CathVision

AUTOMATED ASSESSMENT OF PULMONARY VEIN ISOLATION USING A NOVEL EP RECORDING SYSTEM (PVISION)

Statistical Analysis Plan

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SPONSOR

CathVision ApS
Titangade 11
DK-2200
Copenhagen, DENMARK

CRO

AKRN Scientific Consulting S.L.

[redacted]

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1.0 ACRONYMS AND ABBREVIATIONS

Term	Definition
AE	Adverse Event
ADE	Adverse Device Effect
BPM	Beats-Per-Minute
CDF	Cumulative Distribution Function
CIP	Clinical Investigation Plan
CI	Confidence Interval
d	Superiority limit
EP	Electrophysiology
EGM	Electrogram
FN	False Negative
FP	False Positive
ITT	Intent-To-Treat
NSR	Non-Sinus Rhythm
RF	Radiofrequency
p	Proportion
PFA	Pulsed-field ablation
PPT	Per-Protocol-Treatment
PV	Pulmonary Vein
PVI	Pulmonary Vein Isolation
SAE	Serious Adverse Event
SADE	Serious Adverse Device Effect
SD	Standard Deviation
SE	Sensitivity: Is the ability of a test/procedure to correctly identify those with the disease (true positive rate)
SP	Specificity: Is the ability of the test to correctly identify those without the disease (true negative rate).
SR	Sinus Rhythm
TN	True Negative
TP	True Positive
UADE	Unanticipated Adverse Device Effect
USADE	Unanticipated Serious Adverse Device Effect

2.0 APPLICABLE DOCUMENTS

External references			
Document Type	**Document Number**	**Document Name**	**Version**
ISO Standard 14155:2020	N/A	ISO 14155:2020 — Clinical investigation of medical devices for human subjects — Good clinical practice	2020
ICH E9	N/A	Statistical Principles for Clinical Trials	01-SEP-1998
EU Regulation	N/A	Regulation (EU) 2017/745	N/A
Internal references			
Study Protocol	CPVI-002	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

3.0 SYNOPSIS OF STUDY DESIGN

3.1 Purpose of Statistical Analysis Plan

This statistical analysis plan is intended to provide a detailed and comprehensive description of the planned methodology and analysis to be used for the "Automated assessment of pulmonary vein isolation (PVI) using a novel electrophysiology (EP) procedure recording system (CathVision Cube® System)" clinical investigation. This plan is based on the CPVI-002 [redacted] Clinical Investigation Plan.

3.2 Clinical Investigation Objectives

The main objective in this study is to evaluate the performance of automated PVI Analyzer software with the CathVision Cube® system in radiofrequency (RF), cryo-balloon and pulsed-field ablation (PFA) procedures.

The primary objective of the study is to validate the PVI Analyzer software with a novel EP recording system (CathVision Cube® System) for assisting assessment of isolation status following PVI ablation, while the secondary objectives include the assessment of the accuracy of automated PVI Analyzer classification of pulmonary vein isolation procedures, the determination of the feasibility of "real-time" assessment of PVI analysis, and the assessment of rhythm-dependent performance using the PVI Analyzer and CathVision Cube® System, among other analyses.

3.3 Clinical Investigation Design

The PVISION clinical study is a prospective, multi-center study with the CathVision Cube® system and the PVI Analyzer software in pulmonary vein isolation procedures.

The study population is expected to be up to 120 subjects, distributed in three different procedures: RF, cryo-balloon and PFA. [redacted]

Up to 30 subjects will be enrolled for PFA, [redacted]

3.4 Endpoints

3.4.1 Primary endpoint

The primary performance endpoint is to validate the PVI Analyzer analysis software with a novel EP recording system (CathVision Cube® System) for assessment of isolation status following PVI ablation. The overall performance of pulmonary vein (PV) isolation classification shall be superior to a specified level of performance.

- Automated PVI Analyzer classification of PV isolation in sinus rhythm (SR) during PVI ablation treatment with a specificity and sensitivity both superior to 80%.

[redacted]

[redacted]

3.4.2 Safety endpoint

The safety endpoint of the Study is to evaluate the adverse events (AEs) and/or device deficiencies reported with the use of the CathVision Cube® System. [redacted] it is expected that AEs related to the device and device deficiencies will be minimal or absent.

3.4.3 Secondary performance endpoints

The secondary performance endpoints have been established to determine the feasibility of time-critical assessment of PVI analysis and rhythm-dependent performance using the PVI Analyzer software with the CathVision Cube® System through the following items:

1. Accuracy of automated PVI Analyzer classification of PV isolation in SR during PVI Cryo-balloon ablation
2. Accuracy of automated PVI Analyzer classification of PV isolation in SR during RF ablation
3. Assessment of automated PVI Analyzer classification of PV isolation in SR after PFA
4. Feasibility of continuous "real-time" assessment of isolation
5. Feasibility of assessment of isolation during AF rhythm
6. Feasibility of assessment of isolation at time of expert-defined isolation before the end of the ablation procedure
7. Comparison of device performance on same data recorded by CathVision Cube and Boston Scientific LSPro

“Classification” in secondary performance endpoints also follows the definition described for the primary endpoint.

3.5 Randomization and blinding

Randomization and blinding are not applicable to this study. [redacted]

4.0 ANALYSIS CONSIDERATIONS

4.1 Analysis Populations

Enrolled population includes up to 120 patients fulfilling all inclusion criteria, [redacted].
If any of the exclusion criteria are met, the patient is excluded from the clinical investigation and cannot be enrolled.

4.1.1 Intent-to-treat population (ITT)

[redacted]

4.1.2 Per-protocol treatment (PPT)

[redacted]

4.2 Data Processing

[redacted]

[redacted]

4.3 Statistical Methods

4.3.1 Descriptive statistics for continuous variables

Continuous variables (e.g., age, beats per minute (BPM), etc.), will be summarized using standard quantitative statistics: number of non-missing observations, mean, standard deviation, median, quartiles and range (minimum and maximum observed values), with 95% confidence intervals (CI) where specified in the table mockups. The number of missing observations, if any, will also be summarized.

4.3.2 Descriptive statistics for categorical variables

For categorical variables (e.g., gender, diabetic status, etc.), results will be summarized using classical frequency statistics: number of non-missing observations and percentages/rates by categories, and where specified in the table mockups, with exact 95% Clopper-Pearson CI.

4.4 Endpoint Analysis

4.4.1 Primary endpoint

The primary performance endpoint for this investigation is to validate the PVI Analyzer analysis software with a novel EP recording system (CathVision Cube® System) for assessment of isolation status following PVI ablation[redacted]

The performance is evaluated separately for specificity and sensitivity;[redacted]

[redacted]

[redacted]

[redacted]

[redacted] a clinically relevant lower limit of performance has been established and defined as 80% specificity and 80% sensitivity. [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

4.4.2 Safety endpoint

The safety endpoint of the study will evaluate the AEs and/or device deficiencies reported with the use of the CathVision Cube® System [redacted]

4.4.3 Secondary endpoints

The secondary performance endpoints will determine the feasibility of time-critical assessment of PVI analysis and rhythm-dependent performance using the PVI Analyzer software with the CathVision Cube® System. [redacted]

- Accuracy of automated PVI Analyzer classification of PV isolation in SR during Cryo-balloon ablation. [redacted]
- Accuracy of automated PVI Analyzer classification of PV isolation in SR during RF ablation. [redacted]

[redacted]

- Assessment of automated PVI Analyzer classification of PV isolation in SR after PFA. [redacted]
- Automated PVI Analyzer classification of PV isolation in NSR. [redacted]
- Feasibility of "real-time" assessment of isolation. [redacted]
- PVI Analyzer classification accuracy at the time of expert-defined isolation. [redacted]
- Comparison of device performance with conventional system. [redacted]

4.5 Sample Size Calculations

The sample size calculation is based on the primary performance endpoint to demonstrate that the PVI Analyzer software is superior to clinically relevant performance level, as established by prior publications. [redacted]

[redacted] a maximum of 90 subjects will be required.

[redacted]

A cohort of 30 subjects undergoing PFA will be added to the study, and this additional data will be analyzed posteriorly. This PFA cohort does not relate to the primary endpoint and therefore does not affect the primary endpoint analysis nor the sample size calculation.

4.6 [redacted]

[redacted]

[redacted]

4.7 Timing of Analysis

[redacted]

4.8 Study Success

[redacted]

4.9 [redacted]

[redacted]

[redacted]

[redacted]

4.10 Handling of Missing Data

Missing data will be counted and summarized in the descriptive analysis for continuous and categorical variables.

Missing data will not be replaced or imputed.

[redacted]

4.11 [redacted]

[redacted]

4.12 [redacted]

[redacted]

[redacted]

5.0 DESCRIPTIVE ENDPOINTS AND ADDITIONAL DATA

5.1 Baseline and Demographic Characteristics

The following baseline and demographic variables will be summarized for the subjects enrolled: gender, age, atrial fibrillation and cardiovascular history, cardiac medications, implant procedural characteristics, etc.

5.2 Adverse Events

All of the adverse device effects (ADEs), serious adverse device effects (SADEs), unanticipated adverse device effects (UADEs), and unanticipated serious adverse device effects (USADEs) will be summarized for all subjects who are enrolled in this study, [redacted]

5.3 Subject Early Termination

Reasons for premature study discontinuation will be collected and summarized when provided or available.

5.4 Protocol Deviation

All protocol deviations, including reasons and associated visit, will be categorized and summarized.

[redacted]

5.5 Number of Subject Imbalance

All efforts will be made to maintain a balanced enrollment among the 4 study centers and among RF and cryo-balloon procedures. A maximum of 25 subjects for RF and 25 subjects for cryo-balloon is set per site. Similarly, balanced enrollment will be attempted for the additional 30 PFA subjects, with a maximum of 15 subjects enrolled per site.

[redacted]

[redacted]

6.0 DOCUMENTATION AND OTHER CONSIDERATIONS

[redacted]

[redacted]

7.0 APPENDICES

APPENDIX A: MOCK-UP TABLES

Table 1. Subject disposition

Parameter		Total (N=XX)
Subjects enrolled	Yes	
	No	

Abbreviations: n: counts, N: total, %: percentage

Table 2. Study exit

Parameter		n/N (%)
Study exit due to	Completion of study as planned	
	Discontinued prematurely	
Reason for withdrawal	Inclusion/exclusion criteria not met	
	Subject withdrew consent	
	Subject death	
	Subject terminated by investigator	
	Not specified	
	Other	

Abbreviations: n: counts, N: total, %: percentage

Table 3. Subject enrolment and analysis populations per site

Site name	Country	Number of subjects enrolled[1]	Number of Screening Failures
Clinique Pasteur Toulouse	France		
UZ Ghent	Belgium		
AZ Sint-Jan Brugge	Belgium		
UZ Brussels	Belgium		

[1]Values are presented as n/N (%)
Abbreviations: AZ: Algemeen Ziekenhuis; PPT: per-protocol treatment; UZ: Universitair Ziekenhuis.

Table 4. Analysis populations

Site name	PPT population (n/N, %) N=X	ITT population (n/N, %) N=X

Abbreviations: ITT: intent-to-treat; PPT: per-protocol treatment; n: counts, N: total, %: percentage

Table 5. Baseline Demographics, Physical exam, and Vital signs

Demographics	Total (N=XX)
Age, years (at enrolment)[1]	
Gender[2] Female Male	
Height[1] [cm]	
Weight[1] [kg]	
Systolic Blood Pressure[1] [mmHg]	
Diastolic Blood Pressure[1] [mmHg]	
Heart Rate[1] [BPM]	
Respiratory Rate[1] [breaths/min]	
Body Temperature[1] [°C]	

[1]Values are presented as mean±SD
[2]Values are presented as n/N (%)
Abbreviations: BPM: beats per minute; cm: centimetres; ECG: electrocardiogram; kg: kilograms; min: minute; mmHg: millimeter of mercury; n: counts; N: total; SD: standard deviation; °C: degree Celsius; %: percentage

Table 6. Atrial Fibrillation

Characteristics	Total measurements (N=XX)
AF history[1]: TTM ECG Holter Other	
Characteristics	Total Subjects (N=XX)
Time from first AF diagnosis to ablation[2] [days]	
AF type[1]: Paroxysmal Persistent Long-term persistent	

[1]Values are presented as n/N (%)
[2]Values are presented as mean ± SD
[3]Values are presented as mean percentage (range) ± SD
Abbreviations: AF: atrial fibrillation; ECG: electrocardiogram; N: total subjects; TTM: transtelephonic monitor; %: percentage

Table 7. Cardiovascular History

Characteristics	Total Subjects (N=XX)
CHA_2DS_2Vasc score[2]	
Hypertension[1]: Yes No	
Structural heart disease[1]: Yes	

No	
Diabetes mellitus[1]: Yes No	
LVEF[3]	
LA diameter (mm)[2]	

[1]Values are presented as n/N (%)
[2]Values are presented as mean ± SD
[3]Values are presented as mean percentage (range) ± SD
Abbreviations: CHA_2DS_2Vasc: congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, stroke or transient ischemic attack (TIA), vascular disease, age 65 to 74 years, sex category; LA: left atrial; LVEF: left ventricular ejection fraction; mm: millimeters; N: total subjects; %: percentage

Table 8. Concomitant medication

Indication	Medication name	n/N (%)
	Any medication	

Abbreviations: n: counts; N: total; %: percentage

Table 9. Index procedure overview

Characteristic	Total (N=XX)
Procedure type: Carto RF Cryoballoon PFA	
General anaesthesia: Yes No	
Cardioversion performed at the beginning of the procedure: Yes No Patient already in SR	
Patient in SR throughout the procedure: Yes No	
Patient had AF during the procedure and cardioversion was performed: Yes No N/A (patient in SR all the time)	
3D mapping done: Yes No N/A	

Abbreviations: AF: atrial fibrillation, n: counts; N: total; N/A: not applicable, RF: radiofrequency, SR: sinus rhythm, %: percentage

Table 10. Radiofrequency procedure overview

Characteristic	Total (N=XX)
Name of ablation catheter: "SmartTouch SF" "SmartTouch" "Navistar" "…"	n/N (%)

Name of circular mapping catheter in the PVs: "LASSO" "LASSO NAV Eco" "…"	n/N (%)
Circular mapping catheter electrodes: 10 20	n/N (%)
Name of CS catheter: "…"	n/N (%)
Other catheters: Yes No	n/N (%)
Data Log Form filled: Yes No	n/N (%)
Isolation at the right circle after or during deployment of first CLOSE circle: Yes At 1-25% circle completion At 26-50% circle completion At 51-75% circle completion At 76-99% circle completion At 100% circle completion (after full circle) Carto RF Tag ID No first-pass isolation Additional touch-up ablations Number of touch-up ablations No additional touch-up ablations	 n Mean SD 95% LCLM 95% UCLM Q1 Median Q3 Min Max n Mean SD 95% LCLM 95% UCLM Q1 Median Q3 Min Max
Isolation at the left circle after or during deployment of first CLOSE circle: Yes At 1-25% circle completion At 26-50% circle completion At 51-75% circle completion At 76-99% circle completion At 100% circle completion (after full circle) Carto RF Tag ID	n/N (%) n

No first-pass isolation Additional touch-up ablations Number of touch-up ablations	Mean SD 95% LCLM 95% UCLM Q1 Median Q3 Min Max
No additional touch-up ablations	n Mean SD 95% LCLM 95% UCLM Q1 Median Q3 Min Max
Pacing to verify isolation at the right circle (after first circle or first circle + touch ups): Yes Correct original isolation assessment Incorrect original isolation assessment No	n/N (%)
Pacing to verify isolation at the left circle (after first circle or first circle + touch ups): Yes Correct original isolation assessment Incorrect original isolation assessment No	n/N (%)

Unless otherwise specified, data are presented as n/N (%)
Abbreviations: CS: coronary sinus; ID: identification; LCLM: lower confidence limit for mean; Max: maximum; Min: minimum; n: counts; N: total; PVs: pulmonary veins; Q1: first quartile; Q3: third quartile; RF: radiofrequency; UCLM: upper confidence limit for mean; %: percentage

Table 11. Cryoballoon procedure overview

Parameter	Total (N=XX)
Name of ablation catheter: "Arctic Front Advance" "…"	n/N (%)
Name of circular mapping catheter in the PVs: "Achieve" "Achieve Advance"	n/N (%)
Circular mapping catheter electrodes: 8 [..]	n/N (%)
Type of CS catheter: "…"	n/N (%)
Other catheters: Yes No	n/N (%)
Data Log Form filled:	n/N (%)

Yes No	
Isolation at the RSPV during or after the first freeze attempt: Yes After <1 min from start of the freeze After <2 min from start of the freeze After <3 min from start of the freeze After <4 min from start of the freeze After 4 min or after session end (waiting time) No Additional freeze attempts 1 2 3 or more Isolation achieved Isolation not achieved No additional freeze attempts	n/N (%)
Isolation at the RIPV during or after the first freeze attempt: Yes After <1 min from start of the freeze After <2 min from start of the freeze After <3 min from start of the freeze After <4 min from start of the freeze After 4 min or after session end (waiting time) No Additional freeze attempts 1 2 3 or more Isolation achieved Isolation not achieved No additional freeze attempts	n/N (%)
Isolation at the LSPV during or after the first freeze attempt: Yes After <1 min from start of the freeze After <2 min from start of the freeze After <3 min from start of the freeze After <4 min from start of the freeze After 4 min or after session end (waiting time) No Additional freeze attempts 1 2 3 or more Isolation achieved Isolation not achieved No additional freeze attempts	n/N (%)
Isolation at the LIPV during or after the first freeze attempt: Yes After <1 min from start of the freeze After <2 min from start of the freeze After <3 min from start of the freeze After <4 min from start of the freeze After 4 min or after session end (waiting time) No	n/N (%)

Additional freeze attempts 1 2 3 or more Isolation achieved Isolation not achieved No additional freeze attempts	
Pacing to verify isolation at the RSPV (after all freeze attempts): Yes Correct isolation assessment Incorrect isolation assessment No	n/N (%)
Pacing to verify isolation at the RIPV (after all freeze attempts): Yes Correct isolation assessment Incorrect isolation assessment No	n/N (%)
Pacing to verify isolation at the LSPV (after all freeze attempts): Yes Correct isolation assessment Incorrect isolation assessment No	n/N (%)
Pacing to verify isolation at the LIPV (after all freeze attempts): Yes Correct isolation assessment Incorrect isolation assessment No	n/N (%)

Unless otherwise specified, data are presented as n/N (%)
Abbreviations: CS: coronary sinus; ID: identification; LCLM: lower confidence limit for mean; LIPV: left inferior pulmonary vein; LSPV: left superior pulmonary vein; Max: maximum; Min: minimum; n: counts; N: total; PVs: pulmonary veins; Q1: first quartile; Q3: third quartile; RF: radiofrequency; RIPV: right inferior pulmonary vein; RSPV: right superior pulmonary vein; UCLM: upper confidence limit for mean; %: percentage

Table 12. PFA procedure overview

Parameter	Total (N=XX)
Name of ablation catheter: "…"	n/N (%)
Name of circular mapping catheter in the PVs: "…"	n/N (%)
Number of Circular mapping catheter electrodes: 8 [..]	n/N (%)
Type of CS catheter: "…"	n/N (%)
Other catheters used: Yes No	n/N (%)
Data Log Form filled: Yes No	n/N (%)
Isolation at the RSPV after the first PFA attempt: Yes No Additional freeze attempts 1 2	n/N (%)

3 or more Isolation achieved Isolation not achieved No additional freeze attempts	
Isolation at the RIPV after the first PFA attempt: Yes No Additional freeze attempts 1 2 3 or more Isolation achieved Isolation not achieved No additional freeze attempts	n/N (%)
Isolation at the LSPV after the first PFA attempt: Yes No Additional freeze attempts 1 2 3 or more Isolation achieved Isolation not achieved No additional freeze attempts	n/N (%)
Isolation at the LIPV after the first PFA attempt: Yes No Additional freeze attempts 1 2 3 or more Isolation achieved Isolation not achieved No additional freeze attempts	n/N (%)
Pacing to verify isolation at the RSPV (after all PFA attempts): Yes Correct isolation assessment Incorrect isolation assessment No	n/N (%)
Pacing to verify isolation at the RIPV (after all PFA attempts): Yes Correct isolation assessment Incorrect isolation assessment No	n/N (%)
Pacing to verify isolation at the LSPV (after all PFA attempts): Yes Correct isolation assessment Incorrect isolation assessment No	n/N (%)
Pacing to verify isolation at the LIPV (after all PFA attempts): Yes Correct isolation assessment Incorrect isolation assessment No	n/N (%)

Adverse events reported during the procedure Yes No	n/N (%)
Protocol deviations identified during the procedure Yes No	n/N (%)

Table 13. Overview of PVI Analyzer classification result

Patient ID	Vein	Label	PVI Analyzer output*		Classification result**	
			Cube	Conventional	Cube	Conventional
	LSPV	Baseline				
	LSPV	Final				
	LIPV	Baseline				
	LIPV	Final				
	RSPV	Baseline				
	RSPV	Final				
	RIPV	Baseline				
	RIPV	Final				
…						

*isolated/not isolated
**TN, TP, FN, FP
Abbreviations: FN: false negative, FP: false positive, LIPV: left inferior pulmonary vein, LSPV: left superior pulmonary vein, PVI: pulmonary vein isolation, RIPV: right inferior pulmonary vein, RSPV: right superior pulmonary vein, TN: true negative, TP: true positive

Table 14. Patient discharge

Discharge visit	
Cardiac medications recorded[1]: Yes No	
12 lead ECG performed[1]: Yes No	
Systolic Blood Pressure[2] [mmHg]	
Diastolic Blood Pressure[2] [mmHg]	
Heart Rate[2] [BPM]	
Respiratory Rate[2] [breaths/min]	
Body Temperature[2] [°C]	

[1]Values are presented as n/N (%)
[2]Values are presented as mean±SD
Abbreviations: BPM: beats per minute; ECG: electrocardiogram; mmHg: millimetres of mercury; n: counts; N: total; SD: standard deviation; °C: degree Celsius; %: percentage

[redacted]

Table 15. Protocol deviations

Classification	Description	Protocol Deviations (N=XX) (n/N, %)
Associated visit	Visit 1. Screening	
	Visit 2. Procedure	
	Visit 3. Discharge	
	Not associated to a protocol-defined visit	
Type of protocol deviation	Patient consent not obtained or incomplete	
	Patient consent not signed & dated by the patient	
	Inclusion/exclusion criteria not met	
	Required pregnancy test not performed or out of window	
	Visit not done	
	Assessment not done according to CIP	
	Reporting timelines not followed	
	Other	

Abbreviations: CIP: clinical investigation plan; n: counts; N: total; %: percentage

Table 16. Overview of adverse events by severity

Parameter		Number of events	Number of subjects	Rate per subject (n/N, %) N=XX
Adverse Event (AE) reported				
Severity of AE	Mild			
	Moderate			
	Severe			

Abbreviations: AE: adverse event.

Table 17. Adverse events by relation to the study

Parameter	Relationship	Number of events	Number of subjects	Rate per subject (n/N, %) N=XX
AE relationship to the study	Device related			
	Procedure related			
	Other			

Abbreviations: AE: adverse event.

Table 18. Overview of serious adverse events

Parameter	Number of events	Number of subjects	Rate per subject (n/N, %) N=XX
Any Serious Adverse Event (SAE)			

Abbreviations: N: total subjects; n: counts

Table 19. Classification of SAEs

Classification of SAEs	Number of events	Number of subjects	Rate per subject (n/N, %) N=XX
Led to death			
Led to fetal distress, fetal death or a congenital abnormality or birth defect			
Resulted in a life-threatening illness or injury			
Resulted in a permanent impairment of a body structure or a body function			
Resulted in a patient hospitalization or prolonged an existing hospitalization			
Resulted in a medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function			

Abbreviations: N: total subjects; n: counts

Table 20. Overview of serious adverse device effects (SADEs)

Parameter	Number of events	Number of subjects	Rate per subject (n/N, %) N=XX
Serious adverse device effect (SADE) incidence			

Abbreviations: N: total subjects; n: counts

Table 21. Overview of unanticipated serious adverse device effects (USADEs)

Parameter	Number of events	Number of subjects	Rate per subject (n/N, %) N=XX
Serious unanticipated serious adverse device effect (USADE) incidence			

Abbreviations: N: total subjects; n: counts

Table 23. Overview of device deficiencies

Parameter	Number of events	Number of subjects	Rate per subject (n/N, %) N=XX
Device deficiency incidence			

Abbreviations: N: total subjects; n: counts