exit. Adverse event details to be collected can be found on [REDACTED] ILLUMINATE Study CRFs.

3.3 Procedure Related Terminologies

Healthy volunteers who are eligible for anorectal manometry measurements may undergo high-resolution anorectal manometry (HRAM) procedure to achieve study objectives.

- I. [REDACTED]
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]
- [REDACTED]
 - [REDACTED]
- [REDACTED]
 - [REDACTED]
- [REDACTED]
 - [REDACTED]
- [REDACTED]
 - [REDACTED]
- [REDACTED]
 - [REDACTED]

ILLUMINATE Clinical Study Statistical Analysis Plan

4 Study Design

This is a prospective, multi-center, open label post-market study. The treatment arm (i.e., ARM with Solar catheter) will consist of approximately 81 asymptomatic individuals (volunteers) recruited from the intended patient population. A subset of up to 40 study subjects will be evaluated with two ARM catheters (i.e., Solar and UNITIP catheters). The order of application of the two catheters will not be randomized. A washout period between procedures will be determined by the investigator according to their standard practice and used to mitigate potential confounding impact of patient fatigue on the primary objective.

4.1 Randomization/Blinding

The ARM procedures during the study will be conducted in an open label setting so no blinding will be possible. Also, there will be no randomization. For all study subjects, the Solar catheter will be first in the order of catheter insertion during ARM procedures. The Solar catheter will be the first catheter that will be used in all study subjects, even for the subset of study subjects undergoing ARM procedures with both the Solar and UNITIP catheters. A washout period between procedures to be defined by the investigator in accordance with their standard of practice will be used to mitigate potential confounding impact of patient fatigue on the primary objective.

4.2 Sample Size Determination

This is a descriptive study aimed at estimating parameters used in diagnostic evaluation of gastrointestinal disorders. No formal hypothesis tests are planned for any endpoint, and descriptive statistics and exploratory analyses will be used in reporting outcomes for all endpoints. The sample size is calculated for estimating the mean for specific parameters with a specified precision.

[illegible]

ILLUMINATE Clinical Study Statistical Analysis Plan

5 Statistical Analysis

5.1 General Considerations

Descriptive statistics will be used to analyze data from this study. Continuous variables will be summarized with means, median, standard deviations, IQR, sample size (N), minimums, and maximums. If included, categorical variables will be summarized in frequencies and percentages in the category of interest. Statistical analysis will be conducted in SAS or other validated statistical software package.

5.2 Analysis population

All subjects enrolled and completing the HRAM procedure will be considered in the Full Analysis Set. Enrolled subjects who do not undergo the HRAM procedure or begin the HRAM procedure but do not complete it (for any reason determined by the investigator to be unrelated to the SOLAR™ or UNITIP™ catheters) will not be included in the final analysis and can be replaced.

5.3 Handling of Missing Data

All attempts will be made to limit the amount of missing data. If any CRFs are found to be incomplete, the study monitor will follow up as to the reason. No attempt will be made to impute missing data. If a data point is missing, that data point will not contribute to that portion of the analysis. The number of evaluable observations will be reported in each analysis so that the extent of missing data can be assessed.

5.4 Demographics and Baseline Characteristics

Descriptive statistics will be presented for all baseline demographic, medical history, and clinical characteristic variables collected. The summary of demographics and other baseline characteristics will be completed for the Full Analysis Set as well as stratified by gender.

5.5 Analysis of Study Endpoints

Results provided from the software analysis of the study endpoints will be summarized and reported. [REDACTED]

5.6 Adverse Events (AEs)

All reported adverse events from subject study enrollment to study exit of manometry procedures will be collected and characterized. AEs will be tabulated with the number of events and subjects experiencing the event for each event type and overall.

The tabulation of event type and cross-tabulation of event type by severity and relationship will be presented for the following sets of events:

- Adverse device effects (ADEs)
- Serious adverse device effects (SADEs)
- Unanticipated adverse device effects (UADEs) / Unanticipated serious adverse device effects (USADEs)

All device deficiencies will be reported in a listing format.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]