BIOTRONIK
excellence for life

Document Title:	Statistical Analysis Plan BIO|CONCEPT.Amvia Study
Document Version and Date:	Version 2-0, 17-Nov-2023 plus erratum
ClinicalTrials.gov Identifier:	NCT05610176

Sponsor:	BIOTRONIK SE & Co KG
Study name / EAC code:	BIO|CONCEPT.Amvia Study / BA115
Version and date of the Statistical Analysis Plan:	2-0 from 17Nov2023
Version and date of the underlying Clinical Investigation Plan:	1-0 from 30May2022

Print Name & Title	**Signature**	**Date of Signature** (DD MMM YYYY)
Senior Clinical Project Manager [redacted]	20 Nov 2023	
Scientist [redacted]	20 Nov 2023	
Biostatistician [redacted]	20 Nov 2023	

Table of Content

1 Change History

Version 1.0

[redacted]

Version 2.0

[redacted]

2 Introduction

2.1 Aim

The aim of this document is to provide detailed instructions on statistical analyses for the interim/final Clinical Investigation Report (CIR) and any additional analyses.

2.2 Data for which quality control is required

Although no endpoints are defined in this study, there will still be Quality Control for selected tables from the Baseline and Data of interest sections. The exact tables will be defined in a separate document.

2.3 Unblinding

Not applicable

2.4 General information

This SAP may contain verbatim excerpts from the version of the CIP specified at the cover sheet. Such excerpts are *italicized with light blue background*.

The main aspects and the design of the clinical investigation are presented in chapters 2-3.

General statistical procedures are summarized in chapter 5. Those methods are used in case there is no other specification within this document.

Analysis set(s) and other global variables are defined in detail in chapter 6.

Descriptive and inferential statistical analyses for endpoint(s) are handled in following chapters. Thereby the following statistical considerations are specified:

- Analysis set: Definition of the analysis population (e.g. Intention-to-Treat or Per-Protocol for controlled clinical investigations or all patients with valid informed consent for single-arm clinical investigations)
- Variable characteristics: Description of all relevant variables (directly addressable from validated tools, e.g. CDMS or CDW, and derived variables) such as variable name, variable label, variable values, and data type.
- Derived variables, if applicable: For variables, which are not directly addressable from validated tools but are derived from other variables, pseudo-code or other instructions for the variable construction shall be provided.
- Missing, unused or spurious data: Specification of all data to be excluded from the specific analysis, e.g. data measured after a pre-specified point in time or implantation date after pre-hospital discharge date; specification whether and –if applicable- how to impute missing data.
- Data analysis: Description of descriptive, exploratory, and confirmatory analyses in text, tables, or pseudo-code shall be provided for unambiguous data analysis.

All variables are defined in tables using the following columns:

Data file: Name of a data file exported from the CDMS and CDW and unique identifier, if applicable (e.g. patient-specific "patient_display_ID_full" or event-specific record_ID); new data files ("data_SAR") may be generated by merging all relevant data from the original CDMS data files and generating derived variables;

Notes: Information whether data shall be presented with "descriptive" methods as defined in this SAP, data for "case listings" of original data for each patient specified, or "no report" for data needed for generating derived variables only;

Variable name: Original name of CDMS data or new name of a derived variables (indicated with a prefix "SAR_" or a suffix "_SAR");

Variable label: Original labels of CDMS data will be used for generating the SAR unless a new label is defined in this document ("NEW");

Variable level: Nominal, ordinal, scale (synonymous for metric, continuous, interval scale and/or ratio scale), or date;

Nominal values: Original values of CDMS of nominal or ordinal data will be used unless new values are defined in this document ("NEW").

Data file, identifier patient_display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values

3 Clinical Investigation

3.1 Objective(s)

CIP chapter 7.2 Objectives

The primary objective of this study is to determine preliminary safety and product performance of the new Amvia /Solvia pacemaker family, and to collect data to support the decision for market release in regions where regulatory approval is already granted.

Secondary objectives comprise the potential support of product approval in other regions, the validation of promotional claims, and the support of future study activities.

3.2 Investigational device

CIP chapter 4.1 Summary description of the device

The investigational devices in this study are the Amvia Sky pacemakers in combination with the related programmer software ('NEO 2204.A/S') and the remote monitoring software ('HMSC Plugin') to be used in conjunction with the Amvia/Solvia family.

Further information is provided in the following sections as well as in the Investigator's Brochure (IB). Furthermore, a technical manual will be provided by the time of study start.

3.3 Design & time course

CIP chapter 8.1.1 Design type of clinical investigation

The study is designed as an explorative, open-label, prospective, non-randomized, multi-center, bi-national study.

CIP chapter 8.1.4 Methods

…

Data will be recorded at the following points in time:

- *Enrollment / Baseline*
- *Implantation*
- *Pre-hospital discharge*
- *1-month follow-up*
- *3-month follow-up*
- *12-month follow-up*
- *Termination*

The following events can be documented at any time

- *Adverse Event*
- *Device Deficiency*
- *Deviation (patient / site related)*

4 Data source

All datasets are exported from the CDMS and CDW. All datasets from CDMS except adverse_event, device_deficiency, deviation forms and investigator_questionnaire are patient-specific, i.e. one data row per patient. [redacted]

Scheduled Patient Forms

Dataset name	Data rows, unique identifier variables except record_id	Data rows unique identifier description	Parent CRF In case of embedded log	Notes
Enrollment	patient_display_id_full	Patient	n.a.	
Baseline - General	patient_display_id_full	Patient	n.a.	
Medical History	patient_display_id_full	Patient	n.a.	
Cardiac Diagnostics	patient_display_id_full	Patient	n.a.	
Device Log	patient_display_id_full & didvtyp	Patient & Device type	n.a.	○ Pacemaker SR-T ○ Pacemaker DR-T ○ CRT-P ○ RA lead ○ RV lead ○ LV lead ○ Other type of lead
Conc. Medication Log	n.a.	…	n.a.	
Implantation	patient_display_id_full	Patient	n.a.	
Lead Measurements	patient_display_id_full & prvisit	Patient & Visit	n.a.	Lead measurement optional at implantation, mandatory at PHD and 1-, 3- and 12-month follow-up. At 1-month FU HM data is acceptable
Pre-hospital Discharge	patient_display_id_full	Patient	n.a.	
Auto LVVO	patient_display_id_full	Patient	n.a.	
MRI system check	patient_display_id_full	Patient	n.a.	
Follow-up - 1M	patient_display_id_full	Patient	n.a.	
Follow-up - 3M	patient_display_id_full	Patient	n.a.	
Follow-up - 12M	patient_display_id_full	Patient	n.a.	
Tachyarrhythmia Episodes	patient_display_id_full	Patient	Follow-up – 3M; Follow-up – 12M	
Study Termination	patient_display_id_full	Patient	n.a.	
[redacted]				

Unscheduled Patient Forms

Dataset name	Data rows, unique identifier variables except record_id	Data rows unique identifier description	Parent CRF in case of embedded log	Notes
Adverse Event	n.a.	Event	n.a.	
Hospitalization Log	n.a.	Event	Adverse Event	
Device Deficiency	n.a.	Event	n.a.	
Deviation (patient related)	dvspid	Deviation ID	n.a.	

Site based forms

Dataset name	Data rows, unique identifier variables except record_id	Data rows unique identifier description	Parent CRF in case of embedded log	Notes
Deviation (site related)	dvspid	Deviation ID	n.a.	

CDW tables ([redacted])

Dataset name	Data rows, unique identifier variables except record_id	Data rows unique identifier description	Parent CRF in case of embedded log	Notes
v_hmstat	studypid & impsn	Study Patient ID & Implant Serial Number	n.a.	
v_brady	studypid & impsn	Study Patient ID & Implant Serial Number	n.a.	

5 General statistical procedures

CIP chapter 12 Statistical Design and Analysis
No hypotheses were formulated, and no endpoints defined for this study.

12.2 Descriptive statistics
Standard descriptive statistical methods are used depending on the type of the available data. For continuous variables, mean value, standard deviation, median, minimum, maximum and quartiles are calculated. For nominal variables, absolute and relative frequencies are calculated based on non-missing data. For ordinal variables, median, minimum, maximum and quartiles or absolute and relative frequencies are calculated for each category based on non-missing data. The SADE-free rate is calculated using the Kaplan-Meier estimate after 12 months.

12.3 Analytical procedures
Standard inferential statistical methods are used depending on the type of the available data. For mean values, confidence intervals are calculated based on a t-distribution. For relative frequencies, confidence intervals are calculated based on a binomial distribution. Thereby, the significance value specified in the following sub-chapter is considered.

12.4 Significance level, statistical power, and statistical testing
Because there are no pre-specified hypotheses, all analyses are exploratory. However, a result of a two-sided statistical test with a p-value less than 5% or a one-sided statistical test with a p-value less than 2.5% is considered statistically significant in that exploratory sense.

12.5 Sample size calculation
Not needed in the SAP

12.6 Number of Procedures
There is no requirement for a minimum number of procedures to be performed by a specific investigator and no pre-planned analysis of such data.

12.7 Pass/fail criteria
Not applicable.

12.8 Interim analyses
It is planned to perform an interim analysis for the internal evaluation of product performance and for the validation of promotional claims at the end of the enrollment period. Additionally, specific data might be provided to competent authorities, if requested.

12.9 Bias
In case of a clear evidence of bias, which was not considered before, the Statistical Analysis Plan (SAP) is updated to avoid any bias.

12.10 Confounding factors
In case of a clear evidence of a confounding factor, which was not considered before, the

Statistical Analysis Plan (SAP) is updated to avoid any bias.

12.11 Multiplicity
There is no multiplicity control foreseen.

12.12 Subgroups
See chapter next chapter

12.13 Missing, unused, and spurious data
All data needed to be analyzed are pre-documented in a Statistical Analysis Plan (SAP). Other data from the Clinical Data Management System (CDMS) might be needed for case reports, e.g. in case of Adverse Events.
During a blind review process before any pre-planned analysis, missing and spurious data, which are relevant are identified. In case such data can't be clarified via a query management process, the Statistical Analysis Plan (SAP) is updated to avoid any bias. If appropriate, analyses will be performed both with/without spurious data.
Number of missing data are reported for each descriptive and inferential analysis in the Statistical Analysis Report (SAR) and Clinical Investigation Report (CIR), if applicable. Spurious data are commented in the Clinical Investigation Report (CIR), if applicable. Drop-outs are reported in the Statistical Analysis Report (SAR) and Clinical Investigation Report (CIR), if applicable.

12.14 Exploratory analysis and sensitivity analysis
Because there are no pre-specified hypotheses, all analyses are exploratory and there is also no specific sensitivity analysis.

12.15 Deviations from the original statistical plan
A Statistical Analysis Plan (SAP) is provided after go-life of the Clinical Data Management System (CDMS). The SAP can be updated before CDMS-freeze or closure based on a blind review of the data, whereby the new version is containing a change history. Any deviation from the valid SAP version with respect to inferential analyses are indicated in the Clinical Investigation Report (CIR), if applicable.

12.16 Imbalance in multicentre clinical investigations
Dataset is divided into two approximately equal groups with higher and lower enrollment to compare the SADE-free rates between the two groups.

12.17 Data pooling
Not applicable.

6 Analysis set(s) and other global variables

A new data file ("data_SAR") might be generated by merging all relevant data from the original CDMS data files and generating derived variables (e.g. Date of first AE episode or any Adverse Device Effect)

6.1 Analysis set of enrolled patients

CIP chapter 12 Statistical Design and Analysis

12.1 Analysis population

All patients with valid patient informed consent are included in the analysis set.

CIP chapter 9.3 Implantation

If the implantation is not performed within 30 days of the informed consent, the patient may be excluded from the study

Data file, identifier patient_display_id_full	Variable name	Variable label	Variable level	Nominal values
enrollment	dmsubsps	Patient signed the informed consent personally	nominal	○ Yes ○ No
enrollment	dmrprsps	An independent witness signed the informed consent since the patient is unable to write	nominal	○ Yes ○ No
data_SAR	analysis_set_enr_SAR	Enrollment analysis set	nominal	○ Yes ○ No

[redacted]

6.2 Subgroups

CIP chapter 12 Statistical Design and Analysis 12.12 Subgroups
If required, SR-T, DR-T, HF-T QP devices as well as men and women can be analyzed separately. The safety analysis will be provided for the total study population.

6.3 Date of enrollment

CIP chapter 8 Design of the CliInical Investigation 8.3.4 Point of enrolment
The point of enrollment is defined as the time of signature of the informed consent form by the patient. Study related procedures, documentation and collection/following of adverse events will start from this time on.

Data file, identifier patient_ display_ id_full	Variable name	Variable label	Variable level	Nominal values
enrollment	dmicdt	Patient: Date of informed consent signature (= Date of Enrollment)	date	n.a.

7 Analyses: CONSORT diagram & "study realization"

7.1 Enrollment

7.1.1 Date of first-patient-in (FPI)

7.1.2 Date of last-patient-in (LPI)

7.1.3 Number of patients

Total number of enrolled patients and number of enrolled patients per investigational site.

7.1.4 Patients excluded from the analysis set

Patients without valid patient informed consent are excluded from the analysis.
Other reasons:

CIP chapter 9.3 Implantation

If the implantation is not performed within 30 days of the informed consent, the patient may be excluded from the study

Inclusion criteria

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
enrollment	descri ptive	tiinc01	Standard indication for pacemaker or cardiac resynchronization therapy pacemaker (CRT-P) implantation, including de novo, upgrade or replacement implantations	nominal	○ Yes ○ No
		tiinc02	Ability to understand the nature of the study	nominal	○ Yes ○ No
		tiinc03	Willingness to provide written informed consent	nominal	○ Yes ○ No
		tiinc04	Ability and willingness to perform all follow-up visits at the study site	nominal	○ Yes ○ No
		tiinc05	Ability and willingness to use the CardioMessenger and acceptance of the BIOTRONIK Home Monitoring concept	nominal	○ Yes ○ No

Exclusion criteria

Data file, identifier patient_display _id_full	Notes	Variable name	Variable label	Variable level	Nominal values
enrollment	descri ptive	tiexc01	Planned for conduction system pacing	nominal	○ Yes ○ No
		tiexc02	Planned for activation of aATP without known history of atrial arrhythmia, or with permanent AF	nominal	○ Yes ○ No
		tiexc03	Planned cardiac surgical procedures or interventional measures other than the study procedure within the next 12 months	nominal	○ Yes ○ No
		tiexc04	Pregnant or breast feeding	nominal	○ Yes ○ No
		tiexc05	Age less than 18 years	nominal	○ Yes ○ No
		tiexc06	Participation in another interventional clinical investigation	nominal	○ Yes ○ No
		tiexc07	Life-expectancy less than 12 months	nominal	○ Yes ○ No

7.2 Termination

7.2.1 Date of first-patient-out (FPO)

7.2.2 Date of last-patient-out (LPO)

7.2.3 Premature study termination / drop-out

Data file: Identifier patient_ display_id_ full	Notes	Variable name	Variable label	Variable level	Nominal values
study_ termination	descriptive	dsrtrm	Regular study termination	nominal	○ Yes ○ No
study_ termination	descriptive for dsrtrm =No	dsetrrea	Reason for early study termination	nominal	○ Patient unable to attend required visits ○ Patient is lost to follow-up ○ Patient withdrew consent to study participation ○ Patient death ○ Drop-out according to protocol ○ Enrollment failure

Data file: Identifier patient_displa y_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
enrollment	Case listing for dsetrrea = Drop-out according to protocol	dmicdt_i	Patient: Date of informed consent signature	date	n.a.
study_ termination		dstrdt_i	Date of study termination	date	n.a.
		dsdrppro	Please specify "Drop-out according to protocol"	nominal	○No implantation attempted within 30 days of enrollment ○Not implanted with an investigational device ○Investigational device was explanted and will not be replaced with corresponding BIOTRONIK device ○Other
		CODRPPRO	Please specify "Drop-out according to protocol - Other"	text	n.a.

7.3 FU duration

Data file: Identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
data_SAR	descriptive and cumulative	FU_duration_SAR	Days from enrollment to termination	scale	n.a

8 Analyses: Baseline

8.1 Analysis set

All analyses are performed for the enrollment analysis set[1].

8.2 Variables

Baseline / demographics

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
baseline_general	descriptive	dmage	Age [Years]	scale	n.a.
		dmsex	Gender	nominal	○ Female ○ Male
		dmrace	Ethnicity	nominal	○ Caucasian ○ Black ○ Asian ○ Indigenous ○ Other
	case listing for dmrace = Indigenous	corace	Specification of indigenous ethnicity	text	n.a.
	case listing for dmrace = Other	coraceot	Specification of other ethnicity	text	n.a.

Baseline / physical examination

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
baseline_general	descriptive	vshght	Height [cm]	scale	n.a.
		vswght	Weight [kg]	scale	n.a.
		vsbmi	BMI [kg/m2]	scale	n.a.

[1] analysis_set_enr_SAR = Yes

Baseline / therapy indication

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
baseline_general	descriptive	cecrt	CRT indication given	nominal	○Yes ○ No
	descriptive for cecrt = Yes	cecrttyp	Type of CRT indication	nominal	○CRT indication in sinus rhythm ○CRT indication in atrial fibrillation ○CRT indication and conventional pacing indication ○Other
	case listing for cecrttyp = Other	cocrtoth	Specification of other CRT indication	text	n.a.
	descriptive	cebcind	Main indication for bradycardia therapy	nominal	○Sinus node disease ○AV block ○AF with bradycardic response ○Reflex syncope ○Bundle branch block ○Other
	case listing for cebcind <> Other	cobcind	Details on indication for bradycardia therapy	text	n.a.
	case listing for cebcind = Other	cobcoth	Specification of other main bradycardia indication	text	n.a.
	descriptive	prim	Previous device implanted	nominal	○Yes ○ No
	descriptive for prim = Yes	primdvty	Type of previously implanted device	nominal	○Pacemaker ○ICD ○CRT pacemaker ○CRT ICD ○Implantable loop recorder

Medical history / known cardiac history - heart failure

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable level	Nominal values
medical_ history	descriptive	mhhf	History of heart failure	nominal	○Yes ○ No
	descriptive for mhhf = Yes	cvnyha	Current NYHA classification	nominal	○ I - Code = 1 ○ II - Code = 2 ○ III - Code = 3 ○ IV - Code = 4
		mhhfe	Primary HF etiology	nominal	○ Ischemic ○ Non-ischemic
		mhhftyp	Type of HF	nominal	○ Left heart failure ○ Right heart failure ○ Global heart failure
		hohf	Hospitalization for worsening of heart	nominal	○ Yes ○ No

Medical history / known cardiac history - coronary artery disease

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable level	Nominal values
medical_ history	descriptive	mhcad	History of coronary artery disease	nominal	○ Yes ○ No
	descriptive for mhcad = Yes	mhaccs	Prior acute coronary syndrome (any type)	nominal	○ Yes ○ No
	descriptive for mhaccs = Yes	mhmi	Prior myocardial infarction	nominal	○ Yes ○ No
	descriptive for mhcad = Yes	prrvc	Prior revascularization (PCI or CABG)	nominal	○ Yes ○ No

Medical history / known cardiac history - brady- and tachyarrhythmias

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable level	Nominal values
medical_ history	descriptive	mhsss	History of sick sinus syndrome	nominal	○ Yes ○ No
		mhavb	History of AV block	nominal	○ Yes ○ No
	descriptive for mhavb = Yes	mhavbtyp	Type of AV block	nominal	○ AV block I° ○ AV block II° ○ AV block III°
	descriptive	mhbbb	History of bundle branch block	nominal	○ Yes ○ No
	descriptive for mhbbb = Yes	mhbbbtyp	Type of bundle branch block	nominal	○ LBBB ○ RBBB ○ Other
	case listing for mhbbbtyp = Other	cobbbtyp	Specification of other type of bundle branch block	text	n.a.
	descriptive	mhcnddot	History of other type of conduction disease	nominal	○ Yes ○ No
	case listing for mhcnddot = Yes	cocnddot	Specification of other type of conduction disease	text	n.a.
	descriptive	mhafb	History of atrial fibrillation	nominal	○ Yes ○ No
	descriptive for mhafb = Yes	cvafbtyp	Type of atrial fibrillation	nominal	○ Paroxysmal ○ Persistent ○ Long-standing persistent ○ Permanent
	descriptive	mhava	History of other atrial/supraventricular arrhythmias	nominal	○ Yes ○ No
	descriptive for mhava = Yes	mhafl	History of atrial flutter	nominal	○ Yes ○ No
		mhat	History of atrial tachycardia	nominal	○ Yes ○ No
		mhsvt	History of supraventricular tachycardia	nominal	○ Yes ○ No
		mhavaoth	History of other type of atrial/supraventricular arrhythmias	nominal	○ Yes ○ No
	case listing for mhavaoth = Yes	coavaoth	Specification of other type of atrial/supraventricular arrhythmias	text	n.a.
	descriptive	mhva	History of ventricular arrhythmia	nominal	○ Yes ○ No
	case listing for mhva = Yes	cova	Specification of history of ventricular arrhythmia	text	n.a.
	descriptive	mhci	Known chronotropic incompetence	nominal	○ Yes ○ No

Medical history / known comorbidities

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable level	Nominal values
medical_ history	descriptive	mhhp	Hypertension (including well-controlled)	nominal	○ Yes ○ No
		mhphp	Pulmonary hypertension	nominal	○ Yes ○ No
		mhvhd	Valvular heart disease	nominal	○ Yes ○ No
	descriptive for mhvhd = Yes	mhaova	Aortic valve affected	nominal	○ Yes ○ No
		mhmiva	Mitral valve affected	nominal	○ Yes ○ No
	descriptive for mhvhd = Yes and cecrt = Yes	mhmiin	Mitral insufficiency	nominal	○ Yes ○ No
		mhmist	Mitral stenosis	nominal	○ Yes ○ No
	descriptive for mhvhd = Yes	mhtrva	Tricuspid valve affected	nominal	○ Yes ○ No
		mhpuva	Pulmonary valve affected	nominal	○ Yes ○ No
	case listing for mhvhd = Yes	covhd	Further specification of valvular heart disease (e.g. type, severity)	text	n.a.
	descriptive	mhcvd	History of cerebrovascular disease (e.g. TIA/Stroke)	nominal	○ Yes ○ No
		mhpvad	Peripheral vascular/arterial disease	nominal	○ Yes ○ No
		mhasth	Asthma or other chronic lung disease (except COPD)	nominal	○ Yes ○ No
		mhcopd	Chronic obstructive pulmonary disease (COPD)	nominal	○ Yes ○ No
		mhckd	Chronic renal insufficiency / chronic kidney disease (CKD) (i.e. eGFR < 60)	nominal	○ Yes ○ No
		mhsap	Sleep apnea	nominal	○ Yes ○ No
	descriptive for mhsap = Yes	mhsaptyp	Type of sleep apnea	nominal	○ Central ○ Obstructive ○ Mixed
	descriptive	mhlivr	Chronic liver disease	nominal	○ Yes ○ No
		mhdiam	Diabetes mellitus	nominal	○ Yes ○ No
		mhanem	Anemia	nominal	○ Yes ○ No
		mhcncr	Cancer	nominal	○ Yes ○ No
		mhhplp	Hyperlipidemia	nominal	○ Yes ○ No
		mhdprssn	Depression	nominal	○ Yes ○ No
		mhcmboth	Other comorbidities	nominal	○ Yes ○ No
	case listings mhcmboth =Yes	cocmboth	Specification of other comorbidities	text	n.a.

Cardiac diagnosis / ECG

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable level	Nominal values
cardiac_ diagnostics	descriptive	preg	ECG recording done within 3 months prior to enrollment	nominal	○ Yes ○ No
	descriptive for preg = Yes	eghrt	Heart rate [bpm]	scale	n.a.
		cvegarh	Atrial rhythm during ECG recording	nominal	○ Sinus rhythm ○ Atrial fibrillation ○ Atrial flutter/other SVT ○ Atrial paced rhythm ○ Other
	case listing for cvegarh = Other	coegarh	Specification of other atrial rhythm during ECG recording	text	n.a.
	descriptive for preg = Yes	cvegvrh	Ventricular rhythm during ECG	nominal	○Intrinsic - atrial conducted ○Intrinsic - escape rhythm ○Ventricular paced rhythm ○Other
	case listing for cvegvrh = Other	coegvrh	Specification of other ventricular rhythm during ECG recording	text	n.a.
	descriptive if not blank	egpri	PR interval [ms]	scale	n.a.
	descriptive for cvegvrh = Intrinsic - atrial conducted OR Intrinsic - escape rhythm	egqrs	QRS width (intrinsic) [ms]	scale	n.a.
		egqrsm	QRS morpholgy	nominal	○ Normal ○ LBBB ○ RBBB ○ Indeterminate

Cardiac diagnosis / left ventricular ejection fraction (LVEF)

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable level	Nominal values
cardiac_ diagnostics	descriptive	ehlvefas	LVEF assessed within 3 months prior to enrollment	nominal	○ Yes ○ No
	Descriptive for ehlvefas = Yes	ehlvef	Left ventricular ejection fraction [%]	scale	n.a.

Medication

Medication is recorded on a continuous medication log documenting free text for trade names. An allocation between trade names and medication categories will be continuously maintained and updated at least during the blind review prior to any data analysis.

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable level	Nominal values
medication_ log_details	no report	cmbl	Baseline medication	nominal	○ Yes ○ No
	no report	cmtrt	Trade name	text	n.a.

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable level	Nominal values
data_SAR	descriptive for cmbl = Yes	aceinhib	BL med: ACE inhibitors	nominal	○ Yes ○ No
		aldost_block	BL med: Aldosterone blocker	nominal	○ Yes ○ No
		angiotens_rec_block	BL med: Angiotensin receptor blocker	nominal	○ Yes ○ No
		antiarrhythmics	BL med: Antiarrhythmics	nominal	○ Yes ○ No
		anticoagulation	BL med: Anticoagulation	nominal	○ Yes ○ No
		antiplatelets	BL med: Antiplatelets	nominal	○ Yes ○ No
		betablocker	BL med: Betablocker (excluding sotalol)	nominal	○ Yes ○ No
		ccblocker	BL med: Calcium channel blocker	nominal	○ Yes ○ No
		digitalis	BL med: Digitalis	nominal	○ Yes ○ No
		diuretics	BL med: Diuretics (other than Aldosterone blocker)	nominal	○ Yes ○ No
		statins	BL med: Statins	nominal	○ Yes ○ No
		other_cv_med	BL med: Other cardiovascular medication	nominal	○ Yes ○ No
		non_cv_med	BL med: Non-cardiovascular medication	nominal	○ Yes ○ No

8.3 Missing, unused or spurious data

See chapter 5.

8.4 Hypotheses & statistical tests

There are no pre-defined statistical hypotheses.

9 Analyses: Primary endpoint(s)

CIP chapter 8.1.3.1 Primary endpoints

As no hypothesis has been defined, no primary endpoint is defined either.

10 Analyses: Secondary endpoint

CIP chapter 8.1.3.2 Secondary endpoints

Due to the low number of use cases per feature, no secondary endpoints are defined.

11 Analyses: Data of interest

[redacted]

11.1 Baseline characteristics and medical history

See chapter 8.

11.2 IPG-related SADE-free rate (see definition below)

CIP chapter 8 Design of the CliInical Investigation 8.1. General considerations

…

Definition of SADEs to be taken into account for the calculation of the SADE-free rate:
SADEs will be adjudicated internally, whereby the seriousness and device relatedness will be reexamined.
If any amply documented external physical influence (e.g. accident, sport, twiddling) or other causative AE led to the SADE, the SADE does not contribute to the calculation of the SADE-free rate. Only SADEs directly related to the investigational device (SADE-d) will be included in the analysis. SADEs which are securely related to the implantation procedure (SADEp) (e.g. pocket infection, etc.) will not be considered for the analysis. Furthermore Twiddler`s syndrome will not be considered for the analysis either.

…

CIP chapter 12 Statistical Design and Analysis 12.2. Descriptive statistics

…

The SADE-free rate is calculated using the Kaplan-Meier estimate after 12 months.

Data file, identifier record_ id	Notes	Variable name	Variable label	Variable level	Nominal values
internal_ adjudication	no report	aestdt	Onset date	date	n.a.
		aerelset	Adverse Event is relevant for SADE-free rate	nominal	○ Yes ○ No

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable level	Nominal values
data_SAR	no report	date_implantation_SAR	Date of implantation	date	n.a.
		date_terminaton_SAR	Date of study termination	date	n.a.
		date_1stsade_SAR	Date of first SADE	date	n.a.
		date_censoring_SAR	Date of censoring (date_1stsade_SAR OR date_terminaton_SAR)	date	n.a.
	descriptive and 95% CI, Kaplan Meier analysis	any_sade_SAR	Any Serious Adverse Device Effect based on internal adjudication	nominal	○ Yes ○ No
		days_impl_censoring_SAR	Days from implantation to censoring	date	n.a.

[redacted]

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable Level	Nominal values
internal_ adjudication	case listing	aestdt	Onset date	date	n.a.
		primdt	Date of implantation	date	n.a.
		aerelidv	Adverse Event is related to the investigational device (device related ADE)	nominal	○ Not related ○ Unlikely ○ Possible ○ Probable ○ Causal relationship
		corelidv	Please specify	text	n.a.
		aeser	Adverse Event is serious	nominal	○ Yes ○ No
		aerelset	Adverse Event is relevant for SADE-free rate	nominal	○ Yes ○ No
		corelset	Please specify reason for "No"		○ Yes ○ No

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable Level	Nominal values
data_SAR	descriptive	any_ade_SAR	Any Adverse Device Effect (serious or non-serious) based on internal adjudication	nominal	○ Yes ○ No
		any_sade_SAR	Any Serious Adverse Device Effect based on internal adjudication	nominal	○ Yes ○ No
		any_dd_SAR	Any Device Deficiency	nominal	○ Yes ○ No
		n_ade_SAR	Number of Adverse Device Effects (serious or non-serious) based on internal adjudication	metric to be reported as nominal	○ 1 ○ 2 ...
		n_sade_SAR	Number of any Serious Adverse Device Effects based on internal adjudication	metric to be reported as nominal	○ 1 ○ 2 ...
		n_dd_SAR	Number of any Device Deficiencies	metric to be reported as nominal	○ 1 ○ 2 ...

[redacted]

11.3 Lead measurements (sensing amplitude, pacing threshold, pacing impedance at implantation and at each follow-up and/or via Home Monitoring)

Lead Measurements

Data file, identifier Patient_display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
lead_ measurements	descriptive	prvisit	Visit	nominal	○ Implantation ○ Pre-hospital discharge ○ 1-Month Follow-up ○ 3-Month Follow-up ○ 12-Month Follow-up
	descriptive by prvisit	duramna	No RA lead measurements available	nominal	○ RA lead measurements not done ○ RA lead not implanted/not active
		durvmna	No RV lead measurements available	nominal	○ RA lead measurements not done ○ RA lead not implanted/not active
		dulvmna	No LV lead measurements available	nominal	○ RA lead measurements not done ○ RA lead not implanted/not active

Lead Measurements - Atrium (RA)

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable level	Nominal values
lead_ measurements	descriptive by prvisit	durasa	RA sensing amplitude [mV], mean value	scale	n.a
		cvrasrh	RA rhythm during sensing measurements	nominal	○ Sinus rhythm ○ Atrial fibrillation ○ Atrial flutter/other SVT ○ Other.
	case listing for cvrasrh = Other	corasrh	Specification of other RA rhythm during sensing measurements	text	n.a.
	descriptive by prvisit	durapt	RA pacing threshold [V]	scale	n.a.
		duraptpw	Pulse width for RA pacing threshold measurement [ms]	scale	n.a.
		durapi	RA pacing impedance [Ohm]	scale	n.a.

Lead Measurements - Right Ventricle (RV)

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable level	Nominal values
lead_ measurements	descriptive by prvisit	durvsa	RV sensing amplitude [mV], mean value	scale	n.a
		cvrvsrh	Ventricular rhythm during sensing measurements	nominal	○ Intrinsic - atrial conducted ○ Escape rhythm ○ Other
	case listing for cvrvsrh = Other	corvsrho	Specification of other ventricular rhythm during sensing measurements	text	n.a
	descriptive by prvisit	durvpt	RV pacing threshold [V]	scale	n.a
		durvptpw	Pulse width for RV pacing threshold measurement [ms]	scale	n.a
		durvpi	RV pacing impedance [Ohm]	scale	n.a

Coronary Sinus (CS) Lead Measurements - Left ventricle (LV)

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable level	Nominal values
lead_ measurements	descriptive by prvisit	dulvsv	Permanently programmed LV sensing vector	nominal	○ LV1 tip to LV2 ring (bipolar) ○ LV1 tip to Can (unipolar)
		dulvsa	LV sensing amplitude [mV], mean value	scale	n.a
		dulvpv	Permanently programmed LV pacing vector	nominal	○ LV1 tip to Can ○ LV1 tip to LV2 ring ○ LV1 tip to LV3 ring ○ LV1 tip to LV4 ring ○ LV1 tip to RV2 ring ○ LV2 ring to Can ○ LV2 ring to LV1 tip ○ LV2 ring to LV3 ring ○ LV2 ring to LV4 ring ○ LV2 ring to RV2 ring ○ LV3 ring to Can ○ LV3 ring to LV1 tip ○ LV3 ring to LV2 ring ○ LV3 ring to LV4 ring ○ LV3 ring to RV2 ring ○ LV4 ring to Can ○ LV4 ring to LV1 tip ○ LV4 ring to LV2 ring ○ LV4 ring to LV3 ring ○ LV4 ring to RV2 ring
		dulvpt	LV pacing threshold [V]	scale	n.a
		dulvptpw	Pulse width for LV pacing threshold measurement [ms]	scale	n.a
		dulvpi	LV pacing impedance [Ohm]	scale	n.a

11.4 Evaluation of appropriate sensing and pacing performance for all available channels (RA, RV, LV) at implantation and at each follow-up

System Performance

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable level	Nominal values
lead_ measurements	descriptive by prvisit	durasad	Adequate RA sensing	nominal	○ Yes ○ No
		durasrea	Reason for inadequate RA sensing	nominal	○ Oversensing ○ Undersensing ○ Other
	case listing for durasrea = Other	corasrea	Please specify reason for inadequate RA sensing	text	n.a
	descriptive by prvisit	durapad	Adequate RA pacing	nominal	○ Yes ○ No
		duraprea	Reason for inadequate RA pacing	nominal	○ Exit block: no capture at maximum output ○ Other
	case listing for duraprea = Other	coraprea	Please specify reason for inadequate RA pacing	text	n.a.
	descriptive by prvisit	durvsad	Adequate RV sensing	nominal	○ Yes ○ No
		durvsrea	Reason for inadequate RV sensing	nominal	○ Oversensing ○ Undersensing ○ Other
	case listing for durvsrea = Other	corvsrea	Please specify reason for inadequate RV sensing	text	n.a
	descriptive by prvisit	durvpad	Adequate RV pacing	nominal	○ Yes ○ No
		durvprea	Reason for inadequate RV pacing	nominal	○ Exit block: no capture at maximum output ○ Other
	case listing for durvprea = Other	corvprea	Please specify reason for inadequate RV pacing	text	n.a.
	descriptive by prvisit	dulvsad	Adequate LV sensing	nominal	○ Yes ○ No
		dulvsrea	Reason for inadequate LV sensing	nominal	○ Oversensing ○ Undersensing ○ Other
	case listing for dulvsrea = Other	colvsrea	Please specify reason for inadequate LV sensing	text	n.a
	descriptive by prvisit	dulvpad	Adequate LV pacing	nominal	○ Yes ○ No
		dulvprea	Reason for inadequate LV pacing	nominal	○ Exit block: no capture at maximum output ○ Other
	case listing for dulvprea = Other	colvprea	Please specify reason for inadequate LV pacing	text	n.a.

11.5 Implantation and device details

Implantation

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable level	Nominal values
implantation	descriptive	primtyp	Type of implantation	nominal	○ De-novo system ○ Upgrade system ○ Device exchange
		prxrt	Total X-ray time [min]	scale	n.a.
		prprtm	Total procedure time [min]	scale	n.a.
	case listing for qsutcrc = Yes	coutcrc	Please specify untypical circumstances influenced the implantation time	text	n.a.

Device details

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable level	Nominal values
device_log_ details	descriptive with "Unknown" to be analyzed as missing data	dxdvloc	Implantation site	nominal	○ Left ○ Right
		dxdvpos	Implant position	nominal	○ Sub-cutaneous ○ Sub-pectoral
	descriptive for Pacemaker OR CRT-P	didvtyp	General type of device	nominal	○ Pacemaker SR-T ○ Pacemaker DR-T ○ CRT-P
	descriptive for RA Lead, RV Lead and LV Lead with "Unknown" to be analyzed as missing data	dxdvmtd	Implantation approach	nominal	○ Subclavian access ○ Cephalic access ○ Extrathoracic subclavian access ○ Axillary access ○ Other ○ Unknown
	case listing for dxdvmtd = Other	codvmtd	Specification of other implantation approach	text	n.a.
	descriptive for didvtyp = RA lead	diramdl	RA lead model	nominal	see Lead Models in CDDS
		dxraloc	RA lead placement	nominal	○ Right atrial appendage ○ Lateral wall ○ Septal wall ○ Other
	descriptive for didvtyp = RV lead and with "Unknown" to be analyzed as missing data	dirvmdl	RV lead model	nominal	see Lead Models in CDDS
		dxrvloc	RV lead placement	nominal	○ Apical ○ Septal ○ Outflow tract ○ Other ○ Unknown
	descriptive for didvtyp = LV lead and with "Unknown" to be analyzed as missing data	dilvmdl	LV lead model	nominal	see Lead Models in CDDS
		dxlvloc	LV lead placement	nominal	○ Posterolateral vein ○ Middle cardiac vein ○ Lateral vein ○ Anterolateral vein ○ Anterior vein ○ Posterior vein ○ Other

					○ Unknown
		dxlvtloc	Wall location of LV lead tip	nominal	○ Basal segment ○ Mid segment ○ Apical segment ○ Unknown
		dulvtyp	Type of LV lead	nominal	○ Coronary sinus lead ○ Endocardial lead ○ Epicardial lead
	case listing for lead model = Other OR didvmnf <> BIOTRONIK	codvmdl	Specification of lead model	nominal	n.a.
	case listing for lead placement = Other	coldloc	Specification other lead placement	text	n.a.
	descriptive	dtdvstat	Status of device	nominal	○ Implanted and active ○ Deactivated but still connected and implanted ○ Capped but still implanted ○ Explanted and returned to manufacturer ○ Explanted and discarded ○ Attempted implantation, then returned to manufacturer ○ Attempted implantation, then discarded ○ Other
	case listing for dtdvstat <> Implanted and active	dtdvstat primstdt dtexdt didvtyp …		n.a.	n.a.
	case listing for dtdvstat = Other	codvstat	Specification of other status of device	text	n.a.

11.6 Device programming settings

Data file, identifier studypid & impsn	Notes	Variable name	Variable label	Variable level	Nominal values
v_brady	descriptive	prgbckupstimulation	Backup stimulation	scale as nominal	n.a.
		prgatratprepintvl	Atrial ATP repetition interval	scale as nominal	n.a.
		prgatratpreprythchng	Atrial ATP repetition through rhythm change	scale as nominal	n.a.
		prgatratptxdly	Atrial ATP therapy delay	scale as nominal	n.a.
		prgatratp1type	Atrial ATP1 type	scale as nominal	n.a.
		prgatratp2type	Atrial ATP2 type	scale as nominal	n.a.
		prgatratp1nrattmps	Atrial ATP1 attempts	scale as nominal	n.a.
		prgatratp2nrattmps	Atrial ATP2 attempts	scale as nominal	n.a.
		prgatratp1nrs1	Atrial ATP1 number S1	scale as nominal	n.a.
		prgatratp2nrs1	Atrial ATP2 number S1	scale as nominal	n.a.
		prgatratp1adds1	Atrial ATP1 add S1	scale as nominal	n.a.
		prgatratp2adds1	Atrial ATP2 add S1	scale as nominal	n.a.
		prgatratp1ps1intvl	Atrial ATP1 P-S1 interval	scale as nominal	n.a.
		prgatratp2ps1intvl	Atrial ATP2 P-S1 interval	scale as nominal	n.a.
		prgatratp1s1decr	Atrial ATP1 S1 decrement	scale as nominal	n.a.
		prgatratp2s1decr	Atrial ATP2 S1 decrement	scale as nominal	n.a.
		prgatratp1scndecr	Atrial ATP1 scan decrement	scale as nominal	n.a.
		prgatratp2scndecr	Atrial ATP2 scan decrement	scale as nominal	n.a.

11.7 Home Monitoring transmission performance

Data file, identifier studypid & impsn	Notes	Variable name	Variable label	Variable level	Nominal values
v_hmstat	descriptive	hmperfrm	HM Performance	scale	n.a.

11.8 Usage and assessment or CRT AutoAdapt ('ON' in at least 5 patients; HF-T QP only)

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable level	Nominal values
follow_up_3_m/ follow_up_12_m	descriptive	duauaon01	CRT AutoAdapt "ON" (at start of follow-up)	nominal	○ Yes ○ No
	descriptive for duauaon01 = Yes	duavdapo	Optimized AV delay after pace [ms]	scale	n.a.
		duavdaso	Optimized AV delay after sense [ms]	scale	n.a.
		duauaoas	Overall assessment of the CRT AutoAdapt feature	nominal	○ Very good ○ Good ○ Adequate ○ Poor ○ Very poor
	case listing for duauaoas = Poor OR Very poor	coauaoas	Please specify	text	
	case listing for duauaon02 = No	coauaon02	Please specify assessment of CRT AutoAdapt	text	

11.9 CRT AutoAdapt (3M FU and 12M FU)

Data file, identifier studypid & impsn	Notes	Variable name	Variable label	Variable level	Nominal values
v_brady	descriptive	hmpercrt	CRT Pacing	scale	n.a.
		hmadapbivp	Adaptive BiV pacing	scale	n.a.
		hmprgbivp	Programmed BiV pacing	scale	n.a.
		hmadaplvp	Adaptive LV pacing	scale	n.a.
		hmmeanadaavdlyaftpc	Mean adapted AV delay after pace	scale	n.a.
		hmmeanadaavdlyaftsns	Mean adapted AV delay after sense	scale	n.a.

11.10Usage and assessment of Auto LV VectorOpt

Data file, identifier studypid & impsn	Notes	Variable name	Variable label	Variable level	Nominal values
auto_lv_ vectoropt	descriptive	dulvvtnd	Automatic LV VectorOpt test not done	nominal	○ True ○ False
	case listing by dulvvt for dulvvtnd = True	colvvtnd	Please specify not performing Auto LV VectorOpt test	text	n.a.
	descriptive for dulvvtnd = False	durvlvct	Did you perform the RV-LV conduction time test?	nominal	○Yes, only RVp-LVs ○Yes, only RVs-LVs ○Yes, both: RVp-LVs and RVs-LVs ○No
	descriptive for dulvvtf = No, other number tested	dunvst	Other number of vectors tested	scale	n.a.
	descriptive for dulvvtnd = False	dupv01	LV1 tip to LV2 ring	nominal	○ True ○ False
		dupv02	LV1 tip to LV3 ring	nominal	○ True ○ False
		dupv03	LV1 tip to LV4 ring	nominal	○ True ○ False
		dupv04	LV1 tip to RV2 ring	nominal	○ True ○ False
		dupv05	LV1 tip to Can	nominal	○ True ○ False
		dupv06	LV2 ring to LV1 tip	nominal	○ True ○ False
		dupv07	LV2 ring to LV3 ring	nominal	○ True ○ False
		dupv08	LV2 ring to LV4 ring	nominal	○ True ○ False
		dupv09	LV2 tip to RV2 ring	nominal	○ True ○ False
		dupv10	LV2 ring to Can	nominal	○ True ○ False
		dupv11	LV3 ring to LV1 tip	nominal	○ True ○ False
		dupv12	LV3 ring to LV2 ring	nominal	○ True ○ False
		dupv13	LV3 ring to LV4 ring	nominal	○ True ○ False
		dupv14	LV3 tip to RV2 ring	nominal	○ True ○ False
		dupv15	LV3 ring to Can	nominal	○ True ○ False
		dupv16	LV4 ring to LV1 tip	nominal	○ True ○ False
		dupv17	LV4 ring to LV2 ring	nominal	○ True ○ False
		dupv18	LV4 ring to LV3 ring	nominal	○ True ○ False
		dupv19	LV4 tip to RV2 ring	nominal	○ True ○ False
		dupv20	LV4 ring to Can	nominal	○ True ○ False
		dulvthat	Time needed to run Auto LV threshold measurement for 20 or selected vectors	scale	n.a.
	descriptive for dupnstnd = False	dupnsnvs	Number of vectors for which the PNS threshold was measured	scale as nominal	○1 ○2 ○3 ○…
	descriptive for dupnstnd = False	dupnsppv	PNS threshold of finally programmed pacing vector [V]	scale	n.a.
	descriptive for dulvvtnd = False	dulvvoas	Overall Handling assessment of the Auto LV VectorOpt feature	nominal	○Very good ○Good ○Adequate ○Poor ○Very poor
	case listing for dulvvoas = Poor OR Very poor	colvvoas	Please specify overall assessment	text	n.a.

11.11 Usage and assessment of atrial ATP (aATP 'ON' in at least 10 pts.; DR-T or HF-T QP only)

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable level	Nominal values
follow_up_3_m/ follow_up_12_m	descriptive	praatp	aATP "ON"	nominal	○ Yes ○ No
	descriptive for praatp= Yes	praatpre	Main reason for activation	nominal	○ Study-related ○ Prevention of progression of AT/AF ○ Prevention of stroke ○ Other
	case listing for praatpre = Other	coaatpre	Specification of "other" reason for activation	text	n.a.
	descriptive for praatp = Yes	prbuvpc	Was ventricular back-up pacing programmed?	nominal	○ Yes ○ No
	case listing for prbuvpc = Yes	cobuvpc	Reasons for programming of ventricular back-up pacing	text	n.a.
	descriptive	ceaep	Did atrial episodes occur since last follow-up?	nominal	○ Yes ○ No
	descriptive for ceaep = Yes	ceaepnum	Number of atrial episodes since last follow-up	scale	n.a.
		cvatb	Atrial burden	scale	n.a.
	descriptive for ceaep = Yes	duaatpdl	Was aATP delivered?	nominal	○ Yes ○ No
	descriptive for duaatpdl = Yes	duepaatp	How many episodes were treated with aATP?	scale	n.a.
tachyarrhythmia_episodes	descriptive as cross table	cvattypd	Type of atrial tachyarrhythmia nominal (detected by device)	nominal	○ AT (initially stable) ○ AF (initially unstable)
		cvattypi	Type of atrial tachyarrhythmia (investigator assessment)	nominal	○ Atrial fibrillation ○ Atrial flutter ○ Sinus tachycardia ○ Other SVT ○ Other
	case listing for cvattypi = Other	coattypi	Specification of other SVT / other atrial tachyarrhythmia	text	n.a.
	descriptive for duaatpdl = Yes	duaatpas	Classification of aATP outcome by device	nominal	○ Successful ○ Unsuccessful

11.13Adverse Events

"Adverse events" will be provided by the Vigilance Department in a safety report.

11.14Device deficiencies

"Device deficiencies”" will be provided by the Vigilance Department in a safety report.

11.15Usage and assessment of MRI Guard 24/7

For patient [redacted], the MRI scan was performed after the 3-month follow-up, but the patient died before the 12-month follow-up. The documentation of the MRI examination is recorded in the CRF Follow-up - 3M.

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable level	Nominal values
mri_system_ check	descriptive	prmriscn	MRI system check not done	nominal	○ True ○ False
	descriptive for prmriscn = True	comriscn	Please specify not performing MRI system check	text	n.a
	descriptive	prmrisc	MRI system check done at	nominal	○ Implantation ○ PHD ○ 1-month Follow-Up ○ 3-month Follow-Up
	descriptive for prmriscn = False	qsmriapr	Is the patient approved for MRI scans?	nominal	○ Yes ○ No
	descriptive for qsmriapr = No	comriapr	Please specify why patient is not approved for MRI scans	text	n.a
	descriptive for prmriscn = False	qsmriprn	Was the MRI suitability certificate printed out?	nominal	○ Yes ○ No
	descriptive for qsmriprn = Yes	qsmrisub	Was the MRI suitability certificate handed out to the patient?	nominal	○ Yes ○ No
	descriptive for prmriscn = False	prmrpm	Programmed MRI mode	nominal	○ Auto ○ A00 ○ V00 ○ D00 ○ V00/BiV ○ D00/BiV
	descriptive for prmrpm <> Auto AND is not missing	comrpm	Please specify reason for not programming 'AUTO' mode	text	n.a

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable level	Nominal values
pre_hospital_ discharge follow_up_1_m/ follow_up_3_m/ follow_up_12_m	descriptive	prmri	Routine MRI scan performed since last follow-up	nominal	○ Yes ○ No
	descriptive for prmri = Yes	prmriact	Was MRI Guard 24/7 active?	nominal	○ Yes ○ No
	descriptive for prmriact = Yes	duhmas	How do you rate the information flow via Home Monitoring to inform you about a performed scan?	nominal	○ Very good ○ Good ○ Adequate ○ Poor ○ Very poor
	case listing for duhmas = Poor OR Very poor	cohmas	Please specify	text	n.a

11.16Usage and assessment of EarlyCheck and QuickCheck

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable level	Nominal values
pre_hospital_ discharge	descriptive	preach	Was EarlyCheck used	nominal	○ Yes ○ No
	descriptive for preach = Yes	ducmetm	When was the CardioMessenger placed in the patient´s vicinity? (minutes after end of implantation)	scale	n.a.
		ducmepos	Where was the CardioMessenger positioned for the EarlyCheck transmission?	nominal	○ On patient´s bed in recovery room ○ In the patient room ○ Other
	case listing for ducmepos = Other	cocmeoth	Specification of "other CM position"	text	n.a.
	descriptive for preach = Yes	dueachas	Completeness and reliability of EarlyCheck data	nominal	○ Very good ○ Good ○ Adequate ○ Poor ○ Very poor
	case listing for dueachas = Poor OR Very poor	coeachas	Specification of completeness and reliability of data	text	n.a.
	descriptive for preach = Yes	dudechas	Is the data set transmitted via EarlyCheck adequate to replace the system integrity check of a PHD visit?	nominal	○ Yes ○ No ○ Cannot judge
	case listing for dudechas = No OR Cannot judge		Specifi cation of EarlyCheck data set	text	n.a.
follow_up_1_m	descriptive	prqcphd	Was QuickCheck used since PHD	nominal	○ Yes ○ No
	descriptive for prqcphd = Yes	prqcrea	Reason for activation of QuickCheck	nominal	○ Routine check (instead of or in addition to scheduled HM follow-ups) ○ Observation in Home Monitoring Data ○ Home Monitoring Alert ○ Patient demand (reassurance) ○ Patient demand (symptoms) ○ Other
	case listing for prqcrea = Other	coqcrea	Please specify other reason for activation of QuickCheck	text	n.a.
	descriptive for prqcphd = Yes	qsqcuse	Could an unnecessary patient in-office visit be avoided through the use of QuickCheck?	nominal	○ Yes ○ No ○ Cannot judge
	case listing for qsqcuse	coqcuse	Please specify if an unnecessary patient in-	text	n.a.

	= No OR Cannot judge		office visit could be avoided through the use of QuickCheck		
	descriptive for prqcphd = Yes	duqcoas	Overall assessment of the QuickCheck feature	nominal	○ Very good ○ Good ○ Adequate ○ Poor ○ Very poor
	case listing for duqcoas = Poor OR Very poor	coqcoas	Please specify overall assessment of the QuickCheck feature	text	○ n.a.
follow_up_3_m/ follow_up_12_m	descriptive	duqcfu	Was QuickCheck used since last follow-up	nominal	○ Yes ○ No
	descriptive for duqcfu = Yes	duqcrea	Reason for activation of QuickCheck	nominal	○ Routine check (instead of or in addition to scheduled HM follow-ups) ○ Observation in Home Monitoring Data ○ Home Monitoring Alert ○ Patient demand (reassurance) ○ Patient demand (symptoms) ○ Other
	case listing for duqcrea = Other	coqcrea	Please specify	text	n.a.
	descriptive for duqcfu = Yes	qsqcuse	Could an unnecessary patient in-office visit be avoided through the use of QuickCheck?	nominal	○ Yes ○ No ○ Cannot judge
	case listing for qsqcuse = No OR Cannot judge	coqcuse	Please specify if an unnecessary patient in officevisit could be avoided through the use of QuickCheck	text	n.a.
	descriptive for duqcfu = Yes	duqcoas	Overall assessment of the QuickCheck feature	nominal	○ Very good ○ Good ○ Adequate ○ Poor ○ Very poor
	case listing for duqcoas = Poor OR Very poor	coqcoas	Please specify overall assessment of the QuickCheck feature	text	n.a.

11.17Usage and assessment of leadless ECG

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable level	Nominal values
pre_ hospital_ discharge/ follow_up_1_m/ follow_up_3_m	descriptive	dulecgfa	Was the leadless ECG feature assessed	nominal	○ Yes ○ No
	descriptive for dulecgfa = Yes	dulecgas	How do you rate the legibility of the leadless ECG?	nominal	○ Very good ○ Good ○ Adequate ○ Poor ○ Very poor
	case listing for dulecgas = Poor OR Very poor	colecgas	Specification of legibiltiy of leadless ECG	text	n.a.

11.18Usage of CLS enhancements (DDI-CLS, VV delay with CLS)

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable level	Nominal values
follow_up_3_m/ follow_ up_12_m	descriptive	duddicls	Was DDI-CLS programmed?	nominal	○ Yes ○ No
	descriptive	duclsvvd	Was CSL programmed with VV delay?	nominal	○ Yes ○ No
	case listing for duddicls = Yes OR duclsvvd = Yes	coclsenh	Specification of rationale for programming of CLS enhancement	text	n.a.
	descriptive for duddicls = Yes OR duclsvvd = Yes	qsclsas	How do you rate the benefit of the CLS enhancement for your patient?	nominal	○ Very good ○ Good ○ Adequate ○ Poor ○ Very poor
	case listing for qsclsas = Poor OR Very poor	coclsas	Please specify	text	n.a.

[redacted]

11.20 Occurrence of additional events in HM (early lead failure detection, high average heart rate)

Early lead failure detection

Data file, identifier studypid & impsn	Notes	Variable name	Variable label	Variable level	Nominal values
v_brady	descriptive[2]	hmshrtintvlcntday	Short interval count per day	scale	n.a.
		hmfastnsvt	Fast non-sustained VT per Day	scale	n.a.

[redacted]

High ventricular rate

Data file, identifier studypid & impsn	Notes	Variable name	Variable label	Variable level	Nominal values
v_brady	descriptive	hmhvrcnt	High Ventricular Rate Counter	scale	n.a.
		prghvrlim[3]	High Ventricular Rate Limit	scale as nominal	n.a.

[2] See box below.
[3] Please note that the variable prghvrlim_state should not be considered in the analysis.

11.21Investigator Questionnaire

Atrial ATP

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable level	Nominal values
investigator_ questionnaire	descriptive	aATP_usage	I used atrial ATP (aATP) for some of my patients	nominal	○Yes ○ No
	descriptive for aATP_usage = Yes	aATP_assess_ 01	The user interface of aATP is simple and quick to use	nominal	○Strongly agree ○Somewhat agree ○Neither agree nor disagree ○Somewhat disagree ○Strongly disagree
	case listing for aATP_usage = Yes	aATP_assess_ 01_txt	Please comment your answer (optional)	text	○n.a.
	descriptive for aATP_usage = Yes	aATP_assess_ 02	The lead position check supports safe usage of aATP, as it avoids ATP delivery through dislocated leads	nominal	○Strongly agree ○Somewhat agree ○Neither agree nor disagree ○Somewhat disagree ○Strongly disagree
	case listing for aATP_usage = Yes	aATP_assess_ 02_txt	Please comment your answer (optional)	text	○n.a.
	descriptive for aATP_usage = Yes	aATP_assess_ 03	Amvia's in-office and remote atrial monitoring capabilities and aATP help manage the development of AF early on	nominal	○Strongly agree ○Somewhat agree ○Neither agree nor disagree ○Somewhat disagree ○Strongly disagree
	case listing for aATP_usage = Yes	aATP_assess_ 03_txt	Please comment your answer (optional)	text	○n.a.
	descriptive for aATP_usage = Yes	aATP_assess_ 04	aATP may reduce atrial burden, thus helping to avoid atrial remodeling	nominal	○Strongly agree ○Somewhat agree ○Neither agree nor disagree ○Somewhat disagree ○Strongly disagree
	case listing for aATP_usage = Yes	aATP_assess_ 04_txt	Please comment your answer (optional)	text	○n.a.
	descriptive for aATP_usage = Yes	aATP_assess_ 05	I would program ventricular back-up pacing during use of aATP to improve patient safety	nominal	○Strongly agree ○Somewhat agree ○Neither agree nor disagree ○Somewhat disagree ○Strongly disagree
	case listing for aATP_usage = Yes	aATP_assess_ 05_txt	Please comment your answer (optional)	text	○n.a.
	case listing for aATP_usage = Yes	aATP_assess_ 06	For which patient characteristics would you use ventricular backup pacing during aATP delivery?	text	○n.a.

CRT AutoAdapt

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable level	Nominal values
investigator_ questionnaire	descriptive	AutoAdapt_ usage	I used CRT AutoAdapt for some of my patients	nominal	○Yes ○ No
	descriptive for AutoAdapt_ usage = Yes	AutoAdapt_ assess_01	CRT AutoAdapt is easy and quick to program	nominal	○Strongly agree ○Somewhat agree ○Neither agree nor disagree ○Somewhat disagree ○Strongly disagree
	case listing for AutoAdapt_ usage = Yes	AutoAdapt_ assess_01_t xt	Please comment your answer (optional)	text	○n.a.
	descriptive for AutoAdapt_ usage = Yes	AutoAdapt_ assess_02	The programmability of the parameters 'adaptive AV reduction' and the 'adaptive AV lower limit' Allows high flexibility in the CRT optimization process	nominal	○Strongly agree ○Somewhat agree ○Neither agree nor disagree ○Somewhat disagree ○Strongly disagree
	case listing for AutoAdapt_ usage = Yes	AutoAdapt_ assess_02_t xt	Please comment your answer (optional)	text	○n.a.

QuickCheck

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable level	Nominal values
investigator_ questionnaire	descriptive	QuickCheck_usage	I used QuickCheck for some of my patients	nominal	○Yes ○ No
	descriptive for QuickCheck _usage = Yes	QuickCheck_assess_01	QuickCheck reduces time required for in-clinic follow-up by enabling me to focus on the most clinically relevant data	nominal	○Strongly agree ○Somewhat agree ○Neither agree nor disagree ○Somewhat disagree ○Strongly disagree
	case listing for QuickCheck _usage = Yes	QuickCheck_assess_01_txt	Please comment your answer (optional)	text	○n.a.
	descriptive for QuickCheck _usage = Yes	QuickCheck_assess_02	QuickCheck supports immediate clarification of the patient‘s and device’s status	nominal	○Strongly agree ○Somewhat agree ○Neither agree nor disagree ○Somewhat disagree ○Strongly disagree
	case listing for QuickCheck _usage = Yes	QuickCheck_assess_02_txt	Please comment your answer (optional)	text	○n.a.
	descriptive for QuickCheck _usage = Yes	QuickCheck_assess_03	QuickCheck gives me the opportunity to reassure the patient timely and remotely of the device function	nominal	○Strongly agree ○Somewhat agree ○Neither agree nor disagree ○Somewhat disagree ○Strongly disagree
	case listing for QuickCheck _usage = Yes	QuickCheck_assess_03_txt	Please comment your answer (optional)	text	○n.a.
	descriptive for QuickCheck _usage = Yes	QuickCheck_assess_04	QuickCheck saves time and supports more efficient, simple and flexible patient-care as a result from optimized workflows in the clinic	nominal	○Strongly agree ○Somewhat agree ○Neither agree nor disagree ○Somewhat disagree ○Strongly disagree
	case listing for QuickCheck _usage = Yes	QuickCheck_assess_04_txt	Please comment your answer (optional)	text	○n.a.
	descriptive for QuickCheck _usage = Yes	QuickCheck_assess_05	I expect that with QuickCheck the number of spontaneous hospital visits can be reduced	nominal	○Strongly agree ○Somewhat agree ○Neither agree nor disagree ○Somewhat disagree ○Strongly disagree
	case listing for QuickCheck _usage = Yes	QuickCheck_assess_05_txt	Please comment your answer (optional)	text	○n.a.

EarlyCheck

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable level	Nominal values
investigator_ questionnaire	descriptive	EarlyCheck_ assess01	EarlyCheck can replace the pre-hospital discharge interrogation as an in-office FU, supporting efficient workflow and saving time for patients and clinicians	nominal	○Strongly agree ○Somewhat agree ○Neither agree nor disagree ○Somewhat disagree ○Strongly disagree
	case listing	EarlyCheck_ assess01_txt	Please comment your answer (optional)	text	○n.a.

Assessment of MRI Guard 24/7

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable level	Nominal values
investigator_ questionnaire	descriptive	MRI_assess_reduces_visits	MRI Guard 24/7 avoids additional physician visits (before and after the MRI scan), allowing for swift access to MRI scans and helping to reduce the number of physical examinations	nominal	○Strongly agree ○Somewhat agree ○Neither agree nor disagree ○Somewhat disagree ○Strongly disagree
	case listing	MRI_assess_reduces_visits_txt	Please comment your answer (optional)	text	○n.a.
	descriptive	MRI_assess_status_window	The MRI Status Confirmation window, appearing on the programmer 6 months after the previous MRI system check, helps to ensure that the implanted system fulfills the required MRI conditions	nominal	○Strongly agree ○Somewhat agree ○Neither agree nor disagree ○Somewhat disagree ○Strongly disagree
	case listing	MRI_assess_status_window_txt	Please comment your answer (optional)	text	○n.a.
	descriptive	MRI_assess_new_icons	Newly added icons (conflict: ! / hint: ? / confirmed: √) on the programmer interface help to easily confirm that all parameters are suitable for programming MRI Guard 24/7 'ON'	nominal	○Strongly agree ○Somewhat agree ○Neither agree nor disagree ○Somewhat disagree ○Strongly disagree
	case listing	MRI_assess_new_icons_txt	Please comment your answer (optional)	text	○n.a.
	descriptive	MRI_assess_pacing_rate	The automatic adaption of the pacing rate in MRI mode results in appropriate and individualized pacing rates during the scan	nominal	○Strongly agree ○Somewhat agree ○Neither agree nor disagree ○Somewhat disagree ○Strongly disagree
	case listing	MRI_assess_pacing_rate_txt	Please comment your answer (optional)	text	○n.a.
	descriptive	MRI_assess_time_savings	The automatic MRI mode allows for MRI scans without pre- and post-scan programming appointments. MRI Guard 24/7 streamlines the workflow around (scheduled) MRI scans and consequently saves time for the care teams and the patients	nominal	○Strongly agree ○Somewhat agree ○Neither agree nor disagree ○Somewhat disagree ○Strongly disagree
	case listing	MRI_assess_time_savings_txt	Please comment your answer (optional)	text	○n.a.
	descriptive	MRI_performed	Did any of your patients have an MRI scan during study participation?	nominal	○Yes ○ No
	descriptive	MRI_assess_scan_report	The BIOTRONIK Home Monitoring report, which is automatically sent after each MRI scan, provides complete	nominal	○Strongly agree ○Somewhat agree ○Neither agree nor disagree

			insight into patient and device status allowing for proper documentation and information transfer between clinicians		○Somewhat disagree ○Strongly disagree
	case listing	MRI_assess_scan_report_txt	Please comment your answer (optional)	text	○n.a.

Assessment of leadless ECG

Data file, identifier patient_display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
investigator_questionnaire	descriptive	ecg_assess_01	The usage of the leadless ECG is fast, easy, and convenient	nominal	○Strongly agree ○Somewhat agree ○Neither agree nor disagree ○Somewhat disagree ○Strongly disagree
	case listing	ecg_assess_01_txt	Please comment your answer (optional)	text	○n.a.
	descriptive	ecg_assess_02	The usage of the leadless ECG simplifies my workflow	nominal	○Strongly agree ○Somewhat agree ○Neither agree nor disagree ○Somewhat disagree ○Strongly disagree
	case listing	ecg_assess_02_txt	Please comment your answer (optional)	text	○n.a.

Use of Home Monitoring and CardioMessenger

Data file, identifier patient_display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
investigator_questionnaire	descriptive	HM_assess_01	Automatic Home Monitoring activation and pairing of the device with a suitable CardioMessenger Smart (CM smart) ensures an easy and simple access to HM features	nominal	○Strongly agree ○Somewhat agree ○Neither agree nor disagree ○Somewhat disagree ○Strongly disagree
	case listing	HM_assess_01_txt	Please comment your answer (optional)	text	○n.a.
	descriptive	HM_assess_02	The automatic activation of HM avoids unnecessary physician visits and helps reducing the number of physical contacts	nominal	○Strongly agree ○Somewhat agree ○Neither agree nor disagree ○Somewhat disagree ○Strongly disagree
	case listing	HM_assess_02_txt	Please comment your answer (optional)	text	○n.a.

aATP

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable level	Nominal values
investigator_ questionnaire	descriptive	ICD_assess_ 01	Would your assessment for Amvia pacemakers regarding the statement 'The lead position check allows safe usage of Atrial Therapies, as it avoids ATP delivery through dislocated leads' also be true for an ICD/CRT-D population?	nominal	○Yes ○No ○I don't feel able to judge
	case listing	ICD_assess_ 01_txt	Please comment your answer (optional)	text	○n.a.
	descriptive	ICD_assess_ 02	Would your assessment for Amvia pacemakers regarding the statement 'I would program ventricular back-up pacing during use of Atrial Therapies to improve patient safety' also be true for an ICD/CRT-D population?	nominal	○Yes ○No ○I don't feel able to judge
	case listing	ICD_assess_ 02_txt	Please comment your answer (optional)	text	○n.a.

EarlyCheck and automatic Home Monioring activation

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable level	Nominal values
investigator_ questionnaire	descriptive	ICD_assess_ 03	Would your assessment for Amvia pacemakers regarding the statement 'EarlyCheck can replace the pre-hospital discharge interrogation as an in-office FU, supporting efficient workflow and saving time for patients and clinicians.' also be true for an ICD/CRT-D population?	nominal	○Yes ○No ○I don't feel able to judge
	case listing	ICD_assess_ 03_txt	Please comment your answer (optional)	text	○n.a.
	descriptive	ICD_assess_ 04	Would your assessment for Amvia pacemakers regarding the Statement 'Automatic Home Monitoring activation and pairing of the device with a suitable CardioMessenger Smart (CM smart) ensures an easy and simple access to HM features' also be true for an ICD/CRT-D population?	nominal	○Yes ○No ○I don't feel able to judge
	case listing	ICD_assess_ 04_txt	Please comment your answer (optional)	text	○n.a.

12 Abbreviations

- ADE Adverse Device Effect
- AE Adverse Event
- CDMS Clinical Data Management System
- CDW Clinical Data Warehouse
- CI Confidence Interval
- CIP Clinical Investigation Plan
- CIR Clinical Investigation Report
- CRF Case Report Form
- DD Device Deficiency
- FU(P) Follow-up
- PHD Pre-hospital discharge
- SADE Serious Adverse Device Event
- SAE Serious Adverse Event
- SAP Statistical Analysis Plan
- SAR Statistical Analysis Report
- SOP Standard Operating Procedure
- SD Standard Deviation

Sponsor:	BIOTRONIK SE & Co KG
Study name / EAC code:	BIO|CONCEPT.Amvia Study / BA115
Version and date of the Statistical Analysis Plan:	Erratum from 07 Oct 2024 to SAP Version 2.0 from 17 Nov 2023
Version and date of the underlying Clinical Investigation Plan:	1.0 from 30 May 2022

Print Name & Title	**Signature**	**Date of Signature** (DD MMM YYYY)
Biostatistician [redacted]		

Erratum to SAP Version 2-0 from 17Nov2023

8 Analyses: Baseline

8.2 Variables

Medication

SAP 2-0:

Medication is recorded on a continuous medication log documenting free text for trade names. An allocation between trade names and medication categories will be continuously maintained and updated at least during the blind review prior to any data analysis.

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable level	Nominal values
medication_ log_details	no report	cmbl	Baseline medication	nominal	○ Yes ○ No
		cmtrt	Trade name	text	n.a.

Correction:

Medication is recorded on a continuous medication log documenting free text for trade names. An allocation between trade names and medication categories will be continuously maintained and updated at least during the blind review prior to any data analysis. For all patients for whom the medication date matches the date of the baseline, the baseline medication is set to yes.

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable level	Nominal values
medication_ log_details	no report	cmbl	Baseline medication	nominal	○ Yes ○ No
		cmtrt	Trade name	text	n.a.
		cmstdt	Start date	date	n.a.

11 Analyses: Data of interest

SAP 2-0:

[redacted]

Correction:

[redacted]

11.2 IPG-related SADE-free rate (see definition below)

SAP 2-0:

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable Level	Nominal values
internal_ adjudication	case listing	aestdt	Onset date	date	n.a.
		primdt	Date of implantation	date	n.a.
		aerelidv	Adverse Event is related to the investigational device (device related ADE)	nominal	○Not related ○Unlikely ○Possible ○Probable ○Causal relationship
		corelidv	Please specify	text	n.a.
		aeser	Adverse Event is serious	nominal	○Yes ○No
		aerelset	Adverse Event is relevant for SADE-free rate	nominal	○Yes ○No
		corelset	Please specify reason for "No"		○Yes ○No

Corrections:

If no SADEs occurred during the observation period, the binomial confidence interval is calculated in addition to the Kaplan-Meier estimator. Taking into account all patients of the analysis set and in addition only a subgroup of patients with documented 12-month follow-up.

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable Level	Nominal values
internal_ adjudication	case listing if relevant for SADE-free rate	aestdt	Onset date	date	n.a.
		primdt	Date of implantation	date	n.a.
	descriptive if evaluated	aeser	Adverse Event is serious	nominal	○Yes ○No
		aerelidv	Adverse Event is related to the investigational device (device related ADE)	nominal	○Not related ○Unlikely ○Possible ○Probable ○Causal relationship
		aerelset	Adverse Event is relevant for SADE-free rate	nominal	○Yes ○No
	descriptive for aerelset = No	corelidv	Please specify	text	○n.a.
		corelset	Please specify reason for "No"	text	○n.a.

11.3 Lead measurements (sensing amplitude, pacing threshold, pacing impedance at implantation and at each follow-up and/or via Home Monitoring)

Coronary Sinus (CS) Lead Measurements - Left ventricle (LV)

SAP 2-0:

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable level	Nominal values
lead_ measurements	descriptive by prvisit	dulvsv	Permanently programmed LV sensing vector	nominal	○LV1 tip to LV2 ring (bipolar) ○LV1 tip to Can (unipolar)

Correction:

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable level	Nominal values
lead_ measurements	descriptive by prvisit (all values of this variable that are not defined here are analyzed as missing data)	dulvsv	Permanently programmed LV sensing vector	nominal	○LV1 tip to LV2 ring (bipolar) ○LV1 tip to Can (unipolar)

11.5 Implantation and device details

Correction:
Add new table: End of last suturedetails

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable level	Nominal values
device_log_ details	case listing	SN_SAR (DIDVSNR02)	Serial number	text	n.a.
implantation		date_implantation_ SAR	Date of procedure	date	n.a.
		prprtm	Total procedure time [min]	scale	n.a.
		qsutcrc	Have any Untypical circumstances influenced the implantation time?	nominal	○Yes ○ No
		coutcrc	Please specify untypical circumstances influenced the implantation time	text	n.a.
		prsututm	End of last suture	time	n.a.

11.6 Device programming settings (3M FU and 12M FU)

SAP 2-0:

Data file, identifier studypid & impsn	Notes	Variable name	Variable label	Variable level	Nominal values
v_brady	descriptive	prgbckupstimulation	Backup stimulation	scale as nominal	n.a.
		prgatratprepintvl	Atrial ATP repetition interval	scale as nominal	n.a.
		prgatratpreprythchng	Atrial ATP repetition through rhythm change	scale as nominal	n.a.
		prgatratptxdly	Atrial ATP therapy delay	scale as nominal	n.a.
		prgatratp1type	Atrial ATP1 type	scale as nominal	n.a.
		prgatratp2type	Atrial ATP2 type	scale as nominal	n.a.
		prgatratp1nrattmps	Atrial ATP1 attempts	scale as nominal	n.a.
		prgatratp2nrattmps	Atrial ATP2 attempts	scale as nominal	n.a.
		prgatratp1nrs1	Atrial ATP1 number S1	scale as nominal	n.a.
		prgatratp2nrs1	Atrial ATP2 number S1	scale as nominal	n.a.
		prgatratp1adds1	Atrial ATP1 add S1	scale as nominal	n.a.
		prgatratp2adds1	Atrial ATP2 add S1	scale as nominal	n.a.
		prgatratp1ps1intvl	Atrial ATP1 P-S1 interval	scale as nominal	n.a.
		prgatratp2ps1intvl	Atrial ATP2 P-S1 interval	scale as nominal	n.a.
		prgatratp1s1decr	Atrial ATP1 S1 decrement	scale as nominal	n.a.
		prgatratp2s1decr	Atrial ATP2 S1 decrement	scale as nominal	n.a.
		prgatratp1scndecr	Atrial ATP1 scan decrement	scale as nominal	n.a.
		prgatratp2scndecr	Atrial ATP2 scan decrement	scale as nominal	n.a.

Correction:

Data file, identifier studypid & impsn	Notes	Variable name	Variable label	Variable level	Nominal values
v_brady	descriptive as for programmed parameters STATE Variables = "INVALID" are analyzed as missing data	prgbckupstimulation	Backup stimulation	scale as nominal	n.a.
		prgatratprepintvl	Atrial ATP repetition interval	scale as nominal	n.a.
		prgatratpreprythchng_state	Atrial ATP repetition through rhythm change	nominal	n.a.
		prgatratptxdly_state	Atrial ATP therapy delay	nominal	n.a.
		prgatratp1type_state	Atrial ATP1 type	nominal	n.a.
		prgatratp2type_state	Atrial ATP2 type	nominal	n.a.
		prgatratp1nrattmps	Atrial ATP1 attempts	scale as nominal	n.a.
		prgatratp2nrattmps	Atrial ATP2 attempts	scale as nominal	n.a.
		prgatratp1nrs1	Atrial ATP1 number S1	scale as nominal	n.a.
		prgatratp2nrs1	Atrial ATP2 number S1	scale as nominal	n.a.
		prgatratp1adds1_state	Atrial ATP1 add S1	nominal	n.a.
		prgatratp2adds1_state	Atrial ATP2 add S1	nominal	n.a.
		prgatratp1ps1intvl	Atrial ATP1 P-S1 interval	scale as nominal	n.a.
		prgatratp2ps1intvl	Atrial ATP2 P-S1 interval	scale as nominal	n.a.
		prgatratp1s1decr	Atrial ATP1 S1 decrement	scale as nominal	n.a.
		prgatratp2s1decr	Atrial ATP2 S1 decrement	scale as nominal	n.a.
		prgatratp1scndecr	Atrial ATP1 scan decrement	scale as nominal	n.a.
		prgatratp2scndecr	Atrial ATP2 scan decrement	scale as nominal	n.a.

11.7 Home Monitoring transmission performance

SAP 2-0:

Data file, identifier studypid & impsn	Notes	Variable name	Variable label	Variable level	Nominal values
v_hmstat	descriptive	hmperfrm	HM Performance	scale	n.a.

Correction:

Data file, identifier studypid & impsn	Notes	Variable name	Variable label	Variable level	Nominal values
v_hmstat	descriptive	hmperfrm	HM Performance	scale	n.a.
v_brady	descriptive	HM_transmission_rate_SAR	HM transmission rate (%)	scale	n.a.

[redacted]

11.8 Usage and assessment or CRT AutoAdapt ('ON' in at least 5 patients; HF-T QP only)

Correction:
Add new row in the table:

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable level	Nominal values
follow_up_3_m/ follow_up_12_m	descriptive for duauaon01 = Yes	duauaon02	CRT AutoAdapt remains "ON" (at end of follow-up)	nominal	Yes ○ No

11.9 CRT AutoAdapt (3M FU and 12M FU)

SAP 2-0:

Data file, identifier studypid & impsn	Notes	Variable name	Variable label	Variable level	Nominal values
v_brady	descriptive	hmpercrt	CRT Pacing	scale	n.a.
		hmadapbivp	Adaptive BiV pacing	scale	n.a.
		hmprgbivp	Programmed BiV pacing	scale	n.a.
		hmadaplvp	Adaptive LV pacing	scale	n.a.
		hmmeanadaavdlyaftpc	Mean adapted AV delay after pace	scale	n.a.
		hmmeanadaavdlyaftsns	Mean adapted AV delay after sense	scale	n.a.

Correction:

Data file, identifier studypid & impsn	Notes	Variable name	Variable label	Variable level	Nominal values
v_brady	descriptive	hmpercrt_mi	CRT Pacing	scale	n.a.
		hmadapbivp_mi	Adaptive BiV pacing	scale	n.a.
		hmprgbivp_mi	Programmed BiV pacing	scale	n.a.
		hmadaplvp_mi	Adaptive LV pacing	scale	n.a.
		hmmeanadapavdlyap_mi	Mean adapted AV delay after pace	scale	n.a.
		hmmeanadapavdlyas_mi	Mean adapted AV delay after sense	scale	n.a.

11.11 Usage and assessment of atrial ATP

SAP 2-0:

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable level	Nominal values
follow_up_3_m/ follow_up_12_m	descriptive	praatp	aATP "ON"	nominal	Yes ○ No
	descriptive for praatp= Yes	praatpre	Main reason for activation	nominal	Study-related Prevention of progression of AT/AF Prevention of stroke Other
	case listing for praatpre = Other	coaatpre	Specification of "other" reason for activation	text	n.a.
	descriptive for praatp = Yes	prbuvpc	Was ventricular back-up pacing programmed?	nominal	○ Yes ○ No
	case listing for prbuvpc = Yes	cobuvpc	Reasons for programming of ventricular back-up pacing	text	n.a.
	descriptive	ceaep	Did atrial episodes occur since last follow-up?	nominal	○ Yes ○ No
	descriptive for ceaep = Yes	ceaepnum	Number of atrial episodes since last follow-up	scale	n.a.
		cvatb	Atrial burden	scale	n.a.
	descriptive for ceaep = Yes	duaatpdl	Was aATP delivered?	nominal	○ Yes ○ No
	descriptive for duaatpdl = Yes	duepaatp	How many episodes were treated with aATP?	scale	n.a.
tachyarrhythmia_episodes	descriptive as cross table	cvattypd	Type of atrial tachyarrhythmia nominal (detected by device)	nominal	AT (initially stable) AF (initially unstable)
		cvattypi	Type of atrial tachyarrhythmia (investigator assessment)	nominal	Atrial fibrillation Atrial flutter Sinus tachycardia Other SVT Other
	case listing for cvattypi = Other	coattypi	Specification of other SVT / other atrial tachyarrhythmia	text	n.a.
	descriptive for duaatpdl = Yes	duaatpas	Classification of aATP outcome by device	nominal	Successful Unsuccessful

Corrections:

Data file, identifier patient_ display_ id_full	Notes	Variable name	Variable label	Variable level	Nominal values
follow_up_3_m/ follow_up_12_m	descriptive	praatp	aATP "ON"	nominal	○ Yes ○ No
	descriptive for praatp= Yes	praatpre	Main reason for activation	nominal	○Study-related ○Prevention of progression of AT/AF ○Prevention of stroke ○Other
	case listing for praatpre = Other	coaatpre	Specification of "other" reason for activation	text	n.a.
	descriptive for praatp = Yes	prbuvpc	Was ventricular back-up pacing programmed?	nominal	○ Yes ○ No
	case listing for prbuvpc = Yes	cobuvpc	Reasons for programming of ventricular back-up pacing	text	n.a.
	descriptive for praatp= Yes	ceaep	Did atrial episodes occur since last follow-up?	nominal	○ Yes ○ No
	descriptive for ceaep = Yes	duaatpdl	Was aATP delivered?	nominal	○ Yes ○ No
	case listing for praatp= Yes	coaatp	Comments on aATP	text	n.a.
follow_up_3_m	descriptive for ceaep = Yes	ceaepnum	Number of atrial episodes since last follow-up	scale	n.a.
		cvatb	Atrial burden	scale	n.a.
	descriptive for duaatpdl = Yes	duepaatp	How many episodes were treated with aATP?	scale	n.a.

Add new table for atrial episodes at 12 month follow up:

Data file, identifier studypid & impsn	Notes	Variable name	Variable label	Variable level	Nominal values
v_brady	descriptive as for count variables for praatp = Yes at 12m FU	HMATREPITHPY_LT	Number of atrial episodes	scale as nominal	n.a.
		HMATRATPDLVCNT_LT	Delivered atrial ATP	scale as nominal	n.a.
		HMATRATPSUCCNT_LT	Successful atrial ATP	scale as nominal	n.a.
		unsuccessfulaatp_SAR	Unsuccessful atrial ATP	scale as nominal	n.a.

[redacted]

11.15Usage and assessment of MRI Guard 24/7

SAP 2-0:

For patient [redacted], the MRI scan was performed after the 3-month follow-up, but the patient died before the 12-month follow-up. The documentation of the MRI examination is recorded in the CRF Follow-up - 3M.

Correction:

For patients [redacted] and [redacted], the MRI scan was performed after the 3-month follow-up, but the patients died before the 12-month follow-up. The documentation of the MRI examination is recorded in the CRF Follow-up - 3M

11.16 Usage and assessment of EarlyCheck and QuickCheck

Correction:
New:
The questions "Completeness and reliability of EarlyCheck data" and "Is the data set transmitted via EarlyCheck adequate to replace the system integrity check of a PHD visit?" should be evaluated once for all sites and once without [redacted], as the PHD was carried out too early in this site, contrary to the CIP. (see document [redacted])

11.20 Occurrence of additional events in HM (early lead failure detection, high average heart rate)

SAP 2-0:

Early lead failure detection

Data file, identifier studypid & impsn	Notes	Variable name	Variable label	Variable level	Nominal values
v_brady	descriptive[1]	hmshrtintvlcntday	Short interval count per day	scale	n.a.
		hmfastnsvt	Fast non-sustained VT per Day	scale	n.a.

[redacted]

High ventricular rate

Data file, identifier studypid & impsn	Notes	Variable name	Variable label	Variable level	Nominal values
v_brady	descriptive	hmhvrcnt	High Ventricular Rate Counter	scale	n.a.
		prghvrlim[2]	High Ventricular Rate Limit	scale as nominal	n.a.

[redacted]

Correction:

Early lead failure detection

Data file, identifier studypid & impsn	Notes	Variable name	Variable label	Variable level	Nominal values
v_brady	no report	hmshrtintvlcntday_mi	Short interval count per day	scale	n.a.
		hmfastnsvt_mi	Fast non-sustained VT per Day	scale	n.a.

The relevant entries per patient and FU period are reported, as defined below:

[redacted]

High ventricular rate

Data file, identifier studypid & impsn	Notes	Variable name	Variable label	Variable level	Nominal values
v_brady	descriptive	hmhvrcnt_lt	High Ventricular Rate Counter	scale	n.a.
	descriptive as for count variables	hmhvrcnt_lt	High Ventricular Rate Counter	scale as nominal	n.a.

Additional Analysis not in SAP 2-0:

Add new table: "Percentage of pacing since last follow-up recorded at 3-month follow-up"

Data file, identifier studypid & impsn	Notes	Variable name	Variable label	Variable level	Nominal values
v_brady	descriptive for the average percentage of pacing in the period between 30 and 91 days after implantation	hmpercrt_mi	CRT Pacing	scale as nominal	n.a.
		hmadapbivp_mi	Adaptive BiV pacing	scale as nominal	n.a.
		hmprgbivp_mi	Programmed BiV pacing	scale as nominal	n.a.
		hmadaplvp_mi	Adaptive LV pacing	scale as nominal	n.a.