T-DOC® NXT Study

STUDY NUMBER:

TDOC-NXT-01

STUDY NAME:

T-DOC® NXT Clinical Investigation:

Assessing the Performance, Safety and Usability of our Next Generation T-DOC® NXT Catheter for Performing Urodynamic Studies

NCT NUMBER:

NCT03615001

DOCUMENT:

STATISTICAL ANALYSIS PLAN

DOCUMENT VERSION & DATE:

Version 1.0

November 8, 2018

CLINICAL STUDY STATISTICAL ANALYSIS PLAN

DEVICE:

T-DOC® NXT Air-Charged Urodynamic Catheters

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Assessing the Performance, Safety and Usability of our Next Generation T-DOC® NXT Catheter for Performing Urodynamic Studies

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November 8, 2018

SIGN-OFF

Statistician	Print Name	[redacted]	Date	12 Nov. 2018
	Signature	[redacted]		

This document has been reviewed by LABORIE (Refer to Entropy PRC# 023486).

Contents

Introduction

The purpose of this statistical analysis plan (SAP) is to provide clarification about the statistical considerations and methods to be implemented for the analysis of data from the T-DOC NXT clinical study. This statistical analysis plan is based on protocol version 1.0 (TDOC-NXT-01-PR-V1.0). The protocol clearly describes the study endpoints, but the hypothesis testing procedures and criteria for study success requires additional details. The SAP is written by an independent statistician [redacted] with no access to or knowledge of accumulating trial data. Any revisions to the SAP will be made prior to database lock and reasons for such revisions will be described in the final clinical study report.

Study Objectives and Endpoints

The following are the objectives and endpoints of the TDOC-NXT-01 clinical study:

OBJECTIVES	ENDPOINTS
Primary	
To confirm the T-DOC® NXT vesical and abdominal catheters as a safe and effective means of measuring urodynamic pressure in adults.	The primary endpoint will be measured by recording the clinician safety and effectiveness rating for each patient on their CRF. The clinician will indicate whether the T-DOC® NXT vesical and abdominal catheters are safe and effective for measuring urodynamics pressure in patients who enrolled and completed the urodynamic procedure.
Exploratory Objective 1	
To evaluate the usability of the device by collecting clinical user feedback and evaluating the following subjective measures using defined ordinal scales: ease of use, ease of insertion, presence of artefacts, stability of the tracing, perceived time savings, ease of voiding around catheter, presence of use errors and overall satisfaction.	The usability performance endpoint will be captured in a questionnaire format. The trained clinical users will rate the T-DOC® NXT performance on a scale of 1-5 on the study outcome questionnaire.
Exploratory Objective 2	
To explore whether the newly designed, smaller sized T-DOC® NXT catheters causes undue discomfort based on subjective subject feedback regarding the discomfort and pain level, for those able to communicate such feedback.	This exploratory endpoint will be measured by collecting patient feedback regarding the level of discomfort and pain experienced during their Urodynamic test using the Numeric Pain Rating Scale (NPRS). Patients capable of providing feedback on a scale, will grade their discomfort/pain at 5 or lower, on the NPRS from 0 (“No Hurt”) to 10 (“Hurts worst”).

Analysis Populations

All subjects enrolled and completed the urodynamic procedure will be considered in the final analysis. Enrolled subjects who do not undergo the urodynamic procedure or begin the urodynamic procedure but do not complete it (for any reason determined by the investigator to be unrelated to the T-DOC® NXT catheters) will not be included in the final analysis and can be replaced.

If any CRFs are found to be incomplete, the study monitor will follow-up as to the reasoning. If for some reason a clinical user is unable to complete their questionnaire, the questions they have completed will be included in the analysis.

Primary Endpoint

The primary safety and effectiveness endpoint is a binary clinician response after each UDS study using the T-DOC® NXT catheter to determine whether the ability to measure UDS pressure was clinically adequate (success) or inadequate (failure).

In the statistical analysis plan, the null hypotheses for the safety and effectiveness endpoints are designed to rule out success rates ≤ 75%.

The allowable Type I error (α) for each hypothesis will be 5% (1-sided), and the Type II error is calculated to be 10% (90% power).

Safety and effectiveness will be evaluated separately via the following sets of hypotheses:

Primary Hypothesis for Safety

H_0: Safety Success Rate is ≤ 75%

versus

H_A: Safety Success Rate is > 75%

Primary Hypothesis for Effectiveness

H_0: Effectiveness Success Rate is ≤ 75%

versus

H_A: Effectiveness Success Rate is > 75%

The study will be declared a success if both null hypotheses for safety and efficacy are ruled out.

Exploratory Endpoints

Exploratory Objective 1 for Usability Performance

This exploratory endpoint was collected to reflect that the goal of qualitatively describing users' interactions with the device as described in regulatory guidance for usability testing (*FDA's guidance- 'Applying Human Factors and Usability Engineering to Medical Device's, 2016*). A clinical user who completed the T-DOC® NXT clinical study, shall rate the T-DOC® NXT catheter usability performance on a scale of 1-5 for the clinical user questionnaire, comparing their experience with use of their currently used urodynamics catheter on per urodynamic day basis.

Since there will be only daily responses from one user for each of the questions, the results are thus not well-suited to statistical analysis and hypothesis testing is not appropriate. Instead, descriptive statistics will be used to summarize and analyse the results of each question, including: ease of use, ease of insertion, presence of artefacts, presence of coughs/Valsalva response, measurements and tracings of urethral pressure profiles, stability of the tracing, perceived time savings, ease of voiding around catheter, presence of errors and overall satisfaction.

The reported value in the usability performance survey will be analysed using proportions of levels and cumulative proportions of groupings at 95% confidence interval. This includes levels (1 to 5), "Yes and no", "better, same or worse" and any other questions related to usability.

Additionally, the results will be plotted over time to observe the trend as the study continues (preferably a line plot with daily responses over time).

Exploratory Objective 2 for Discomfort/Pain

To satisfy this exploratory endpoint for subject experience, a categorical response variable using the Numeric Pain Rating Scale (NPRS) from 0 ("No Hurt") to 10 ("Hurts worst") will be used. Subjects will grade their discomfort/pain on the scale from 0 ("No Hurt") to 10 ("Hurts worst"). Descriptive statistics will be used to summarize and analyse the results of questionnaires completed per patient for questions about pain during insertion, during test and during removal of the T-DOC® NXT catheters.

The reported value in the patient survey will be analysed using proportions of levels and cumulative proportions of groupings at 95% confidence interval. This includes levels (0 to 10) and "Yes and No".