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

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0 Change History

Version 1.0: Initial document.

Version 2.0: [redacted]

Version 3.0: [redacted]

1 Introduction

1.1 Aim

The aim of this document is to provide detailed instructions on all mandatory descriptive and inferential statistical analyses for the Clinical Investigation Report (CIR).

1.2 Data for which quality control is required

A quality control is needed for analyses of all endpoints(s) as defined in the clinical investigation plan (CIP) and referenced in this document.

1.3 General information

The text contains verbatim excerpts from the CIP. Such excerpts are italicized with grey background; e.g.

....

The main aspects and the design of the clinical investigation are presented in chapters 2 - 4

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

Definitions of the specific dates, e.g. effective randomization and termination are presented in chapter 6.

Specific analysis sets are defined in chapter 0.

Statistical analyses are handled in following chapters.

Thereby the following statistical considerations are specified:

- Definition of the analysis set for the following analyses, e.g. excluding patients without any measured or imputed data for this endpoint.
- Definition of the endpoint(s) to be analyzed including references to the source data, e.g. CRF sheet and item.
- Treatment of missing and spurious data for evaluation of the above endpoint(s).
- Exclusion of particular information from the evaluation of the above endpoint(s) in addition to the exclusion of patients from the analysis set.
- Descriptive analyses including tables and figures
- Statistical alternative hypothesis/hypotheses (HA) to analyze the above endpoint(s) if available.
- Statistical tests intended to analyze the above hypothesis/hypotheses if available.

All variables are defined in tables using the following columns:

- Data file — Name of a data file exported from the CDMS with one data row per unique identifier (e.g. patient specific "patient_display_ID_full") additionally, a new data file ("SAR_data") is generated by merging all relevant data from the original CDMS data files and generating derived variables (e.g. BMI from weight and height or date of first AE episode)
- Notes — Information e.g. whether data has to be presented with descriptive methods as defined in the following sub-chapter ("desc"), as case listings or data needed for generating of derived variables only ("no report")
- Variable name — Original name of a variable in the CDMS data file or name of a derived variables (indicated with a suffix "_SAR");
- Variable label — Original labels from the CDMS data will be used for generating the SAR unless a new label is defined in this document ("NEW"); labels might be omitted or shortened ("…") if remaining clear
- Variable level — Nominal, ordinal, scale (metric, continuous), text, or date
- Nominal values — Original values from CDMS data will be used for generating the SAR unless new nominal values are defined in this document ("NEW"); values might be omitted or shortened ("…") if remaining clear; for numeric data this information is not applicable (n.a.)

Data file, unique identifier patient_display_id_full patient_display_id_full Patient display ID nominal …	Notes	Variable name	Variable label	Variable level	Nominal values

2 Objectives

CIP chapter 7.1.Objectives

This study is designed as post market clinical follow-up study to identify and evaluate residual risks associated with the use of the Cor Family ICDs and the Plexa S DX lead that remained unrevealed even after risk analysis, risk mitigation and successful conformity assessment.

Moreover, the study aims at providing additional data, as required by regulatory authorities outside the CE-region. Furthermore, the performance and efficacy of the Cor Family devices and their features, as well as of the Plexa S DX lead shall be assessed. The results will be used for updating the clinical evaluation.

The primary objective of the clinical investigation is to confirm the clinical safety of the Cor Family ICDs by the analysis of the Cor Family-related SADEs until the 3-month follow-up.

Secondary objectives are the Kaplan-Meier estimate of the SADE-free rate at 3 and 12 months after implantation, the assessment of the automatic LV VectorOpt test, as well as the assessment of the CRT AutoAdapt feature.

3 Investigational Device

CIP chapter 4.1 Summary description of the device and its intended purpose

The investigational devices used in this clinical investigation are the ICDs and CRT-Ds of the Acticor/Rivacor ICD family and the Plexa ProMRI S DX ICD lead.

The ICDs/CRT-Ds of the Acticor/Rivacor family are state-of-the art implantable defibrillators intended for defibrillator therapy in patients with indication for primary or secondary prevention of sudden cardiac death. Triple-chamber devices (CRT-D) are additionally indicated for cardiac resynchronization therapy (CRT) for patients with congestive heart failure with ventricular asynchrony.

The Plexa ProMRI S DX ICD lead is intended for implantation in the right ventricle to deliver ATP and shock therapies during ventricular tachycardia. The lead provides sensing and pacing in the right ventricle, as well as sensing in the right atrium (floating atrial dipole).

Both the Acticor/Rivacor ICD family and the Plexa ProMRI S DX lead are equipped with a DF4 connector.

For better legibility in the following text, the investigational devices listed above are referred to as Cor Family ICDs and Plexa S DX lead, unless otherwise stated.

4 Study Design & Time Course

CIP chapter 8.1.4 Methods

During the course of the study, all clinical procedures are performed according to clinical routine. More detailed information can be found in the technical manual and in supporting study documents. The Automatic LV VectorOpt test for LV vector selection, and the AV Opt test or CRT AutoAdapt feature for AV delay optimization have to be used mandatorily in the respective devices unless contraindicated. The corresponding time schedule is described in section 9.1. All parameters and measurements that are recorded within the study are described in this section and are documented on the corresponding electronic Case listing forms (eCRFs). The investigator is required to use an electronic signature to approve the content of the data reported in the eCRFs. BIOTRONIK will monitor the content of the eCRFs as described in section 10. Data will be documented at the following points in time:

-Enrollment/Baseline
-Implantation
-Pre-Hospital Discharge
-3-month follow-up
-6-month follow-up
-12-month follow-up
-Termination

The following events can be documented at any time:

-Adverse Events
-Device Deficiencies
-Premature termination

CIP chapter 9.1 Overview

Table 5 : Overview of study procedures. The exact reference time for the 3-, 6- and 12-month follow-up is defined as 92 days, 183 days and 365 days after implantation, respectively. The applicable time window is ± 30 days around this reference time.

Investigations	Enroll-ment	Implan-tation	PHD	3-Month FU	6-Month FU	12-Month FU
Verification of in- and exclusion criteria	x					
Patient informed consent	x					
Documentation of demographic and health status data	x					
Documentation of cardiovascular medication	x	x	x	x	x	x
Documentation of indication for ICD/CRT-D therapy (incl. available diagnostics)	x					
ICD/CRT-D implantation		x				
Assessment of ICD/CRT-D shape		x				
Assessment of Plexa S DX Lead handling		x				
Assessment of Selectra catheter handling		x				
Record device based sensing, pacing threshold and impedance values		x	x	x	x	x
Evaluation of system performance		x	x	x	x	x
Evaluation of tachyarrythmia episodes		x	x	x	x	x
Registration at HM Service Center, hand out CardioMessenger		(x)	x			
Home Monitoring 'ON'		x	x	x	x	(x)
Recording Episode IEGMs (event triggered): 'ON'		x	x	x	x	(x)
Automatic LV VectorOpt test		(x)	x	(x)		
CRT AutoAdapt 'ON' (Acticor/Rivacor 7 CRT-D)		(x)	x	(x)	(x)	(x)
Evaluation of CRT Auto Adapt Feature (Acticor/ Rivacor 7 CRT-D)				x		(x)[4]
AV Opt Test (VR-T DX/ DR-T/Rivacor 5 CRT-D)			x	(x)		
Documentation of Quick Check				x	x	x
Documentation of MPP settings (for HF-T QP)		x	x	x	x	x
Documentation of MRI examination			x	x	x	x
Assessment of patient´s wearing comfort (in case of exchange)				x		
Evaluation of ATP statistics page						x
eCRF completion	x	x	x	x	x	x
Provision of programmer data via ReportShare		x	x	x	x	x
Adverse event and device deficiency reporting	x	x	x	x	x	x
Regular study termination						x

x=if applicable, (x)=optional

5 General Statistical Procedures

5.1 Descriptive analyses

CIP chapter 11.1 Statistical design, method and analytical procedures

... For continuous variables descriptive statistics (mean, standard deviation, median, minimum, maximum and quartiles) will be calculated. For nominal variables absolute and relative frequencies will be calculated based on non-missing data. Ordinal variables are described similarly as continuous data (minimum, 1. quartile, median, 3. quartile, and maximum) or by absolute and relative frequencies based on non-missing data of each category.

For illustration, see the following standard tables with and without subgroup analyses based on dummy data.

5.1.1 Nominal – dichotomous data

Variable (N total = 10)	Category	N non-missing	Absolute frequency	Relative frequency [%]
Sex	Female	9	5	55.6
History of AF	Yes	8	4	50.0

Variable (N total = 10)	Category	Group Randomization group	N non-missing	Absolute frequency	Relative frequency [%]
Sex	Female	Control (N group = 3)	3	2	66.7
		Therapy 1 (N group = 4)	4	3	75.0
		All	9	5	55.6
History of AF	Yes	Control	2	0	0.0
		Therapy 1	4	3	75.0
		All	8	4	50.0

5.1.2 Nominal data – more than two categories

Variable (N total = 10)	N non-missing	Very good N(%)	Good N(%)	Medium N(%)	Poor N(%)
Patient self assessment at enrollment	7	2 (28.6%)	2 (28.6%)	1 (14.3%)	2 (28.6%)
Patient self assessment at 12m FU	8	1 (12.5%)	3 (37.5%)	3 (37.5%)	1 (12.5%)

Variable (N total = 10)	Group Randomization group	N non-missing	Very good N(%)	Good N(%)	Medium N(%)	Poor N(%)
Patient self assessment at enrollment	Control (N group = 3)	2	1 (50.0%)	0 (0.0%)	0 (0.0%)	1 (50.0%)
	Therapy 1 (N group = 4)	3	0 (0.0%)	1 (33.3%)	1 (33.3%)	1 (33.3%)
	All	7	2 (28.6%)	2 (28.6%)	1 (14.3%)	2 (28.6%)
Patient self assessment at 12m FU	Control	2	0 (0.0%)	1 (50.0%)	1 (50.0%)	0 (0.0%)
	Therapy 1	4	0 (0.0%)	2 (50.0%)	1 (25.0%)	1 (25.0%)
	All	8	1 (12.5%)	3 (37.5%)	3 (37.5%)	1 (12.5%)

5.1.3 Scale / metric data

Variable (N total = 10)	N non-missing	Mean	SD	Min	Lower quartile	Median	Upper quartile	Max
Age [years]	7	51.7	15.0	25.0	40.0	57.0	60.0	70.0
Height [cm] as measured at enrollment	8	177.3	14.4	150.0	170.0	179.0	187.5	195.0

Variable (N total = 10)	Group Randomization group	N non-missing	Mean	SD	Min	Lower quartile	Median	Upper quartile	Max
Age [years]	Control (N group = 3)	2	55.0	7.1	50.0	50.0	55.0	60.0	60.0
	Therapy 1 (N group = 4)	3	56.7	15.3	40.0	40.0	60.0	70.0	70.0
	All	7	51.7	15.0	25.0	40.0	57.0	60.0	70.0
Height [cm] as measured at enrollment	Control	3	183.3	10.4	175.0	175.0	180.0	195.0	195.0
	Therapy 1	3	175.0	21.8	150.0	150.0	185.0	190.0	190.0
	All	8	177.3	14.4	150.0	170.0	179.0	187.5	195.0

5.1.4 Ordinal data

Variable (N total = 10)	N missing	Min	Lower quartile	Median	Upper quartile	Max
NYHA class enrollment	2	1.0	1.0	1.0	2.5	4.0
NYHA class 24m	3	1.0	1.0	1.0	3.0	4.0

Variable (N total = 10)	Group Randomization group	N non-missing	Min	Lower quartile	Median	Upper quartile	Max
NYHA class enrollment	Control (N group = 3)	3	1.0	1.0	1.0	3.0	3.0
	Therapy 1 (N group = 4)	4	1.0	1.0	1.5	3.0	4.0
	All	8	1.0	1.0	1.0	2.5	4.0
NYHA class 24m	Control	2	1.0	1.0	2.0	3.0	3.0
	Therapy 1	3	1.0	1.0	2.0	4.0	4.0
	All	7	1.0	1.0	1.0	3.0	4.0

5.2 Inferential analyses

CIP chapter 11.1 Statistical design, method and analytical procedures

To test the primary hypothesis an exact binomial tests is carried out. Additionally, an exact 2-sided 95% confidence interval will be generated.

5.3 Significance level

CIP chapter 11.3 Level of significance and the power of the study

For the statistical test of the two-sided primary hypothesis, a two-sided p value less than 5% will be considered statistically significant.

No adjustment for multiple testing is foreseen, i.e. all analyses except those related to the primary end point were considered to be exploratory.

5.4 Missing Data

CIP chapter 11.11 Handling of missing, unused and spurious data

Missing or spurious data will not be imputed.

Free text will be used to clarify other data.
Spurious data will be clarified via the query management, i.e. corrected after approval of an investigator. Remaining outliers will be identified during the review of the data before data base closure. In case of a clear evidence of a measurement error, the Statistical Analysis Plan will be updated in order to avoid any bias. Spurious data, which were not clarified by the query process before database closure, will be indicated. If appropriate, analyses will be performed both with /without such data.

5.5 Exclusion of data from confirmatory data analysis

CIP chapter 11.12 Exclusion of data from the confirmatory data analysis

In the following cases, data are to be excluded from analysis or prevented from inclusion into analysis:

Exclusion of patients from the analysis set of the primary hypothesis:

-No data is allowed to be collected and included in the absence of a documented informed consent.

-Patients that are erroneously enrolled despite violation of inclusion or exclusion criteria at the time of enrollment

-Patients without primary endpoint but premature study termination as defined for the primary endpoint are not included in the analysis set to avoid an over-estimation of the SADE-free rate.

Exclusion of data from patients included in the analysis set of the primary hypothesis:

-Any event occurred later than the pre-specified time window after implantation as defined for the primary endpoint.

-SADEs will be adjudicated by an internal adjudication board, whereby the seriousness and device relatedness will be re-examined. 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 endpoint.

5.6 Subgroups

CIP chapter 11.9 Specification of subgroups

For this clinical investigation there is no specification of subgroups in the sense that analyses will be repeated for subsets of the pre-specified analysis set. However, there are different analysis sets defined for the primary and secondary endpoints.

5.7 Interim analyses

CIP chapter 11.6 Level of significance and the power of the study

An interim analysis is planned after the completion of the 3-month follow-ups of all enrolled patients without prior study termination and final documentation of all prior primary endpoints. After this point in time, the data for testing the primary hypothesis will not be changed until the final analysis, and thus no multiplicity adjustment is required. Analysis of all other data and endpoints is explorative, therefore no multiplicity adjustment is required, either.

On request specific data might be provided to the competent authorities. Such kind of preliminary analysis would not bias the further data because no investigator except the Coordinating Investigator will be informed about the results. Except for safety reasons, no instruction for the further conductance of the clinical investigations will be made based on such preliminary analysis...

5.8 Software

All analyses will be carried out using validated software, e.g. SAS version 9.4 or upgrades.

5.9 CDMS export

The following data files are exported from the CDMS:

- event_evaluation
- follow_up_3m
- follow_up_6m
- follow_up_12m
- adverse_event
- auto_lv_vectoropt
- av_opt
- baseline_general
- cardiac diagnostic
- concomitant_medication_log
- deviation_form_bio
- deviation_form_bio_log
- deviation_form_site
- device_deficiency
- device_log
- device_log_details
- enrollment
- hospitalization_log
- implantation
- lead_measurement
- medical_history
- medication_log_details
- pre_hospital_dicharge
- tachyarrhythmia_episode
- termination

6 Specific Study Dates

6.1 Enrollment date

CIP chapter 8.3.6. Point of enrolment and study termination

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_i	Patient: Date of informed consent signature	date	n.a.
data_SAR	date_enrollment_SAR[1]	Date of enrollment (PIC signature)	date	n.a.

6.2 Implantation date

Data file, identifier record_id & patient_display_id_full	Variable name	Variable label	Variable level	Nominal values
device_log_details	PRIMSTDT	Implantation/Use date	date	n.a.

Data file, identifier patient_display_id_full	Variable name	Variable label	Variable level	Nominal values
implantation	PRIMSTDT_i	Date of procedure (Implantation CRF)	date	n.a.
data_SAR	date_implantation_SAR[2]	Date of implantation	date	n.a.

[redacted]

6.3 Termination date

CIP chapter 8.3.6 Point of enrolment and study termination

The point of study termination is defined as date of 12-month follow-up for patients with regular study termination.

The point of non-regular study termination can be the following:

-Date of the last unsuccessful implantation attempt

-Date of withdrawal of consent

-Date of patient death

-If patient is lost to follow-up, the date of last contact of the site study team (e.g. investigator or study nurse) with the patient

-If patient is a drop-out for any other reason, the date of latest medical information of the patient (e.g. follow-up, IEGM)...

The above criteria are implemented as information for the investigator at the termination CRF. Thus, the date of study termination DSTRDT will be used until there is no contradiction to the date of a performed 12m follow-up.

Data file, identifier patient_display_id_full	Variable name	Variable label	Variable level	Nominal values
follow_up_12m	DSSUBNS → m12_DSSUBNS	NEW 12mFU: Patient NOT SEEN for Follow-up	nominal	○ True ○ False
follow_up_12m	SVFUSTDT_i → m12_SVFUSTDT_i	NEW 12mFU: Date of Follow-up	date	n.a.
termination	DSTRDT_i	Date of study termination	date	n.a.
data_SAR	date_termination_SAR[3]	Minimum date of study termination or date of conducted 12m FU	date	n.a.

[redacted]

6.4 Censoring Date for Interim Analysis (not relevant for final analysis)

CIP chapter 8.1.4 Methods

Data will be documented at the following points in time:

-Enrollment/Baseline
-Implantation
-Pre-Hospital Discharge
-3-month follow-up
-6-month follow-up
-12-month follow-up
-Termination

The following events can be documented at any time:

-Adverse Events
-Device Deficiencies
-Premature termination

The censoring date is defined as the latest study procedure by which a previous AE should have been documented.

Data file, identifier patient_display_id_full	Variable name	Variable label	Variable level	Nominal values
pre_hospital_discharge	DSSUBNS → phd_DSSUBNS	NEW PHD: Patient NOT SEEN for Follow-up	nominal	○ True ○ False
pre_hospital_discharge	SVFUSTDT_i → phd_SVFUSTDT_i	NEW PHD: Date of Follow-up	date	n.a.
follow_up_3m	DSSUBNS → m03_DSSUBNS	NEW 3mFU: Patient NOT SEEN for Follow-up	nominal	○ True False
follow_up_3m	SVFUSTDT_i → m03_SVFUSTDT_i	NEW 3mFU: Date of Follow-up	date	n.a.
follow_up_6m	DSSUBNS → m06_DSSUBNS	NEW 6mFU: Patient NOT SEEN for Follow-up	nominal	○ True ○ False
follow_up_6m	SVFUSTDT_i → m06_SVFUSTDT_i	NEW 6mFU: Date of Follow-up	date	n.a.
adverse_event	AESTDT_i	Onset date	date	n.a.
adverse_event	AEENDT_i	Date of resolution/Date of death	date	n.a.
device_deficiency	DERCDT_i	Date of detection	date	n.a.
data_SAR	date_implantation_SAR	Date of implantation or date of non-successful implantation attempt	date	n.a.
data_SAR	date_termination_SAR	Date of conducted 12m FU or date of study termination	date	n.a.
data_SAR	date_censoring_SAR[4]	Date of censoring (latest date of AE onset, AE resolution, implantation, PHD, 3m FU, 6m FU, 12m FU, or date of study termination)	date	n.a.

[redacted]

7 Analysis Sets

7.1 PIC Analysis Set

[redacted]

Data file, identifier patient_display_id_full	Variable name	Variable label	Variable level	Nominal values
enrollment	DMICDT_i	Patient: Date of informed consent signature	date	n.a.
dat_SAR	analysis_set_signed_PIC_SAR[5]	Analysis set:PIC date available	nominal	○ Yes ○ No

7.2 Implantation Analysis Set

CIP chapter 8.1.6 Replacement of subjects

During the course of the study, patients that drop out prior to any implantation attempt can be replaced as long as enrollment in the study is still ongoing. Patients who are not implanted with an investigational device and who did not come in contact with any investigational device during implantation attempt can also be replaced.

Data file, identifier patient_display_id_full	Variable name	Variable label	Variable level	Nominal values
enrollment	DMICDT_i	Patient: Date of informed consent signature	date	n.a.
data_SAR	analysis_set_implantation_SAR[6]	Analysis set Implantation (implantation or implantation attempt)	nominal	○ Yes ○ No

[5] [redacted]

7.3 Cor Family Analysis Set

CIP chapter 4.3 Model name including software version and accessories, table 1

Table 1: Eligible devices of the Cor Family

Device name	Catalogue number
Acticor 7 VR-T	[redacted]
Acticor 7 VR-T DX	
Acticor 7 DR-T	
Acticor 7 HF-T	
Acticor 7 HF-T QP	
Rivacor 7 VR-T	
Rivacor 7 VR-T DX	
Rivacor 7 DR-T	
Rivacor 7 HF-T	
Rivacor 7 HF-T QP	
Rivacor 5 VR-T	
Rivacor 5 VR-T DX	
Rivacor 5 DR-T	
Rivacor 5 HF-T	
Rivacor 5 HF-T QP	

Data file, identifier record_id & patient_display_id_full	Variable name	Variable label	Variable level	Nominal values
device_log_details	DIICDMDL	CRT-D model	nominal	○ Acticor 7 HF-T ○ Acticor 7 HF-T QP ○ Rivacor 7 HF-T ○ Rivacor 7 HF-T QP ○ Rivacor 5 HF-T ○ Rivacor 5 HF-T QP ...
device_log_details	DIIDVMDL	ICD model	nominal	○ Acticor 7 VR-T ○ Acticor 7 VR-T DX ○ Acticor 7 DR-T ○ Rivacor 7 VR-T ○ Rivacor 7 VR-T DX ○ Rivacor 7 DR-T ○ Rivacor 5 VR-T ○ Rivacor 5 VR-T DX ○ Rivacor 5 DR-T ...

Data file, identifier patient_display_id_full	Variable name	Variable label	Variable level	Nominal values
enrollment	DMICDT_i	Patient: Date of informed consent signature	date	n.a.
data_SAR	analysis_set_corfamily_SAR[7]	Analysis set Cor family: Acticor, Rivacor implantation attempt	nominal	○ Yes ○ No

[redacted]

7.4 CRT Analysis Set

Data file, identifier record_id & patient_display_id_full	Variable name	Variable label	Variable level	Nominal values
device_log_details	DIICDMDL	CRT-D model	nominal	○ Acticor 7 HF-T ○ Acticor 7 HF-T QP ○ Rivacor 7 HF-T ○ Rivacor 7 HF-T QP ○ Rivacor 5 HF-T ○ Rivacor 5 HF-T QP ...

Data file, identifier patient_display_id_full	Variable name	Variable label	Variable level	Nominal values
enrollment	DMICDT_i	Patient: Date of informed consent signature	date	n.a.
data_SAR	analysis_set_CRT_SAR[8]	Analysis set CRT: Acticor HF, Rivacor HF implantation attempt	nominal	○ Yes ○ No

7.5 CRT AutoAdapt Analysis Set

CIP chapter 8.1.4.9 CRT AutoAdapt (only Acticor 7 and Rivacor 7 CRT-Ds)

At implantation and/or Pre-Hospital Discharge CRT AutoAdapt shall mandatorily be programmed 'ON' in all CRT-D patients that are implanted with Acticor 7 or Rivacor 7, with the exception of patients with AV block, for whom this feature is contraindicated. (Note: CRT AutoAdapt is not available in Rivacor 5.)

Data file, identifier record_id & patient_display_id_full	Variable name	Variable label	Variable level	Nominal values
device_log_details	DIICDMDL	CRT-D model	nominal	Acticor 7 HF-T Acticor 7 HF-T QP Rivacor 7 HF-T Rivacor 7 HF-T QP ...

Data file, identifier patient_display_id_full	Variable name	Variable label	Variable level	Nominal values
enrollment	DMICDT_i	Patient: Date of informed consent signature	date	n.a.
data_SAR	analysis_set_CRTAutoAdapt_SAR[9]	Analysis set AutoAdapt: Acticor 7 HF, Rivacor 7 HF implantation attempt	nominal	Yes No

[redacted]

7.6 AV Opt Analysis Set

CIP chapter 8.1.4.5 AV delay optimization (for VR-T DX, DR-T, and Rivacor 5 HF-T and HF-T QP devices)

For all patients with VR-T DX or DR-T devices (only if clinically indicated), and for patients with Rivacor 5 triple-chamber devices (as Rivacor 5 is not equipped with CRT AutoAdapt) with sinus rhythm of sufficient intrinsic rate, the AV Opt test has to be performed during the PHD follow-up . Performance of the test during the 3-month follow-up is acceptable if it was not done at PHD.

Data file, identifier record_id & patient_display_id_full	Variable name	Variable label	Variable level	Nominal values
device_log_details	DIICDMDL	CRT-D model	nominal	○ Rivacor 5 HF-T ○ Rivacor 5 HF-T QP ...
device_log_details	DIIDVMDL	ICD model	nominal	○ Acticor 7 VR-T DX ○ Acticor 7 DR-T ○ Rivacor 7 VR-T DX ○ Rivacor 7 DR-T ○ Rivacor 5 VR-T DX ○ Rivacor 5 DR-T ...

Data file, identifier patient_display_id_full	Variable name	Variable label	Variable level	Nominal values
enrollment	DMICDT_i	Patient: Date of informed consent signature	date	n.a.
data_SAR	analysis_set_AVopt_SAR[10]	Analysis set AVopt: Rivacor 5 HF, Acticor DX, Rivacor DX, Acticor DR, Rivacor DR implantation attempt	nominal	○ Yes ○ No

[redacted]

7.7 Plexa ProMRI S DX Analysis Set

CIP chapter 4.3 Model name including software version and accessories, table 2

Table 2: Eligible Plexa S DX leads

Device name	Catalogue number
Plexa ProMRI S DX 65/15	[redacted]
Plexa ProMRI S DX 65/17	

Data file, identifier record_id & patient_display_id_full	Variable name	Variable label	Variable level	Nominal values
device_log_ details	DIRVMDL	RV lead model	nominal	... ○ Plexa ProMRI S DX 65/15 ○ Plexa ProMRI S DX 65/17 ...

Data file, identifier patient_display_id_full	Variable name	Variable label	Variable level	Nominal values
enrollment	DMICDT_i	Patient: Date of informed consent signature	date	n.a.
data_SAR	analysis_set_plexadx_SAR[11]	Analysis set Plexa: Plexa ProMRI S DX implantation attempt	nominal	○ Yes ○ No

7.8 Investigational Device Analysis Set

Data file, identifier patient_display_id_full	Variable name	Variable label	Variable level	Nominal values
data_SAR	analysis_set_corfam_ plexadx_SAR[12]	Analysis set investigational device: Acticor OR Rivacor OR Plexa ProMRI S DX implantation attempt	nominal	○ Yes ○ No

[1] [redacted]

7.9 Data for a CONSORT diagram and CIR-chapter "study realization"

All analyses are performed for the PIC analysis set [13] if not mentioned otherwise.

7.9.1 Number of patients

- Number of enrolled patients = number of patients in the PIC analysis set
- Number of enrollments per country from patient_display_id_full
- Number of enrollments per investigational site from patient_display_id_full
- Number of patients with implantation attempts = number of patients in the implantation analysis set
- Number of patients with implantation attempts of an investigational device= number of patients in the investigational device analysis set
- Number of patients with implantation attempts of a Cor family device= number of patients in the Cor Family analysis set
- Number of patients with implantation attempts of a Cor family CRT device= number of patients in the CRT analysis set
- Number of patients with implantation attempts of a Plexa ProMRI S DX lead = number of patients in the Plexa ProMRI S DX analysis set
- Number of patients with baseline[14]
- Number of patients with Pre-Hospital Discharge[15]
- Number of patients with 3mo FU[16]
- Number of patients with 6mo FU[17]
- Number of patients with 12mo FU[18]

Data file, identifier patient_display_id_full	Variable name	Variable label	Variable level	Nominal values
baseline_general	SVBLDT_i	Date of baseline assessment	date	n.a.
data_SAR	date_implantation_ SAR	Date of implantation	date	n.a.
pre_hospital_discharge follow_up_3m follow_up_6m follow_up_12m	DSSUBNS → phd_DSSUBNS →m03_DSSUBNS →m06_DSSUBNS →m12_DSSUBNS	Patient NOT SEEN for Follow-up →Discharge Patient NOT SEEN for Follow-up → 03mFU: Patient NOT SEEN for Follow-up → 06m FU: Patient NOT SEEN for Follow-up → 12m FU: Patient NOT SEEN for Follow-up	nominal	○ True ○ False
pre_hospital_discharge follow_up_3m follow_up_6m follow_up_12m	SVFUSTDT → phd_SVFUSTDT →m03_SVFUSTDT →m06_SVFUSTDT →m12_SVFUSTDT	Date of Follow-up →Discharge Date of Follow-up → 03mFU: Date of Follow-up → 06m FU: Date of Follow-up → 12m FU: Date of Follow-up	date	n.a.

[redacted]

7.9.2 Study dates

- Date of first-patient-in (FPI)
- Date of last-patient-in (LPI)
- Date of last-patient-out (LPO)

7.9.3 Study duration

Descriptive statistics to be reported for the PIC and for the implantation analysis set, respectively.

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
data_SAR	descri ptive	days_PIC_term_SAR[19]	Days from PIC to termination	scale	n.a.
data_SAR	descri ptive	days_implant_term_SAR[20]	Days from implantation attempt to termination	scale	n.a.

[redacted]

7.9.4 Premature termination

To be reported for the investigational PIC analysis set. [21]

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
enrollment	case listings for 12m_SVFUSTDT = missing OR 12m_DSSUBNS = True	DMICDT	Patient: Date of informed consent signature	date	n.a.
data_SAR		analysis_set_plexadx_SAR	Analysis set of patients with Plexa ProMRI S DX ...	nominal	○ Yes ○ No
data_SAR		analysis_set_corfarm_SAR	Analysis set of patients with Acticor or Rivacor ...		○ Yes ○ No
termination		DSTRDT	Date of study termination	date	n.a.
termination		DSRTRM	Regular study termination	nominal	○ Yes ○ No
termination		COETRREA	Please specify reason for early termination	text	n.a.
termination		DSETRREA	Reason for early study termination	nominal	○ Patient moved away from investigational center ○ Patient is lost to follow-up ○ Patient withdrew consent to study participation ○ Patient death ○ Judgement of physician ○ Drop-out according to protocol ○ Enrollment failure ○ Other
termination	Case listings for DSETRREA = Patient withdrew consent to study participation	DSSSDUSE	The patient allowed the further use of the already collected pseudonymized data …	nominal	○ Yes ○ No / Not specified
termination	Case listings for DSETRREA = Drop-out according to protocol	DSDRPPRO	Please specify "Drop-out according to protocol"	nominal	○ Patient is not implanted with a product of the Cor Family of ICDs/CRT-Ds for any reason … ○ An explantation or replacement of the Cor Family ICD/CRT-D was performed … ○ Missing acceptance/compliance of the patient … ○ Significant worsening of general or pre-existing condition of the patient … ○ Other
termination		CODRPPRO	Please specify "Drop-out according to protocol – Other"	text	n.a.

[redacted]

7.9.5 Investigational device not active

Data file, identifier patient_display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
device_log_ details	Case listings for DTDVSTAT ≠Implanted and active	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
		PRIMSTDT	Implantation/ Use date	date	n.a.
		DIICDMDL	CRT-D model	nominal	...
		DIIDVMDL	ICD model	nominal	...
		DIRVMDL	RV lead model	nominal	...

8 General data

8.1 Analysis set

The following analyses are performed for the investigational device analysis set[22] and separately for the Plexa analysis set[23].

- Baseline characteristics and medical history
- Lead measurements
- Sensing and pacing assessment
- Adverse Events
- Device Deficiencies

The following analyses are performed for the Cor family analysis set[24]

- Assessment of ICD/CRT-D design
- Arrhythmias and their treatment by the ICD/CRT-D system
- Usage of QuickCheck
- Assessment of statistic for ATP optimization
- RV/LV active capture control at permanent DDI mode

The following analyses are performed for the AV Opt analysis set[25]

- AV delay optimization feature

8.2 Variables

8.2.1 Baseline characteristics, medical history, and implantation

Baseline-general / Demographics

Data file, identifier patient_display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
baseline_general	descr.	DMSEX	Gender	nominal	○ Male ○ Female
	descr.	DMAGE	Age [Years]	scale	n.a.
data_SAR	descr.	DMAGE_65_SAR[26]	Age dichotomous greater than or equal 65 years	nominal	○ Age >= 65 years ○ Age < 65 years
	descr.	DMAGE_75_SAR[27]	Age dichotomous greater than or equal 75 years	nominal	○ Age >= 75 years ○ Age < 75 years

[redacted]

Baseline-general / Physical examination

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
baseline_general	descr.	VSHGHT	Height [cm]	scale	n.a.
	descr.	VSWGHT	Weight [kg]	scale	n.a.
	descr.	VSBMI	BMI [kg/m2]	scale	n.a.
	descr.	CVNYHA	Current NYHA classification	ordinal data to be reported as nominal variable	○ 1 ○ 2 ○ 3 ○ 4

Medical 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	MHHFE	Primary HF etiology	nominal	○ Ischemic ○ Non-ischemic
	descriptive	MHHFTYP	Type of HF	nominal	○ Left heart failure ○ Right heart failure ○ Global heart failure
	descriptive with "Unknown" to be analyzed as missing data	HOHF	Hospitalization for worsening of heart failure within the previous 12 months	nominal	○ Yes ○ No ○ Unknown
	No report	HOHFDT	Date of last hospitalization for heart failure	date	n.a.
	descriptive	days_hfhosp_ pic_SAR[28]	Days from last hospitalization for heart failure to PIC	scale	n.a.
	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	MHMI	Prior myocardial infarction	nominal	○ Yes ○ No
	descriptive	PRRVC	Prior revascularization (PCI or CABG)	nominal	○ Yes ○ No

[redacted]

Medical history / Brady- and tachyarrhythmias

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
medical_history	desciptive	MHSSS	History of sick sinus syndrome	nominal	○ Yes ○ No
	descriptive	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°
	desciptive	MHBBB	History of bundle branch block	nominal	○ Yes / No
	desciptive for MHBBB = Yes	MHBBBTYP	Type of bundle branch block		○ LBBB ○ RBBB ○ Other
	desciptive	MHCNDDOT	History of other type of conduction disease	nominal	○ Yes ○ No
	desciptive	MHAFB	History of atrial fibrillation	nominal	○ Yes ○ No
	desciptive for MHAFB = Yes	CVAFBTYP	Type of atrial fibrillation	nominal	○ Paroxysmal ○ Persistent ○ Long-standing persistent ○ Permanent
	desciptive	MHAVA	History of other atria/supraventricular arrhythmias	nominal	○ Yes / No
	desciptive	MHVA	History of ventricular arrhythmia	nominal	○ Yes / No

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
medical_history	case listings for MHBBBTYP = Other	COBBBTYP	Specification of other type of bundle branch block	text	n.a.
	case listings for MHCNDDOT = Yes	COCNDDOT	Specification of other type of conduction disease	text	n.a.
	case listings for MHAVA = Yes	COAVA	Specification of other atrial/supraventricular arrhythmias	text	n.a.
	case listings for MHVA = Yes	COVA	Specification of history of ventricular arrhythmia	text	n.a.

Medical history / Known comorbidities

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
medical_history	descriptive	MHCMB	Any Comorbidities known?	nominal	○ Yes ○ No
	descriptive	MHHP	Hypertension (including well-controlled)	nominal	○ Yes ○ No
	descriptive	MHVHD	Valvular heart disease	nominal	○ Yes ○ No
	Descriptive for MHAOVA = Yes	MHAOVA	Aortic valve affected	nominal	○ Yes ○ No
		MHMIVA	Mitral valve affected	nominal	○ Yes ○ No
		MHMIIN	Mitral insufficiency	nominal	○ Yes ○ No
		MHMIST	Mitral stenosis	nominal	○ Yes ○ No
		MHTRVA	Tricuspid valve affected	nominal	○ Yes ○ No
		MHPUVA	Pulmonary valve affected	nominal	○ Yes ○ No
	descriptive	MHCVD	History of cerebrovascular disease (e.g. TIA / Stroke)	nominal	○ Yes ○ No
	descriptive	MHPVAD	Peripheral vascular/arterial disease	nominal	○ Yes ○ No
	descriptive	MHASTH	Asthma or other chronic lung disease (except COPD)	nominal	○ Yes ○ No
	descriptive	MHCOPD	Chronic obstructive pulmonary disease (COPD)	nominal	○ Yes ○ No
	descriptive	MHCKD	Chronic renal insufficiency / chronic kidney disease (CKD) (i.e. eGFR < 60)	nominal	○ Yes ○ No
	descriptive	MHSAP	Sleep apnoea	nominal	○ Yes ○ No
	descriptive for MHSAP = Yes	MHSAPTYP	Type of sleep apnoea	nominal	○ Central ○ Obstructive ○ Mixed
	descriptive	MHLIVR	Chronic liver disease	nominal	○ Yes ○ No
	descriptive	MHDIAM	Diabetes mellitus	nominal	○ Yes ○ No
	descriptive	MHANEM	Anemia	nominal	○ Yes ○ No
	descriptive	MHCNCR	Cancer	nominal	○ Yes ○ No
	descriptive	MHHPLP	Hyperlipidemia	nominal	○ Yes ○ No
	descriptive	MHCMBOTH	Other comorbidities	nominal	○ Yes ○ No

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
medical_history	case listings	COVHD	Further specification of valvular heart disease (e.g. type, severity)	text	n.a.
	case listings for MHCMBOTH =Yes	COCMBOTH	Specification of other comorbidities	text	n.a.

Cardiac diagnostic / ECG

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
cardiac_ diagnostic	descriptive	EGHRT	Heart rate [bpm]	scale	n.a.
	descriptive	CVEGARH	Atrial rhythm during ECG recording	nominal	○ Sinus rhythm ○ Atrial fibrillation ○ Atrial flutter/other SVT ○ Atrial paced rhythm ○ Other
	descriptive	CVEGVRH	Ventricular rhythm during ECG	nominal	○ Intrinsic – atrial conduced ○ Intrinsic – escape rhythm ○ Ventricular paced rhythm ○ Other
	descriptive for CVEGVRH ≠ ventricular paced rhythm	EGPRI	PR interval [ms]	scale	n.a.
	descriptive	EGQRS	QRS width (intrinsic) [ms]	scale	n.a.
	descriptive	EGQRSM	QRS morpholgy	nominal	○ Normal ○ LBBB ○ RBBB ○ Indeterminate

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
cardiac_ diagnostic	case listings for CVEGARH = Other	COEGARH	Specification of other atrial rhythm during ECG recording	text	n.a.
	case listings for CVEGVRH = Other	COEGVRH	Specification of other ventricular rhythm during ECG recording	text	n.a.

Cardiac diagnostic / LVEF

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
cardiac_ diagnostic	descr.	EHLVEF	Left ventricular ejection fraction [%]	scale	n.a.

Cardiac diagnostic / therapy indication

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
cardiac_ diagnostic	descr.	CECRT	CRT indication given	nominal	○ Yes ○ No
	descr.	CECRTTYP	Type of CRT indication	nominal	○ CRT indication in sinus rhythm ○ CRT indication in atrial fibrillation ○ CRT indication and conventional pacing indication ○ Other
	descr.	CEICDIND	ICD indication given	nominal	○ Yes ○ No
	descr.	CEICDTYP	Type of ICD indication	nominal	○ Ventricular fibrillation (VF) ○ Symptomatic ventricular tachycardia (VT) ○ Asymptomatic ventricular tachycardia ○ Inducible VT/VF at EP study ○ Syncope ○ Primary prevention ○ Other
	descr.	CEBCINAS	Bradycardia indication given	nominal	○ Yes ○ No
	descr.	PRIM	Previous device implanted	nominal	○ Yes ○ No
	descr.	PRIMDVTY	Type pf previously implanted device	nominal	○ Pacemaker ○ ICD ○ CRT pacemaker ○ CRT ICD ○ Implantable loop recorder

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
cardiac_ diagnostic	case listings for CECRTTYP = Other	COEGVRH	Specification of other CRT indication	text	n.a.
	case listings for CEICDTYP = Other	COICDOTH	Specification of other ICD indication	text	n.a.

Baseline 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 record_id & 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

Implantation / investigational device system

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
implantation	descr.	PRIMTYP	Type of implantation	nominal	○ De-novo system ○ Upgrade system ○ Device exchange
	descr.	PRIMRATY	Type of RA lead implantation	nominal	○ New RA lead ○ Previously implanted RA lead ○ No RA lead implanted
	descr.	PRIMRVTY	Type of RV lead implantation	nominal	○ New RV lead ○ Previously implanted RV lead ○ No RV lead implanted
	descr.	PRIMLVTY	Type of LV CS lead implantation	nominal	○ New LV CS lead ○ Previously implanted LV lead ○ No attempt to implant LV CS lead ○ Unsuccessful attempt to implant LV CS lead ○ No LV lead implanted

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
implantation	case listings for PRIMLVTY = No attempt to implant LV CS lead	PRLVCSRE	Reason for no attempt to implant LV CS lead	nominal	○ Use of LV epicardial lead ○ Use of LV endocardial lead ○ Other
		COLVCSRE	Specification of other reason for no attempt to implant LV CS lead	text	n.a.
	case listings for PRIMLVTY = Unsuccessful attempt to implant LV CS lead	PRIMLVRE	Main reason for failure to implant LV CS lead	nominal	○ Coronary sinus not identified ○ No suitable coronary vein identified ○ Extracardiac stimulation (e.g. n. phrenicus) ○ Other complication ○ LV lead deficiency ○ Other reason not related to a complication
		COIMLVOT	Specification of other main reason for failure to implant LV CS lead	text	n.a
		PRIMLVP	Further attempts to implant an LV lead	nominal	○ Endocardial LV lead planned/performed ○ Epicardial LV lead planned/performed ○ No LV lead planned

Implantation/ Procedural data on LV CS lead implantation (only for CRT-D devices)

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
implantation	descriptive for PRIMLVTY = New LV CS lead OR unsuccessful attempt to implant LV CS lead with "unknown" to be analyzed as missing data	PRLVVNG	Venogram performed prior to LV lead implantation	nominal	○ Yes ○ No ○ Unknown
		PRLVGCTH	Guide catheter used for LV lead implantation	nominal	○ Yes ○ No ○ Unknown
		PRLVGW	Guide wire used for LV lead implantation	nominal	○ Yes ○ No ○ Unknown
		PRLVSTL	Stylet used for LV lead implantation	nominal	○ Yes ○ No ○ Unknown

Implantation / Usage of further accessories used

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
implantation	descriptive with "not applicable ..." OR "unknown" to be analyzed as missing data	DUBACSUP	Used BIOTRONIK accessories were	nominal	○ Supplied with lead/device ○ Obtained separately (NOT supplied with lead/device) ○ Both Supplied with lead/device and Obtained separately ○ Not applicable - no BIOTRONIK accessories have been used ○ Unknown
	descriptive for DUBACSUP = supplied... obtained ... both ...	DUBACPRB	Did any problems with any used BIOTRONIK accessories occur	nominal	○ No – all used BIOTRONIK accessories were successfully used ○ Yes – problems with used BIOTRONIK accessories have occurred
	case listings for DUBACPRB = Yes	COBACPRB	Please specify the type of accessory and the type of problem	text	n.a.

Implantation / Programmer type

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
implantation	descriptive	DUPRGTYP	Programmer Type used	nominal	○ Renamic ○ Renamic Neo

Implantation / initial devices (not restricted to investigational devices)

Data file	Notes	Variable name	Variable label	Variable level	Nominal values
device_log_details	No report	PRIMSTDT	Implantation/Use date	date	n.a.
device_log_details	No report	DTEXDT	Explantation/deactivation date	date	n.a.
device_log_details	No report	DIDVTYP	General type of device	nominal	○ ICD ○ CRT-D ○ RA lead ○ RV lead ○ LV lead
device_log_details	Descriptive for each DIDVTYP	DIDVMDL	Device/lead model	text	n.a.

8.2.2 Assessment of ICD/CRT-D design (size and shape)

CIP chapter 8.1.4.5 Assessment of ICD/CRT-D design (size and shape)

The implanting investigator will be asked to assess the new design of the Cor Family devices ... In case of device exchanges, the patient will be asked about their wearing comfort compared to their previous device at the 3-month follow-up.

Implantation/ Assessment of ICD/CRT –D design

Data file, identifier patient_display_id_full	Notes	Variable name	Variable label	Variable level	Ordinal values
implantation	descriptive	DXIMLAS_R	Required length of incision	nominal	○ Very good ○ Good ○ Adequate ○ Poor ○ Very poor
	descriptive	DULDCAS	Lead connection		
	descriptive	DULDBAS	Lead body leading out of the header		

Data file, identifier patient_display_id_full	Notes	Variable name	Variable label	Variable level	Ordinal values
implantation	case listings	COIMLAS	Please specify required length of incision	text	n.a.
		COLDCAS	Please specify lead connection	text	n.a.
		COLDBAS	Please specify lead body leading out of the header	text	n.a.

Implantation/ Comparison of properties with BIOTRONIK's predecessor devices

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
implantation	descr.	DIPRDV	Provide information on predecessor devices	nominal	○ Lumax ○ Idova ○ Iforia ○ Ilesto ○ Ilivia ○ Inlexa ○ Intica ○ Inventra ○ Iperia ○ Itrevia ○ Other
	descr.	DUPCMKAS	Ease / time needed for making the pocket for predecessor	nominal	○ Much more convenient ○ More convenient ○ Similar ○ Worse ○ Much worse
	descr.	DUSZPHAS	Assessment of size and shape for the patient' s comfort for predecessor		
	descr.	DUISPLAS01	Ease, securing, and placement for predecessor		
	descr.	DUCSMTAS	Cosmetic outcome for predecessor	nominal	○ Much better ○ Better ○ Similar ○ Worse ○ Much worse
	descr.	DUPHSHAS	Interference for predecessor	nominal	○ Much less (most physiological) ○ Less (more physiological) ○ Similar ○ More (less physiological) ○ Much more (least physiological)

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level
implantation	case listings for DIPRDV = Other	COPRDV	Please provide name of other predecessor device	text
	case listings	COPCMKAS	comment on ease/time needed for making the pocket for predecessor	text
	case listings	COSZPHAS	comment on assessment of size and shape for the patient' s comfort for predecessor	text
	case listings [redacted]	COISPLAS01	comment on ease, securing, and placement for predecessor	text
	case listings	COCSMTAS	comment on cosmetic outcome for predecessor	text
	case listings	COPHSHAS	comment on for predecessor	text

Implantation/ Comparison of properties with competitor devices

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
implantation	descriptive with "Unknown" to be analyzed as missing data	DIDVMNF	Provide information on most frequently used competitor device (Manufacturer)	nominal	○ Boston Scientific ○ Medtronic ○ Sorin Group / LivaNova ○ Abbott / St. Jude ○ Other ○ Unknown
	descriptive	DIDVNAM	Provide name of competitor device	nominal	...

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
implantation	descr.	DUPCMKAS01	Ease / time needed for making the pocket for competitor	nominal	○ Much more convenient ○ More convenient ○ Similar ○ Worse ○ Much worse
	descr.	USZPHAS01	Assessment of size and shape for the patient' s comfort for competitor		
	descr.	DUISPLAS02 NOTE deviating index	Ease, securing, and lead placement for competitor		
	descr.	DUCSMTAS01	Cosmetic outcome for competitor	nominal	○ Much better ○ Better ○ Similar ○ Worse ○ Much worse
	descr.	DUPHSHAS01	Interference for competitor	nominal	○ Much less (most physiological) ○ Less (more physiological) ○ Similar ○ More (less physiological) ○ Much more (least physiological)

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level
implantation	case listings for DIDVMNF = Other	CODVMNF	Please provide name of "other" competitor	text
	case listings	COPCMKAS01	comment on ease/time needed for making the pocket for competitor	text
	case listings	COSZPHAS01	comment on assessment of size and shape for the patient' s comfort for competitor	text
	case listings NOTE deviating index	COISPLAS02	comment on ease, securing, and placement for competitor	text
	case listings	COCSMTAS01	comment on cosmetic outcome for competitor	text
	case listings	COPHSHAS01	comment on interference for competitor	text

follow_up_3m / Wearing Comfort in case of Device Exchange

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Ordinal values
implantation	no report	PRIMTYP	Type of implantation	nominal	○ De-novo system ○ Upgrade system
follow_up_3m	descriptive for PRIMTYP=Upgrade system	DUWCDVAS	How did the patient assess the wearing comfort of the device compared to its predecessor	nominal	○ Much more convenient ○ More convenient ○ Similar ○ Worse o Much worse

8.2.3 AV delay optimization feature (AV Opt)

CIP chapter 8.1.4.5 AV delay optimization (for VR-T DX, DR-T, and Rivacor 5 HF-T and HF-T QP devices)

For all patients with VR-T DX or DR-T devices (only if clinically indicated), and for patients with Rivacor 5 triple-chamber devices (as Rivacor 5 is not equipped with CRT AutoAdapt) with sinus rhythm of sufficient intrinsic rate, the AV Opt test has to be performed during the PHD follow-up . Performance of the test during the 3-month follow-up is acceptable if it was not done at PHD.

AV Opt test / AV delay optimization

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	nominal values
av_opt	descriptive with "Not done" to be analyzed as missing data	DUAVT	AV Opt test run	nominal	○ Between Implantation and PHD ○ At PHD ○ At 3-month Follow-up ○ Not done
	descriptive	DUOAVT	Did the test suggest sensed and/or paced AV delay values?	nominal	○ Yes ○ No

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	nominal values
av_opt	descriptive for DUAVT= Not done	DUAVTND01	General lack of trust in automated test routines	nominal	○ True ○ False
		DUAVTND02	Personal or institutional preference for use of alternative	nominal	○ True ○ False
		DUAVTND03	Patient conditions prescribe AV delay settings without need for additional diagnostic aids	nominal	○ True ○ False
		DUAVTND04	Atrial fibrillation	nominal	○ True ○ False
		DUAVTND05	No sufficient intrinsic rate	nominal	○ True ○ False
		DUAVTND10	Other	nominal	○ True ○ False
		COAVTND	Please comment on reasons for not running AV Opt Test	text	n.a.

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	nominal values
av_opt	descriptive	DUPCAVD	Suggested paced AV delay duration [ms]	scale	n.a.
	descriptive	DUSEAVD	Suggested sensed AV delay duration [ms]	scale	n.a.

AV Opt test / Final programmed AV delay settings

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	nominal values
av_opt	descr.*	DUAVDAP01	AV Delay after pace 01	scale	n.a.
	descr.*	DUAVDAP02	AV Delay after pace 02	scale	n.a.
	descr.*	DUAVDASE01	AV Delay after sense 01	scale	n.a.
	descr.*	DUAVDASE02	AV Delay after sense 02	scale	n.a.
	descr.*	DUHRT01	AV Delay at rate 01	scale	n.a.
	descr.*	DUHRT02	AV Delay at rate 02	scale	n.a.
	descr.	DUAVDCLA01	NEW: Do you consider the **first** suggested AV delay clinically acceptable?	nominal	○ Yes ○ No
	descr.	DUAVDCLA02	NEW: Do you consider the **second** suggested AV delay clinically acceptable?	nominal	○ Yes ○ No
	descr.	DUAVTOUT	NEW: **Final programmed AV delay settings** based upon the AV Opt test output	nominal	○ Yes ○ No
	descr.	DUAVDPIP	Based upon the use of a personal/ institutional preference	nominal	○ Yes ○ No
	descr.	DUAVDFUD	Based upon data from other follow-up affiliated diagnostics	nominal	○ Yes ○ No
	descr.	DUAVDSPR	Adoption of values from the device's standard program	nominal	○ Yes ○ No
	descr.	DUAVDIPR	Retention of AV delay settings from interrogated program	nominal	○ Yes ○ No
	descr.	DUAVDVPC	Long AV delay to avoid ventricular pacing	nominal	○ Yes ○ No
	descr.	DUAVDOTH	NEW: Other reason (please specify) **for the final programmed AV delay settings**	nominal	○ Yes ○ No

[redacted]

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	nominal values
av_opt	case listings for DUAVDCLA01 = No	COAVDREA01	NEW: Reason for not considering **first** suggested AV delay acceptable	text	n.a.
	case listings for DUAVDCLA02 = No	COAVDREA02	NEW: Reason for not considering **second** suggested AV delay acceptable	text	n.a.
	Case listing for DUAVDOTH = Yes	COAVDOTH	NEW: Please specify other reason **for the final programmed AV delay settings**	text	n.a.

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
av_opt	descriptive	DUAVOTAS	How do you rate the AV Opt tool?	nominal	○ Very good ○ Good ○ Adequate ○ Poor ○ Very poor

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	nominal values
av_opt	case listings for DUAVOTAS = Poor OR DUAVOTAS = Very poor	COAVOTAS	Please specify AV Opt tool rating	text	n.a.

8.2.4 Lead measurements (pacing thresh., sensing ampl., shock imp., lead imp.)

CIP chapter 8.1.4.15 Lead measurements with Renamic programmer at implantation and each follow-up

The system performance, i.e. appropriate sensing and pacing is evaluated at the end of the implantation procedure and at the end of each follow-up by either manually or automatically triggered lead measurements ...

The following "lead measurements" analyses have to be performed for implantation, Pre-Hospital Discharge, 3m follow-up, 6m follow-up, and 12m follow-up, whereby the variables labels have to be indicated, respectively.

Data file, identifier PRVISIT & patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
lead_ measurement	No report	PRVISIT	Visit	nominal	○ Implantation ○ Pre-Hospital Discharge ○ 3m Follow-up ○ 6m Follow-up ○ 12m Follow-up

Lead measurements /Right Atrium (RA)

Data file PRVISIT & patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
lead_ measurement	descr.	DURAMNA	No RA lead measurements available	nominal	○ RA lead measurements not done ○ RA lead not implanted/not active
	descr.	DURAMRH with "unknown" to be analyzed as missing data and missing data not considered for percentages	RA rhythm during sensing measurements	nominal	○ Sinus rhythm ○ Atrial fibrillation ○ Atrial flutter/other SVT ○ Atrial paced rhythm ○ Other ○ Unknown
	descr.	DURASA	RA sensing amplitude [mV], mean value	scale	n.a.
	descr.	DURAPT	RA pacing threshold [V]	scale	n.a.
	descr.	DURAPTPW	Pulse width for RA pacing threshold measurements [ms]	scale	n.a.
	descr.	DURAPI	RA pacing impedance [Ω]	scale	n.a.

Lead measurements / Right Ventricle (RV)

Data file PRVISIT & patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
lead_ measurement	descr.	DURVMNA	No RV lead measurements available	nominal	○ RV lead measurements not done ○ RV lead not implanted/not active
	descr.	DURVMRH	RA rhythm during sensing measurements	nominal	○ Intrinsic – atrial conducted ○ Ventricular paced rhythm ○ Other atrial conducted ○ Ventricular paced rhythm ○ Other
	descr.	DURVSA	NEW: RV sensing amplitude [mV], mean value	scale	n.a.
	descr.	DURVPT	RV pacing threshold [V]	scale	n.a.
	descr.	DURVPTPW	Pulse width for RV pacing threshold measurement [ms]	scale	n.a.
	descr.	DURVPI	RV pacing impedance [Ω]	scale	n.a.
	descr.	DURVSI	Painless shock impedance [Ω]	scale	n.a.

Lead Measurements / Left Ventricle (LV)

Data file PRVISIT & patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
lead_ measurement	descr.	DULVMNA	No LV lead measurements available	nominal	○ LV lead measurements not done ○ LV lead not implanted/not active
	descr.	DULVTYP	type of LV lead	nominal	○ Bipolar ○ Quadripolar
	descr.	DULVSV	Permanently (first) programmed LV sensing vector	nominal	○ LV1 tip to LV2 ring (bipolar) ○ LV1 tip to Can (unipolar) ○ LV2 ring to LV3 ring ○ LV2 ring to Can ○ LV3 ring to LV4 ring ○ LV3 ring to Can ○ LV4 ring to Can
	descr.	DULVPV01	Permanently programmed (first) LV pacing vector	scale	○ LV1 tip to LV2 ring ○ LV1 tip to LV3 ring ○ LV1 tip to LV4 ring ○ LV1 tip to RV coil/ring ○ LV1 tip to Can ○ LV2 ring to LV1 tip ○ LV2 ring to LV3 ring ○ LV2 ring to LV4 ring ○ LV2 ring to RV coil/ring ○ LV2 ring to Can ○ LV3 ring to LV1 tip ○ LV3 ring to LV2 ring ○ LV3 ring to LV4 ring ○ LV3 ring to RV coil/ring ○ LV3 ring to Can ○ LV4 ring to LV1 tip ○ LV4 ring to LV2 ring ○ LV4 ring to LV3 ring ○ LV4 ring to RV coil/ring ○ LV4 ring to Can
	descr.	DULVSA	(first) LV sensing amplitude [mV], mean value	scale	n.a.
	descr.	DULVPT01	(first) LV pacing threshold [V]	scale	n.a.
	descr.	DULVPTPW01	Pulse width for (first) LV pacing threshold measurements [ms]	scale	n.a.
	descr.	DULVPI01	(first) LV pacing impedance [Ω]	scale	n.a.

Lead measurements for the second vector are reported in chapter 9.2.3 Usage and settings of MultiPole pacing (MPP) .

Data file patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
data_SAR	Descr.	DULVPV01_ type_SAR[29]	First pacing vector (New: LV1t-LV3r, LV2r-LV3r, LV2r-C, LV3r-LV1t, LV3r-C,LV4r-LV1t, LV4r-LV3r, LV4r-C)	nominal	○ New vector ○ Old vector
data_SAR	No report here– variable needed for MPP analysis	DULVPV02_ type_SAR[30]	Second pacing vector (New: LV1t-LV3r,LV2r-LV3r,LV2r-C,LV3r-LV1t, LV3r-C,LV4r-LV1t, LV4r-LV3r, LV4r-C)	nominal	○ New vector ○ Old vector

[redacted];

8.2.5 Sensing and pacing assessment

CIP chapter 8.1.4.15 Lead measurements with Renamic programmer at implantation and each follow-up

The investigator is asked to assess the sensing and pacing performance at the end of each follow-up...

Lead Measurements / System performance RA

Data file PRVISIT & patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
lead_ measurement	descr.	DURASAAD	Adequate RA sensing	nominal	○ Yes ○ No
	case listings for DURASAAD = No	DURASARE	Reason for inadequate RA sensing	nominal	○ No intrinsic signal ○ Oversensing ○ Undersensing ○ Other
	descr.	DURAPCAD	Adequate RA pacing	nominal	○ Yes ○ No
	case listings for DURAPCAD = No	DURAPCRE	Reason for inadequate RA pacing	nominal	○ No overpacing possible ○ Exit block: no capture at maximum output ○ Other

Data file PRVISIT & patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
lead_ measurement	case listings for DURASARE =Other	CORASAOT	Specification of other reason for inadequate RA sensing	text	n.a.
	case listings for DURAPCRE=Other	CORAPCOT	Specification of other exit block for inadequate RA pacing	text	n.a.

Lead Measurements / System performance RV

Data file PRVISIT & patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
lead_ measurement	descr.	DURVSAAD	Adequate RV sensing	nominal	○ Yes ○ No
	descr.	DURASARE [redacted]	Reason for inadequate RV sensing	nominal	○ No intrinsic signals ○ Oversensing ○ Undersensing ○ Other
	descr.	DURAPCAD	Adequate RV pacing	nominal	○ Yes ○ No
	descr.	DURVPCRE	Reason for inadequate RV pacing	nominal	○ No overpacing possible ○ Exit block: no capture at maximum output ○ Other

Data file PRVISIT & patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
lead_ measurement	case listings for DURVSARE=Other	CORVSAOT	Specification of other reason for inadequate RV sensing	text	n.a.
	case listings for DURVPCRE=Other	CORVPCOT	Specification of other exit block for inadequate RV pacing	text	n.a.

Lead Measurements / System performance LV

Data file PRVISIT & patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
lead_ measurement	descr.	DULVSAAD	Adequate LV sensing	nominal	○ Yes ○ No
	descr.	DULVSARE	Reason for inadequate LV sensing	nominal	○ No intrinsic signal ○ Oversensing ○ Undersensing ○ Other
	descr.	DULVPCAD	Adequate LV pacing	nominal	○ Yes ○ No
	descr.	DULVPCRE	Reason for inadequate LV pacing	nominal	○ No overpacing possible ○ Exit block: no capture at maximum output ○ Other

Data file PRVISIT & patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
lead_ measurement	case listings for DULVSARE=Other	COLVSAOT	Specification of other reason for inadequate LV sensing	text	n.a.
	case listings for DULVPCRE=Other	COLVPCOT	Specification of other exit block for inadequate LV pacing	text	n.a.

[redacted]

8.2.6 Arrhythmias and their treatment by the ICD/CRT-D system

CIP chapter 8.1.4.16 Tachyarrhythmia episodes

During the course of the study the following tachyarrhythmia episodes have to be recorded, analyzed and evaluated on the tachyarrhythmia episode form:

- All episodes detected in the VT-1, VT-2 or VF-zone

- All episodes with attempted and/or delivered therapies (ATP and/or shock)

- The first new and last two AF and/or SVT episodes between two follow-ups.

The appropriateness of the episode detection and the success of the delivered ATPs and/or shocks to terminate the episode will be evaluated...

Detection zone and assessment

Data file CEEPNUM	Notes	Variable name	Variable label	Variable level	Nominal values
tachy-arrhythmia_episode	no report	CEEPNUM	Episode number	nominal	...
	5 x7 table CEEPLOC x CEEPAS_corr_SAR	CEEPLOC	Detection zone	nominal	○ nsVT/nsT ○ ATR ○ SVT ○ VT1 / VT2 ○ VF
	No report	CEEPAS	Episode assessment	nominal	○ AF ○ Atrial flutter ○ Sinus tachycardia ○ Other SVT ○ Non-sustained VT / VF ○ Sustained VT / VF ○ Oversensing / Other
tachy-arrhythmia_episode_SAR	5 x7 table CEEPLOC x CEEPAS_corr_SAR	CEEPAS_corr_SAR[31]	Episode assessment - corrected	nominal	○ AF ○ Atrial flutter ○ Sinus tachycardia ○ Other SVT ○ Non-sustained VT / VF ○ Sustained VT / VF ○ Oversensing / Other

[redacted]

Therapy in VF zone

Data file CEEPNUM	Notes	Variable name	Variable label	Variable level	Nominal values
tachy-arrhythmia_episode	No report	DX1THAT01	First therapy delivered	nominal	○ ATP one-shot ○ Shock ○ No therapy (shock charging aborted)
		DXATPOSA01	ATP one-shot successfully terminated the episode	nominal	○ Yes ○ No
		DXSHKTOT01	Number of shocks delivered in VF zone	ordinal	n.a.
		DXSHKAS01	Shock(s) successfully terminated the episode in VF zone	nominal	○ Yes ○ No
		CEEPOUT01	Episode outcome in VF zone	nominal	○ Spontaneously self-terminated ○ Successful external defibrillation ○ Patient death ○ Other
		COEPOUT01	Specification episode outcome in VF zone	text	n.a.

Therapy in VT zone

Data file CEEPNUM	Notes	Variable name	Variable label	Variable level	Nominal values
tachy-arrhythmia_episode	No report	DX1THAT02	First therapy delivered in VT zone	nominal	○ ATP ○ Shock ○ No therapy (shock charging aborted)
		DXATPTOT02	Number of ATP attempts in VT zone	nominal	○ n.a.
		DXATPRES02	ATP results in VT zone	nominal	○ Episode terminated by ATP ○ Shock(s) delivered after ATP failure ○ No shock delivered after ATP failure
		DXSHKTOT02	Number of shocks delivered in VT zone	ordinal	n.a.
		DXSHKAS02	Shock(s) successfully terminated the episode in VT zone	nominal	○ Yes ○ No
		CEEPOUT02	Episode outcome in **VT** zone	nominal	○ Spontaneously self-terminated ○ Successful external defibrillation ○ Patient death ○ Other
		COEPOUT02	Specification episode outcome in **VT** zone	text	n.a.

Appropriateness of episode detection per episode

Appropriateness of episode detection will be evaluated with respect to the consequences the detection has on the delivery of an ICD therapy.

- Detection zones that (may) result in delivery of a therapy (depending on the programming): VT1/VT2 or VF
- Detection zone that will never result in the delivery of a therapy: nsVT/nsT, ATR, or SVT
- Rhythm (episode assessment) that requires a therapy: sustained VT/VF and non-sustained VT/VF (with successful therapy; see below)
- Rhythm (episode assessment) that does not require a therapy: The remaining options for episode assessment and non-sustained VT/VF (without successful therapy, see below)

[redacted]

	Rhythm that requires a therapy	Rhythm that does not require a therapy
Detection zone that (may) result in delivery of a therapy (depending on the programming)	Appropriate detection of ventricular arrhythmia (true positive)	Inappropriate detection (non-ventricular arrhythmia falsely detected; false positive)
Detection zone that will never result in the delivery of a therapy	Inappropriate detection (ventricular arrhythmia not detected; false negative)	Appropriate detection (non-ventricular arrhythmia correctly detected; true negative)

[redacted]

Data file patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
tachy-arrhythmia_ episode_SAR	descriptive; case listings for all fn and fp episodes	tp_episode_detection_SAR[33]	Appropriate detection of ventricular arrhythmia (true positive)	nominal	○ 1 ○ 0
		fn_episode_detection_SAR[34]	Inappropriate detection (ventricular arrhythmia not detected; false negative)	nominal	○ 1 ○ 0
		tn_episode_detection_SAR[35]	Appropriate detection (non-ventricular arrhythmia correctly detected; true negative)	nominal	○ 1 ○ 0
		fp_episode_detection_SAR[36]	Inappropriate detection (non-ventricular arrhythmia falsely detected; false positive)	nominal	○ 1 ○ 0

The episode detection is evaluated by the following values:

- Sensitivity = sum tp / (sum tp + sum fn)
- Specificity = sum tn / (sum tn + sum fp)
- PPV = sum tp / (sum tp + sum fp)
- NPV = sum tn / (sum tn + sum fn)

[redacted]

Appropriateness of episode detection per patient

Data file patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
data_SAR	descri ptive	any_tachy_detection_SAR[37]	Any tachy-arrhythmia episode with non-missing information about the detection zone	nominal	○ Yes ○ No
		any_tachy_detection_VTVF_SAR[38]	Any tachy-arrhythmia episode with detection in the VT1/VT2 or VF zone	nominal	○ Yes ○ No
		only_tachy_app_detection_SAR [39]	All tachy-arrhythmia episodes with appropriate detection (all true positive or true negative)	nominal	○ Yes ○ No
		any_tachy_inapp_detection_SAR[40]	Any tachy-arrhythmia episode with inappropriate detection (any false positive or false negative)	nominal	○ Yes ○ No

[redacted]

ATP efficacy per tp episode

Only applicable for true positive tachy-arrhythmia episodes[41] as defined before.

Data file patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
tachy-arrhythmia_ episode_SAR	descri ptive	tpVF_ATP_SAR[42]	True positive episode in VF zone with ATP-one-shot therapy	nominal	○ 1 ○ 0
		tpVF_ATP_success_SAR[43]	True positive episode in VF zone with successful ATP-one-shot therapy	nominal	○ 1 ○ 0

Data file patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
tachy-arrhythmia_ episode_SAR	descri ptive	tpVT_ATP_SAR[44]	True positive episode in VT1/VT2 zone with at least one ATP therapy	nominal	○ 1 ○ 0
		tpVT_ATP_success_SAR[45]	True positive VT1/VT2 episode with successful ATP therapy	nominal	○ 1 ○ 0
		n_ATP_tpVT_SAR[46]	Number of ATP-attempts per true positive VT1/VT2 episode	Metric reported as nominal	○ 1 ○ 2 …

The ATP efficacy is evaluated by the following values:

- ATP VF efficacy rate = sum{VFtp_ATP_success_SAR}/ sum{VFtp_ATP_SAR}
- ATP VT efficacy rate = sum{VTtp_ATP_success_SAR}/ sum{VTtp_ATP_SAR}

[redacted]

ATP efficacy per patient (for tp episodes)

Only applicable patients with any true positive tachy-arrhythmia episodes[47] as defined before.

Data file patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
data_SAR	descri ptive	any_tpVF_ATP_SAR[48]	Any true positive VF episode with ATP one-shot therapy	nominal	○ Yes ○ No
		only_tpVF_noATP_SAR[49]	All true positive VF episodes without ATP one-shot therapy	nominal	○ Yes ○ No
		only_tpVF_ATP_success_SAR[50]	All true positive VF episodes with ATP one-shot therapy were successful	nominal	○ Yes ○ No
		any_tpVF_ATP_nosuccess_SAR[51]	Any true positive VF episode with delivered but not successful ATP one-shot therapy	nominal	○ Yes ○ No
		any_tpVT_ATP_SAR[52]	Any true positive VT episode with ATP therapy	nominal	○ Yes ○ No
		only_tpVT_noATP_SAR[53]	All true positive VT episodes without ATP therapy	nominal	○ Yes ○ No
		only_tpVT_ATP_success_SAR[54]	All true positive VT episodes with ATP therapy were successful	nominal	○ Yes ○ No
		any_tpVT_ATP_nosuccess_SAR[55]	Any true positive VT episode with delivered but not successful ATP therapy	nominal	○ Yes ○ No

[redacted]

Shock efficacy per tp episode

Only applicable for true positive tachy-arrhythmia episodes[56] as defined before.

Data file patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
tachy-arrhythmia_ episode_SAR	descri ptive	tpVF_shock_SAR[57]	True positive episode in VF zone with at least one shock therapy	nominal	○ 1 ○ 0
		tpVF_shock_success _SAR[58]	True positive episode in VF zone with successful shock therapy	nominal	○ 1 ○ 0
		n_shock_tpVF_SAR[59]	Number of shocks per true positive episode in VF zone	Metric reported as nominal	○ 1 ○ 2 …
		tpVT_shock_SAR[60]	True positive episode in VT zone with at least one shock therapy	nominal	○ 1 ○ 0
		tpVT_shock_success _SAR[61]	True positive episode in VT zone with successful shock therapy	nominal	○ 1 ○ 0
		n_shock_tpVT_SAR[62]	Number of shocks per true positive episode in VT zone	Metric reported as nominal	○ 1 ○ 2 …

The shock efficacy is evaluated by the following values:

- Shock VF efficacy rate = sum{tpVF_shock_success_SAR}/ sum{tpVF_shock_SAR}
- Shock VT efficacy rate = sum{tpVT_shock_success_SAR}/ sum{tpVT_shock_SAR}

[redacted]

Shock efficacy per patient (for tp episodes)

Only applicable for patients with any true positive tachy-arrhythmia episodes[63] as defined before.

Data file patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
data_SAR	descriptive	any_tpVF_shock_SAR[64]	Any true positive VF episode with shock therapy	nominal	○ Yes ○ No
		only_tpVF_noshock_SAR[65]	All true positive VF episodes without shock therapy	nominal	○ Yes ○ No
		only_tpVF_shock_success_SAR[66]	All true positives VF episodes with shock therapy were successful	nominal	○ Yes ○ No
		any_tpVF_shock_nosuccess_SAR[67]	Any true positive VF episode with not successful shock therapy	nominal	○ Yes ○ No
		any_tpVF_shock_SAR[68]	Any true positive VT episode with shock therapy	nominal	○ Yes ○ No
		only_tpVF_noshock_SAR[69]	All true positive VT episodes without shock therapy	nominal	○ Yes ○ No
		only_tpVF_shock_success_SAR[70]	All true positive VT episodes with shock therapy were successful	nominal	○ Yes ○ No
		any_tpVF_shock_nosuccess_SAR[71]	Any true positive VT episode with not successful shock therapy	nominal	○ Yes ○ No

[redacted]

Therapy efficacy per patient (for tp episodes)

Only applicable for patients with any true positive tachy-arrhythmia episodes[72] as defined before.

Data file patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
data_SAR	descri ptive	any_tpVF_therapy_SAR[73]	Any true positive VF episode with ATP or shock therapy	nominal	○ Yes ○ No
		only_tpVF_therapy_success_SAR[74]	All true positive VF episodes with ATP or shock therapy were successful	nominal	○ Yes ○ No
		any_tpVF_therapy_nosuccess_SAR[75]	Any true positive VF episode with not successful shock or ATP therapy	nominal	○ Yes ○ No
data_SAR	descri ptive	any_tpVT_therapy_SAR[76]	Any true positive VT episode with ATP or shock therapy	nominal	○ Yes ○ No
		only_tpVT_therapy_success_SAR[77]	All true positive VT episodes with ATP and shock therapy were succesful	nominal	○ Yes ○ No
		any_tpVT_therapy_nosuccess_SAR[78]	Any true positive VT episode with not successful ATP or shock therapy	nominal	○ Yes ○ No

Inappropriate therapies per fp episode

Only applicable for false positive tachy-arrhythmia episodes[79] as defined before.

Data file patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
tachy-arrhythmia_ episode_SAR	descriptive	fp_episode_ATP_SAR[80]	False positive episode with inappropriate ATP or ATP one-shot therapy	nominal	○ 1 ○ 0
		fp_episode_shock_SAR[81]	False positive episode with inappropriate shock therapy	nominal	○ 1 ○ 0
		fp_episode_ATP_shock_SAR[82]	False positive episode with inappropriate ATP, ATP-one-shot, or shock therapy	nominal	○ 1 ○ 0

Data file patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
tachy-arrhythmia_ episode_SAR	descriptive or case listing	n_ATP_fp_episode_SAR[83]	Number of inappropriate ATPs (ATP one-shot counts as 1) per false positive episode	Metric reported as nominal	○ 1 ○ 2 ○ …
		n_shock_fp_episode_SAR [84]	Number of inappropriate shocks per false positive episode	Metric reported as nominal	○ 1 ○ 2 ○ …
		n_ATP_shock_fp_episode_SAR [85]	Number of inappropriate ATPs (ATP one-shot counts as 1) or shocks per false positive episode	Metric reported as nominal	○ 1 ○ 2 …

[redacted]

Inappropriate therapies per patient (for fp episodes)

Only applicable for patients with any false positive tachy-arrhythmia episodes[86] as defined before.

Data file patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
data_SAR	descri ptive	any_fp_ATP_therapy_SAR[87]	Any false positive episode with inappropriate ATP therapy	nominal	○ Yes ○ No
		any_fp_shock_therapy_SAR[88]	Any false positive episode with inappropriate ATP or shock therapy	nominal	○ Yes ○ No
		any_fp_ATP_shock_therapy_SAR[89]	Any false positive VF episode with inappropriate ATP or shock therapy	nominal	○ Yes ○ No

[redacted]

8.2.7 Usage of Quick check

CIP chapter 8.1.4.11 Quick check

The use of QuickCheck is optional during the study...

The following analyses have to be performed for the 3m follow-up, 6m follow-up, and 12m follow-up , whereby the variables labels have to be indicated, respectively.

Data file patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
follow_up_3m follow_up_6m follow_up_12m	descriptive	DUQCSUB	Was QuickCheck used?	nominal	○ Yes ○ No
	descriptive for DUQCSUB = 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
		DUQCTRG	QuickCheck was triggered	nominal	○ While patient was on the phone ○ After the patient has contacted the site ○ After the site has contacted the patient ○ Without patient contact
		DUQCTRGB	QuickCheck was triggered by	nominal	○ Nurse ○ Physician ○ Cardiac technician ○ Other
		DUQCTRNS	Was the QuickCheck transmission fast enough?	nominal	○ Yes ○ No ○ No opinion
	descriptive	DUQCOAS	Overall assessment of the QuickCheck feature	nominal	○ Very good ○ Good ○ Adequate ○ Poor ○ Very poor

Data file patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
follow_up_3m follow_up_6m follow_up_12m	case listings for DUQCTRGB = Other	COQCTRGB	Specification for Other Trigger for QuickCheck	text	n.a.
	case listings for poor assessments	COQCOAS	Comment on Overall assessment of QuickCheck	text	n.a.

8.2.8 Assessment of statistic for ATP optimization

CIP chapter 8.1.4.17 Assessment of statistic for ATP optimization

If ATP optimization was programmed 'ON' (optional), the investigator will be asked to assess the statistics for ATP optimization at the 12-month follow-up for patients that experienced tachyarrhythmia episodes treated with ATP in the course of the study.

Data file patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
follow_up_12m	descriptive	DUATPON	Was ATP optimization programmed "on"?	nominal	○ Yes ○ No
	descriptive for DUATPON =Yes	DUATPSAS01	How was the comprehensibility of the new ATP Statistics page?	nominal	○ Very good ○ Good ○ Adequate ○ Poor ○ Very poor
	Yes for DUATPON =Yes	DUATPSAS02	How was the usefullness of the new ATP Statistics page?	nominal	○ Very good ○ Good ○ Adequate ○ Poor ○ Very poor

Data file patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
follow_up_12m	case listings for poor assessments	COATPSAS01	How was the comprehensibility of the new ATP Statistics page?	text	n.a.
		COATPSAS02	How was the usefullness of the new ATP Statistics page?	text	n.a.

8.2.9 RV/LV active capture control at permanent DDI mode

CIP chapter 8.1.4.18 RV/LV Capture Control at permanent DDI mode

Home Monitoring data will be analyzed to identify any patients in permanent DDI mode in whom capture control is activated in at least one of the ventricular channels (RV, LV and/or LV2). The AE database will be searched for Adverse Device Effects related to loss of capture that occurred in these patients.

Information for the CIR will be based on the Vigilance AE report and on separate Home Monitoring analyses.

8.2.10 MRI examinations, if performed independently from the study

CIP chapter 8.1.4.14 MRI examinations

If an MRI examination was performed during the course of the study (independently from the study), the following data will be recorded: Use of MRI AutoDetect, Use of MRI Test Mode, Adverse Events/Device Deficiencies related to the MRI procedure or activation of MRI AutoDetect.

The following case listings have to be reported for each 3m follow-up, 6m follow-up, or 12m follow-up with MRI scan performed since last follow-up.
Other information for the CIR will be based on the Vigilance AE report.

Data file patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
follow_up_3m follow_up_6m follow_up_12m	no report	PRFUMRI	Routine MRI scan performed since last follow-up?	nominal	○ Yes ○ No
	case listings for PRFUMRI = Yes	PRMRSTDT	Date of MRI scan	date	n.a.
		PRMRAD	MRI AutoDetect feature used or attempted to be used	nominal	○ Yes ○ No
		PRMRADAS	MRI AutoDetect could be successfully programmed	nominal	○ Yes ○ No
		COMRADAS	Please specify	text	n.a.
		PRMRTM	Was the 'MRI Test Mode' used to test the effect of programming the patient to MRI mode	nominal	○ Yes ○ No
		PRDAMRHM	Was deactivation of MRI mode checked via Home Monitoring the day after the scan	nominal	○ Yes ○ No
		PRADEMR	Were any Adverse Events / Device Deficiencies detected in regard to the MRI AutoDetect?	nominal	○ Yes ○ No
		COSUM	General Comments	text	n.a.

8.2.11 Adverse Events (including assessment of causality – device or procedure relation)

Information for the CIR will be based on the Vigilance AE report.

8.2.12 Device Deficiencies

Information for the CIR will be based on the Vigilance AE report.

8.3 Treatment of Missing and Spurious Data

See general definitions in chapter 5.4.

8.4 Exclusion of Particular Information

See general definitions in chapter 5.5.

8.5 Descriptive Analyses

See general definitions in chapter 5.1. and notes previous variable tables.

8.6 Hypotheses & Statistical Tests

There are no pre-defined statistical hypotheses.

9 CRT Devices (HF-T and HF-T QP)

9.1 Analysis set

All analyses are performed for the CRT analysis set[90] or CRT AutoAdapt analysis set[91] respectively.

9.2 Variables

9.2.1 Handling assessment of Selectra catheter

CIP chapter 8.1.4.14 Assessment of Selectra catheter handling (if applicable)
If a Selectra catheter (outer or outer and inner) is used to position the left ventricular lead, the implanting investigator will be asked to assess its features ...

Implantation / Usage of Selectra catheter and accessories

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
implantation	descriptive	DUCTH	Was the Selectra catheter used?	nominal	○ Yes ○ No
	descriptive	COCTH	NEW: Please specify type(s) of **Selectra** catheter	nominal	○ Outer catheter ○ Outer and inner catheter
	descriptive for DUCTH=Yes	DUACCRAS01	NEW: Have there been any difficulties when using **specific Selectra** accessories?	nominal	○ Yes ○ No
	case listings for DUACCRAS01=Yes	COACCRAS01	Please specify the difficulties when using Selectra accessories	text	n.a.

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
implantation	descriptive for DUCTH=Yes	DUSLTT	Slitter tool	nominal	○ True ○ False
		DUSRLL	Syringe with luer lock	nominal	○ True ○ False
		DUOWSC	One-way stop-cock	nominal	○ True ○ False
		DUSGW	Seldinger guide wire	nominal	○ True ○ False
		DUTRQR	Torquer	nominal	○ True ○ False
		DUSLCP	Sealing cap	nominal	○ True ○ False
		DUTVIT	Transval vularinsertion tool	nominal	○ True ○ False
		DUBDCV	Bi –directional check valve	nominal	○ True ○ False
		DUTBAD	Tuohy Borst Adapter (if available)	nominal	○ True ○ False

[redacted]

[redacted]

Implantation / Assessment of Selectra and Selectra slitter tool handling

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
implantation	descriptive	DUTRQRAS	Torqueability	nominal	○ Very good ○ Good ○ Adequate ○ Poor ○ Very poor
	descriptive [redacted]	DUFLXAS02	Flexibility (distal end)		
	descriptive	DUGLDNAS	Gliding properties		
	descriptive	DULDDLAS	Lead delivery		
	descriptive	DUSLTAAS	Slittability		
	descriptive [redacted]	DUXRVSAS03	X-ray visibility		
	descriptive	DUCTHAS	Overall handling of the catheter		
	descriptive	DULDFXAS	Lead fixation mechanism		
	descriptive	DUHNDSAS	Handling and design		
	descriptive	DUSLTPAS	Slitting performance		
	descriptive	DUSLTTAS	Overall handling of slitter tool		

Data file, identifier patient_ display_id_full	Notes		Variable name	Variable label	Variable level	nominal values
implantation	case listings for poor assessments		COTRQRAS	Please specify torqueability	text	n.a.
		[redacted]	COFLXAS02	Please specify flexibility (distal end)	text	n.a.
			COGLDNAS	Please specify gliding properties	text	n.a.
			COLDDLAS	Please specify lead delivery	text	n.a.
			COSLTAAS	Please specify slittability	text	n.a.
		[redacted]	COXRVSAS03	Please specify X-ray visibility	text	n.a.
			COCTHAS	Please specify overall handling (catheter)	text	n.a.
			COLDFXAS	Please specify lead fixation mechanism	text	n.a.
			COHNDSAS	Please specify handling and design	text	n.a.
			COSLTPAS	Please specify slitting performance	text	n.a.
			COSLTTAS	Please specify overall handling (slitter tool)	text	n.a.

Implantation / Usage of further accessories used

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
implantation	descriptive with "unknown" to be analyzed as missing data	DUBACSUP	Used BIOTRONIK accessories were	nominal	○ Supplied with lead/device ○ Obtained separately (NOT supplied with lead/device) ○ Both Supplied with lead/device and Obtained separately ○ Not applicable – no BIOTRONIK accessories have been used ○ Unknown
	descriptive for DUBACSUP = ○ supplied... ○ obtained ... ○ both ...	DUBACPRB	Did any problems with any used BIOTRONIK accessories occur	nominal	○ No - all used BIOTRONIK accessories were successfully used ○ Yes - problems with used BIOTRONIK accessories have occurred
	case listings for DUBACPRB = Yes	COBACPRB	Please specify the type of accessory and the type of problem	text	n.a.

Implantation / Programmer type

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
implantation	descriptive	DUPRGTYP	Programmer Type used	nominal	○ Renamic ○ Renamic Neo

9.2.2 Reports about cases with better CRT response using one of the new vectors

CIP chapter 8.1.4.13 Improved CRT response after change of LV pacing vector

At the 6- and 12-month follow-up the investigator is asked to evaluate if a previous change of the LV pacing vector improved CRT response. The formerly used and the new vectors have to be documented.

The following analyses have to be performed for the 6m follow-up and 12m follow-up, whereby the variables labels have to be indicated, respectively.

Data file patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
follow_up_6m follow_up_12m	descr.	DULVPVCH	Did you change the LV pacing vector(s) during the last follow-up?	nominal	○ Yes ○ No
	descr.	CVCRTCHN	Did you observe a change in CRT response since last follow-up?	nominal	○ Yes, improvement ○ Yes, decrease ○ No change
	descr.	CVLVVCRT	In your opinion, did the change of LV pacing vectors influence CRT response?	nominal	○ Very likely ○ Likely ○ No opinion / not assessable ○ Unlikely ○ Very Unlikely

9.2.3 Usage and settings of MultiPole pacing (MPP)

CIP chapter 8.1.4.12 Usage and settings of MultiPole pacing (MPP)

The use of MultiPole Pacing (MPP) is optional within the study. However, if MPP was used in HF-T QP patients, the following data should be recorded: Programmed vectors, pacing thresholds, programmed pacing amplitudes, LV sensing polarity, sensing amplitude, LV-LV delay and LV-RV delay.

The following analyses have to be performed for the implantation, Pre-Hospital Discharge, 3m follow-up, 6m follow-up and 12m follow-up, whereby the variables labels have to be indicated, respectively.

Lead measurements / Documentation of MPP settings

Data file, identifier PRVISIT & patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
lead_ measurement	No report	PRVISIT	Visit	nominal	○ Implantation ○ Pre-Hospital Discharge ○ 3m Follow-up ○ 6m Follow-up ○ 12m Follow-up
	descriptive	DUMPC	Was MultiPole Pacing used?	nominal	○ Yes ○ No
	descriptive or case listings for DUMPC=Yes	DUPCORD	Pacing order		○ RV first ○ LV first
		DULVLVD	LV-LV delay [ms]	scale	n.a.
		DUVVD	VV delay [ms]	scale	n.a.
		DULVSA	(first) LV sensing amplitude [mV], mean value	scale	n.a.

Data file PRVISIT & patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
lead_ measurement	descriptive or case listings for DUMPC=Yes	DULVPV01	Permanently programmed (first) LV pacing vector	nominal	○ LV1 tip to LV2 ring ○ LV1 tip to LV3 ring ○ LV1 tip to LV4 ring ○ LV1 tip to RV coil/ring ○ LV1 tip to Can ○ LV2 ring to LV1 tip ○ LV2 ring to LV3 ring ○ LV2 ring to LV4 ring ○ LV2 ring to RV coil/ring ○ LV2 ring to Can ○ LV3 ring to LV1 tip ○ LV3 ring to LV2 ring ○ LV3 ring to LV4 ring ○ LV3 ring to RV coil/ring ○ LV3 ring to Can ○ LV4 ring to LV1 tip ○ LV4 ring to LV2 ring ○ LV4 ring to LV3 ring ○ LV4 ring to RV coil/ring ○ LV4 ring to Can
		DULVPT01	(first) LV pacing threshold [V]	scale	n.a.
		DULVPTPW01	Pulse width for (first) LV pacing threshold measurements [ms]	scale	n.a.
		DULVPI01	(first) LV pacing impedance [Ω]	scale	n.a.
data_SAR		DULVPV01_ type_SAR	First pacing vector (New: LV1t-LV3r, LV2r-LV3r, LV2r-C, LV3r-LV1t, LV3r-C,LV4r-LV1t, LV4r-LV3r, LV4r-C)	nominal	○ New vector ○ Old vector

Data file, identifier PRVISIT & patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
lead_ measurement	descriptive or case listings for DUMPC=Yes	DULVPV02	Programmed second LV pacing vector	nominal	○ LV1 tip to LV2 ring ○ LV1 tip to LV3 ring ○ LV1 tip to LV4 ring ○ LV1 tip to RV coil ○ LV1 tip to ICD ○ LV2 ring to LV1 tip ○ LV2 ring to LV3 ring ○ LV2 ring to LV4 ring ○ LV2 ring to RV coil ○ LV2 ring to ICD ○ LV3 ring to LV1 tip ○ LV3 ring to LV2 ring ○ LV3 ring to LV4 ring ○ LV3 ring to RV coil ○ LV3 ring to ICD ○ LV4 ring to LV1 tip ○ LV4 ring to LV2 ring ○ LV4 ring to LV3 ring ○ LV4 ring to RV coil ○ LV4 ring to can
		DULVPT02	Second LV Pacing threshold [V]	scale	n.a.
		DULVPTPW02	Pulse width for second LV pacing threshold measurements [ms]	scale	n.a.
		DULVPI02	Second LV pacing impedance [Ω]	scale	n.a.
data_SAR		DULVPV02_ type_SAR	Second pacing vector (New: LV1t-LV3r,LV2r-LV3r,LV2r-C,LV3r-LV1t, LV3r-C,LV4r-LV1t, LV4r-LV3r, LV4r-C)	nominal	○ New vector ○ Old vector

9.2.4 Detailed information on SADEs related to MPP per event

Data file identifier record_id & patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
adverse_ event	case listings for AEMPP = Unlikely/Possible/Probable/Causal relationship AND serious_ae_SAR = Yes	AEMPP	AE is related to MPP	nominal	○ Not related ○ Unlikely ○ Possible ○ Probable ○ Causal relationship
		serious_ae_ade_ SAR[92]	SA(D)E	nominal	○ Yes ○ No
		AEDVID	Please enter the related Device ID(s) from the Device Log below. Use "," to separate multiple entries.	nominal	...
		AESDTH	Event led to death	nominal	○ Yes ○ No
		AESLIFE	a life-threatening illness or injury	nominal	○ Yes ○ No
		AESDISAB	a permanent impairment of a body structure or body function	nominal	○ Yes ○ No
		AESHOSP	in-patient or prolonged hospitalization	nominal	○ Yes ○ No
		AESMIE	medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure/body function	nominal	○ Yes ○ No
		AESCONG	Event led to fetal distress, fetal death or a congenital abnormality or birth defect	nominal	○ Yes ○ No
		AEOUT	Outcome	nominal	○ Resolved ○ Resolved with sequelae ○ Death ○ Ongoing ○ Ongoing at study termination ○ Unknown
		COAEOUT	Please specify	text	n.a.
		AEENDT_i	Date of resolution/Date of death	date	n.a.
data_SAR	Case listing as above	date_implantation _SAR	Date of implantation	date	n.a.

[redacted]

9.2.5 Detailed information on SADEs related to the CRT AutoAdapt feature per event

Data file identifier record_id & patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
adverse_ event	Note misspelling "possbile" case listings for AECRTAUA = Unlikely/Possible/ Probable/Causal relationship AND serious_ae_SAR = Yes	AECRTAUA	AE is related to CRT AutoAdapt	nominal	○ Not related ○ Unlikely ○ Possbile ○ Probable ○ Causal relationship
		serious_ae_SAR	SA(D)E	nominal	○ Yes ○ No
		AEDVID	Please enter the related Device ID(s) from the Device Log below. Use "," to separate multiple entries.	nominal	...
		AESDTH	Event led to death	nominal	○ Yes ○ No
		AESLIFE	a life-threatening illness or injury	nominal	○ Yes ○ No
		AESDISAB	a permanent impairment of a body structure or body function	nominal	○ Yes ○ No
		AESHOSP	in-patient or prolonged hospitalization	nominal	○ Yes ○ No
		AESMIE	medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure/body function	nominal	○ Yes ○ No
		AESCONG	Event led to fetal distress, fetal death or a congenital abnormality or birth defect	nominal	○ Yes ○ No
		AEOUT	Outcome	nominal	○ Resolved ○ Resolved with sequelae ○ Death ○ Ongoing ○ Ongoing at study termination ○ Unknown
		COAEOUT	Please specify	text	n.a.
		AEENDT_i	Date of resolution/Date of death	date	n.a.
data_SAR		date_implantation _SAR	Date of implantation	date	n.a.

9.2.6 Measurement of phrenic nerve stimulation, choice of tested vectors, finally programmed settings and details on the use of the test page using LV VectorOpt

Chapter 7.2.2.2 Secondary endpoint 2: Automatic LV VectorOpt test (CRT only)

... Furthermore, the choice of tested vectors, the number of performed PNS threshold measurements, the finally programmed settings and details on the use of the test page will be recorded as further data of interest ...

Automatic LV VectorOpt Test

Data file identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
auto_lv_ vectoropt	descriptive	DULVVT	Automatic LV VectorOpt test done at	nominal	○ PHD ○ Implantation ○ 3-month Follow-Up
	descriptive	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
	case listings for COLVVTND not missing	COLVVTND	Please specify not performing Auto LVVectorOpt test	text	n.a.

Automatic LV VectorOpt Test / Manual and automatic testing of pacing vectors

Data file identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
auto_lv_ vectoropt	descriptive	DUNVST	Number of vectors selected for testing (minimum 3)	ordinal	...
	descriptive	DUBOTHM	Were both measurements performed with the same subset of vectors?	nominal	○ Yes ○ No
	case listings for DUBOTHM = No	COBOTHM	Please specify difference of tested vectors	text	n.a.

Automatic LV VectorOpt Test / Manual and automatic testing of pacing vectors / HF-T QP

Data file identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
auto_lv_ vectoropt	descr.	DULVVTF01 with "not done" to be analyzed as missing data	Was the automatic LV VectorOpt test performed for all 20 vectors	nominal	○ Yes ○ No, other number tested ○ Not done
	descr.	DUNVST01	NEW: Other number of vectors tested **<>20**	ordinal	...
	descr.	DULVTHAT01	Time needed to run Auto LV threshold measurement for 20 or selected vectors	scale hh:mm:ss has to be converted to min	n.a.

Automatic LV VectorOpt Test / Manual and automatic testing of pacing vectors / HF-T

Data file identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
auto_lv_ vectoropt	descr.	DULVVTF02 with "not done" to be analyzed as missing data	Was the automatic LV VectorOpt test performed for all 5 vectors	nominal	○ Yes ○ No, other number tested ○ Not done
	descr.	DUNVST02	NEW: Other number of vectors tested **<>5**	ordinal	...
	descr.	DULVTHAT02	Time needed to run Auto LV threshold measurement for 5 or selected vectors	scale hh:mm:ss has to be converted to min	n.a.

Automatic LV VectorOpt Test / PNS measurement

Data file identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
auto_lv_ vectoropt	descr.	DUPNSNVS	Number of vectors for which the PNS threshold was measured	ordinal	...
	descr.	DUPNSPPV	PNS threshold of finally programmed pacing vector [V]	scale	n.a.

Automatic LV VectorOpt Test / Assessment

Data file identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
auto_lv_ vectoropt	descriptive with "Not done" to be analyzed as missing data	DURVLVAS	Do you consider the RV-LV conduction time test helpful?	nominal	○ Yes ○ No ○ Not done
	descriptive	DUPRSPV	Preselection of the pacing vectors for the test was done by	nominal	○ Selection of vector in programmer table ○ Selection of 'Setting' button ○ Using toggle buttons ○ Choosing from the LV pacing polarity window ○ Other means

[redacted]

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	nominal values
auto_lv_ vectoropt	case listings for DUPRSPV =Other means	COPRSPV	Please specify other means for preselection of pacing vectors	text	n.a.

9.2.7 Programming of CRT AutoAdapt and overall assessment at 12-month follow-up

CIP chapter 8.1.4.9 CRT AutoAdapt (only Acticor 7 and Rivacor 7 CRT-Ds)

At implantation and/or Pre-Hospital Discharge CRT AutoAdapt shall mandatorily be programmed 'ON' in all CRT-D patients that are implanted with Acticor 7 or Rivacor 7, with the exception of patients with AV block, for whom this feature is contraindicated. (Note: CRT AutoAdapt is not available in Rivacor 5.)

CIP chapter 7.2.2.3 Secondary endpoint 3: CRT AutoAdapt (CRT only)

... Furthermore, information on the programming of the feature and an overall assessment at the 12-month follow-up (if applicable) contribute to the further data of interest ...

The following analyses have to be performed for the 12m follow-up data.[93] [94]

Data file, identifier PRVISIT & patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
lead_ measurement	no report	PRVISIT	Visit	nominal	○ 12m Follow-up ...
	descr.	DUAUAON	NEW: CRT AutoAdapt "ON" **at the end of the 12mFU**	nominal	○ Yes ○ No
	descr.	DUADAVRD	Adaptive AV reduction	nominal to be reported as ordinal data	○ 0.5 ○ 0.6 ○ 0.7 ○ 0.8 ○ 0.9
	descr.	DUADAVLL	Adaptive AV lower limits [ms]	nominal to be reported as ordinal data	○50 ○60 ○70 ○80 ○90 ○100m ○110m ○120m ○130m ○140m ○150m
	descr.	DUVPC	Ventricular pacing	nominal	○ BiV ○ RV ○ LV
	descr.	DUICPH	Initially paced chamber	nominal	○ RV ○ LV
	descr.	DUVVDAVP	VV delay afer Vpace [ms]	scale	n.a.
	descr.*	DUAVDAP	AV Delay after pace 01	scale	n.a.
	descr.*	DUAVDAP01	AV Delay after pace 02	scale	n.a.
	descr.*	DUAVDASE	AV Delay after sense 01	scale	n.a.
	descr.*	DUAVDASE01	AV Delay after sense 02	scale	n.a.
	descr.	DUMCRTP	Mean CRT pacing since last follow-up [%]	scale	n.a.
	descr.	DUAVDAPO	Optimized AV delay after pace [ms]	scale	n.a.
	descr.	DUAVDASO	Optimized AV delay after sense [ms]	scale	n.a.

[redacted]

Data file, identifier PRVISIT & patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
lead_ measurement	descr.	COAUAON for DUAUAON = No	Please specify why CRT AutoAdapt "OFF" or "AV Adapt"	text	n.a

[redacted]

[redacted]

The following analyses have to be performed for the 12m follow-up data. [95] [96]

Data file patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
follow_up_12m	no report	DUAUAON	CRT AutoAdapt "ON"	nominal	○ Yes ○ No
	descriptive for DUAUAON = Yes	DUPRGAS	Programmability	nominal	○ Very easy ○ Easy ○ Adequate ○ Difficult ○ Very difficult
		DUALGRAS	Clinical acceptability of the algorithm's decision	nominal	○ Very good ○ Good ○ Adequate ○ Poor ○ Very poor
		DUAUAOAS	Overall assessment of the CRT AutoAdapt feature	nominal	○ Very good ○ Good ○ Adequate ○ Poor ○ Very poor

Data file patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
	case listings for poor assessments	COPRGAS	Comment on programmability	text	n.a.
		COALGRAS	comment on clinical acceptability of the algorithm's decision	text	n.a.
		COAUAOAS	comment on overall assessment	text	n.a.

9.3 Treatment of Missing and Spurious Data

See general definitions in chapter 5.4.

See Automatic LV VectorOpt Test / Manual and automatic testing of pacing vectors / HF-T QP.

See Automatic LV VectorOpt Test / Assessment.

9.4 Exclusion of Particular Information

See general definitions in chapter 5.5.

9.5 Descriptive Analyses

See general definitions in chapter 5.1 and notes previous variable tables.

9.6 Hypotheses & Statistical Tests

There are no pre-defined statistical hypotheses.

[redacted]

[redacted]

10 Plexa ProMRI S DX

10.1 Analysis set

All analyses are performed for the Plexa ProMRI S DX analysis set[97]

10.2 Variables

10.2.1 Lead handling assessment

CIP chapter 8.1.4.6 Assessment of Plexa S DX lead handling (if applicable)

During implantation, the handling of the Plexa S DX lead will be assessed by the implanting physician.

Implantation / Assessment of Plexa Pro MRI S DX lead handling

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
implantation	descr.	DUFLXAS01 [redacted]	Flexibility of the Plexa ProMRI S DX	nominal	○ Very good ○ Good ○ Adequate ○ Poor ○ Very poor
	descr.	DUPSHAS	Push-ability of the Plexa ProMRI S DX		
	descr.	DUPSBHAS	Positioning behavior of the Plexa ProMRI S DX		
	descr.	DUERBHAS	Extension/retraction behavior of the Plexa ProMRI S DX screw		
	descr.	DUXRVSAS01	X-ray visibility of the extended screw of the Plexa ProMRI S DX		
	descr.	DUFXBHAS	Fixation behavior of the Plexa ProMRI S DX		
	descr.	DUXRVSAS02	X-ray visibility of the Plexa ProMRI S DX in its final position		
	descr.	DUSTLHAS	Stylet handling in regard to the Plexa ProMRI S DX?		

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	nominal values
implantation	case listings	COFLXAS01 [redacted]	Please specify flexibility of the Plexa ProMRI S DX	text	n.a.
	case listings	COPSHAS	Please specify the push-ability of the Plexa ProMRI S DX	text	n.a.
	case listings	COPSBHAS	Please specify the positioning behavior of the Plexa ProMRI S DX	text	n.a.
	case listings	COERBHAS	Please specify extension/retraction behavior of the Plexa ProMRI S DX screw	text	n.a.
	case listings	COXRVSAS01	Please specify X-ray visibility of the extended screw of the Plexa ProMRI S DX	text	n.a.
	case listings	COFXBHAS	Please specify fixation behavior of the Plexa ProMRI S DX	text	n.a.
	case listings	COXRVSAS02	Please specify X-ray visibility of the Plexa ProMRI S DX in its final position	text	n.a.
	case listings	COSTLHAS	Please specify stylet handling in regard to the Plexa ProMRI S DX	text	n.a.

[redacted]

10.2.2 Atrial sensing assessments

Lead Measurements / System performance RA

The following analyses have to be performed for implantation, pre-hospital_ discharge, 3m follow-up, 6m follow-up, and 12m follow-up, whereby the variables labels have to be indicated, respectively.

Data file, identifier PRVISIT & patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
lead_ measurement	no report	PRVISIT	Visit	nominal	○ Implantation ○ Pre-Hospital Discharge ○ 3m Follow-up ○ 6m Follow-up ○ 12m Follow-up
	descriptive	DURASAAD	Adequate RA sensing	nominal	○ Yes ○ No
	descriptive	DURASARE	Reason for inadequate RA sensing	nominal	○ No intrinsic signal ○ Oversensing ○ Undersensing ○ Other

10.2.3 Adverse events related to the Plexa S DX per event

Data file identifier record_id & patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
data_SAR	case listings for the data below	imp_PRIMSTDT	Date of procedure (Implantation CRF)	date	n.a.
device_log_ details	No report	DIRVMDL	RV lead model	nominal	…
		record_id	Record ID	nominal	…
adverse_ event	No report	AEDVID	Please enter the related Device ID(s) from the Device Log below. Use "," to separate multiple entries.	nominal	…
	case listings for AEDVID = record_id with DIRVMDL contains "Plexa" and DIRVMDL contains "DX" NOTE that AEDVID may contain multiple device IDs	AERELIDV	AE is related to the investigational device	nominal	○ Not related ○ Unlikely ○ Possible ○ Probable ○ Causal relationship
		AERELIPR	AE is related to the investigational device procedure	nominal	○ Not related ○ Unlikely ○ Possible ○ Probable ○ Causal relationship
		AESLIFE	a life-threatening illness or injury	nominal	○ Yes ○ No
		AESDISAB	a permanent impairment of a body structure or body function	nominal	○ Yes ○ No
		AESHOSP	in-patient or prolonged hospitalization	nominal	○ Yes ○ No
		AESMIE	medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure/body function	nominal	○ Yes ○ No
		AESCONG	Event led to fetal distress, fetal death or a congenital abnormality or birth defect	nominal	○ Yes ○ No
		AEOUT	Outcome	nominal	○ Resolved ○ Resolved with sequelae ○ Death ○ Ongoing ○ Ongoing at study termination ○ Unknown
		COAEOUT	Please specify	text	n.a.
		AEENDT	Date of resolution/Date of death	date	n.a.

10.2.4 Early detection of atrial fibrillation (episodes)

Data file identifier record_id & patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
tachyarrhythmia_ episode	descriptive	CVAFON	New onset of AF	nominal	○ Yes ○ No
	descriptive and 2x2 table CVAFON x CEFUAFHM	CEFUAFHM	AF episode detected by Home Monitoring prior to follow-up visit	nominal	○ Yes ○ No

10.3 Treatment of Missing and Spurious Data

See general definitions in chapter 5.4.

10.4 Exclusion of Particular Information

See general definitions in chapter 5.5.

10.5 Descriptive Analyses

See general definitions in chapter 5.1 and notes previous variable tables.

10.6 Hypotheses & Statistical Tests

There are no pre-defined statistical hypotheses.

11 Primary Endpoint: Cor Family-related SADE-free rate until 3-month follow-up

11.1 Analysis set

All analyses are performed for the Cor family analysis set[98] excluding the following patients:

CIP chapter11.12 Exclusion of data from confirmatory data analysis

Exclusion of patients from the analysis set of the primary hypothesis:

-No data is allowed to be collected and included in the absence of a documented informed consent[99]

-Patients that are erroneously enrolled despite violation of inclusion or exclusion criteria at the time of enrollment[100]

-Patients without primary endpoint but premature study termination as defined for the primary endpoint[101]

CIP chapter 7.2.1 Primary endpoint and hypotheses: Cor Family-related SADE-free rate until 3-month follow-up

The following patients are not included in the analysis set for this endpoint:

Patients without endpoint but premature study termination before or exactly at 61 days after implantation (3 months defined as 92 days after implantation – 30 days would still be in accordance to the CIP) are not included in the analysis set to avoid an over-estimation of the SADE-free rate.

[redacted]

11.2 Variables

CIP chapter 7.2.1 Primary endpoint and hypotheses: Cor Family-related SADE-free rate until 3-month follow-up

SADEs will be adjudicated by an internal adjudication board, whereby the seriousness and device relatedness will be re-examined. If any amply documented external physical influence (e.g. accident, sport, twiddling) or medical AE caused the SADE, it does not contribute to this endpoint.

Data file record_id & patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
event_ evaluation	no report	AESTDT	Onset date	date	n.a.
event_ evaluation	no report	AERELSET[102]	Adverse Event is relevant for SADE endpoint	nominal	○ Yes ○ No
event_ evaluation	no report	AERELPET[103]	Adverse Event is relevant for primary endpoint	nominal	○ Yes ○ No

Data file record_id & 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.
data_SAR	no report	date_censoring_SAR	Date of censoring (latest date of AE onset, AE resolution, implantation, PHD, 3m FU, 6m FU, 12m FU, or date of study termination)	date	n.a.
data_SAR	descriptive & inferential	any_primep_SAR[104]	Any primary endpoint within the pre-specified time-period	nominal	○ Yes ○ No

[redacted]

11.3 Treatment of Missing and Spurious Data

See general definitions in chapter 5.4.

11.4 Exclusion of Particular Information

CIP chapter 7.2.1 Primary endpoint and hypotheses: Cor Family-related SADE-free rate until 3-month follow-up

SADEs will be adjudicated by an internal adjudication board, whereby the seriousness and device relatedness will be re-examined. If any amply documented external physical influence (e.g. accident, sport, twiddling) or medical AE caused the SADE, it does not contribute to this endpoint. SADEs that occur later than the 3-month follow-up, and SADEs with onset date later than or exactly at 123 days after implantation (3 months defined as 92 days after implantation + 30 days would still be in accordance to the CIP) in case the 3-month follow-up was not conducted or conducted outside the specified time interval do not contribute to this endpoint.

11.5 Descriptive Analyses

See general definitions in chapter 5.1 and notes previous variable tables.

11.6 Hypotheses & Statistical Tests

CIP chapter 7.2.1 Primary endpoint and hypotheses: Cor Family-related SADE-free rate until 3-month follow-up

The safety of the Cor Family ICDs will be evaluated by asking the investigator to record any adverse event. While all adverse events have to be recorded throughout the study, only the Serious Adverse Device Effects (SADE) possibly or securely related to the Cor Family devices (SADE-d_{Cor}) until 3-month follow-up are counted for this primary endpoint. Purely procedure related Serious Adverse Device Effects (SADE-p_{Cor}) are not counted.

... The primary hypothesis evaluates the SADE-d_{Cor} free rate (Cor_{SADE_free}). It is expected, that the rate will be significantly above 90% ...

CIP chapter 11.1 Statistical design, method and analytical procedures

To test the primary hypothesis an exact binomial tests is carried out. Additionally, an exact 2-sided 95% confidence interval will be generated.

12 Sec. Endpoint 1: Kaplan-Meier estimate for the Cor Family related SADE-free rate

12.1 Analysis set

All analyses are performed for the Cor family analysis set[105] excluding the patients that are erroneously enrolled despite violation of inclusion or exclusion criteria at the time of enrollment as defined for the primary endpoint analysis.

12.2 Variables

Data file record_id & patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
event_ evaluation	no report	AESTDT	Onset date	date	n.a.
event_ evaluation	no report	AERELSET	Adverse Event is relevant for SADE endpoint	nominal	○ Yes ○ No

Data file record_id & 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.
	no report	date_censoring_SAR	Date of censoring (latest date of AE onset, AE resolution, implantation, PHD, 3m FU, 6m FU, 12m FU, or date of study termination)	date	n.a.
	no report	date_1stSADE_corfamily_SAR[106]	Date of first Cor family related SADE	date	n.a.
	descriptive and 95% CI, Kaplan Meier analysis	any_SADE_corfamily_SAR[107]	Any Cor family related SADE	nominal	○ Yes ○ No
		days_impl_1stSADE_ corfamily_SAR[108]	Days from implantation to first Cor-family related SADE or censoring	date	n.a.

[redacted]

12.3 Treatment of Missing and Spurious Data

See general definitions in chapter 5.4.

12.4 Exclusion of Particular Information

See general definitions in chapter 5.5.

12.5 Descriptive Analyses

See general definitions in chapter 5.1 and notes previous variable tables. A Kaplan-Meier survival curve has to be reported.

12.6 Hypotheses & Statistical Tests

CIP chapter 7.2.2.1 Secondary endpoint 1: Kaplan-Meier estimate for the Cor Family related SADE-free rate

The Kaplan-Meier method will be applied to estimate the 3-month SADE-free rate at 92 days after implantation (sensitivity analysis of the primary endpoint) and the 12-month SADE-free rate at 365 days after implantation. Thereby all patients will be included in the analysis.

The pointwise 95% confidence interval has to be calculated via the loglog transformation.

13 Sec. Endpoint 2: Automatic LV VectorOpt test (CRT only)

13.1 Analysis set

All analyses are performed for the CRT analysis set.[109]

13.2 Variables

CIP chapter 7.2.2.2 Secondary endpoint 2: Automatic LV VectorOpt test (CRT only)

At Pre-Hospital Discharge or at the latest at 3-month follow-up, the following endpoints related to the automatic LV VectorOpt test will be assessed:

a. time needed to perform the LV threshold measurement manually

b. time needed to perform the LV threshold measurement automatically

c. investigator appraisal (score) of RV-LV conduction time test

d. investigator appraisal (score) of intuitiveness of the threshold test

e. investigator appraisal (score) of ease to find the best LV pacing configuration

f. investigator appraisal (score) of overall handling of the Auto LV VectorOpt feature

g. investigator agreement (score) to different statements relating to programmer-based LV vector optimization

Data file identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
auto_lv_ vectoropt	descriptive (a)	DULVTHMT	Time needed to run the LV threshold measurement manually	scale hh:mm:ss has to be converted to min	n.a.
	descriptive (b)*	DULVTHAT	Time needed to run the LV threshold measurement automatically (same subset of vectors)	scale hh:mm:ss has to be converted to min	n.a.

Data file identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
auto_lv_ vectoropt	descriptive (c)	DURVLVAS with "not done" to be analyzed as missing data	Do you consider the RV-LV conduction time test helpful?	nominal	○ Yes ○ No ○ Not done
	descriptive (d)	DUITHTAS	Intuitiveness of the threshold test	nominal	○ Very intuitive ○ Intuitiv ○ Adequate ○ Difficult ○ Very difficult
	descriptive (e)	DUBLVPAS	Ease to find the best LV pacing configuration	nominal	○ Very easy ○ Easy ○ Adequate ○ Difficult ○ Very difficult
	descriptive (f)	DULVVOAS	Overall Handling assessment of the Auto LV VectorOpt feature	nominal	○ Very good ○ Good ○ Adequate ○ Poor ○ Very poor
	descriptive (g)	DUINVAS01	The parameters RV-LV conduction time, PNS threshold and impact on device longevity (pacing threshold) provide a good decision basis and are sufficient for a clinically acceptable LV vector optimization	nominal	○ Strongly agree ○ Somewhat agree ○ Neither agree nor disagree ○ Somewhat disagree ○ Strongly disagree
	descriptive (g)	DUINVAS02	Auto LV VectorOpt is an ergonomic tool for informed decision making and recommending which vector to select	nominal	○ Strongly agree ○ Somewhat agree ○ Neither agree nor disagree ○ Somewhat disagree ○ Strongly disagree
	descriptive (g)	DUINVAS03	The automatic measurement process simplifies the process of finding a suitable LV pacing vector for CRT	nominal	○ Strongly agree ○ Somewhat agree ○ Neither agree nor disagree ○ Somewhat disagree ○ Strongly disagree

Data file, identifier patient_ display_id_full	Notes	Variable name	Variable label	Variable level	nominal values
auto_lv_ vectoropt	case listings	COITHTAS	Please specify intuitiveness of test	text	n.a.
	case listings	COBLVPAS	Please specify ease of finding LV pacing configuration	text	n.a.
	case listings	COLVVOAS	Please specify overall assessment	text	n.a.

13.3 Treatment of Missing and Spurious Data

See general definitions in chapter 5.4.
See time needed to perform the LV threshold measurement manually.

13.4 Exclusion of Particular Information

See general definitions in chapter 5.5.

13.5 Descriptive Analyses

See general definitions in chapter 5.1 and notes previous variable tables.

13.6 Hypotheses & Statistical Tests

There are no pre-specified hypotheses.

14 Sec. Endpoint 3: CRT AutoAdapt feature (CRT only)

14.1 Analysis set

All analyses are performed for the CRT AutoAdapt analysis set.[110]

14.2 Variables

CIP chapter 7.2.2.2 Secondary endpoint 3: CRT AutoAdapt (CRT only)

At the 3-month follow-up the CRT AutoAdapt feature will be assessed with regard to the following endpoints:

a. percentage of CRT pacing since last follow-up

b. percentage of adaptive BiV pacing since last follow-up

c. percentage of programmed BiV pacing since last follow-up

d. percentage of adaptive LV pacing since last follow-up

e. mean adapted AV delay after pace/sense

f. rate of patients in whom the programming of CRT Autoadapt is maintained beyond the 3-month follow-up

g. reasons for deactivation of CRT AutoAdapt

h. investigator appraisal (score) of programmability

i. investigator appraisal (score) of clinical acceptability

j. investigator appraisal (score) of overall assessment of the CRT AutoAdapt feature

Lead measurements / Percentage of CRT pacing since last follow-up

The following analyses have to be performed for the data of the 3m follow-up[111].

Data file, identifier PRVISIT & patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
lead_ measurement	no report	PRVISIT	Visit	nominal	○ 3m Follow-up ...
	descriptive (a)	DUMCRTP	Mean CRT pacing since last follow-up [%]	scale	n.a
	descriptive (e)	DUAVDAPO	Optimized AV delay after pace [ms]	scale	n.a.
	descriptive (e)	DUAVDASO	Optimized AV delay after sense [ms]	scale	n.a.
	descriptive (f) 2x2 table dis_DUAUAON x m03_DUAUAON	dis_DUAUAON[112] m03_DUAUAON	PHD: CRT AutoAdapt "ON" M03: CRT AutoAdapt "ON"	nominal	○ Yes ○ No

[redacted]

[redacted]

[redacted]

Data file patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
follow_up_3m	descriptive	DUAUAON	NEW: CRT AutoAdapt "ON" **at the end of the 3mo FU**	nominal	○ Yes ○ No
	descriptive for DUAUAON= No (g)	COAUAOFF	Please specify why CRT AutoAdapt "OFF" or "AVAdapt"	nominal	○ Patient has chronic complete AV block (contraindication) ○ Other
	descriptive (h)	DUPRGAS	Programmability	ordinal	○ Very easy ○ Easy ○ Adequate ○ Poor ○ Very poor
	descriptive(i)	DUALGRAS	Clinical acceptability of the algorithm's decision	ordinal	○ Very good ○ Good ○ Adequate ○ Poor ○ Very poor
	descriptive (j)	DUAUAOAS	Overall assessment of the CRT AutoAdapt feature	ordinal	○ Very good ○ Good ○ Adequate ○ Poor ○ Very poor

Data file patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
follow_up_3m	case listings for COAUAOFF = Other	COAUAOTH	Other Reason for CRT AutoAdapt OFF	text	n.a.
	case listings for poor assessments	COPRGAS	Comment on programmability	text	n.a.
		COALGRAS	comment on clinical acceptability of the algorithm's decision	text	n.a.
		COAUAOAS	comment on overall assessment	text	n.a.

Home Monitoring Data

[redacted]

Data file, identifier date & patient_ display_id_full	Notes	Variable name	Variable label	Variable level	Nominal values
V_TACHY (CDW datamart)	descriptive (b)	HMADAPBIVP	Adaptive BiV pacing since last follow-up [%]	metric	n.a.
	descriptive (c)	HMPRGBIVP	Programmed BiV pacing since last follow-up [%]	metric	n.a.
	descriptive (d)	HMADAPLVP	Adaptive LV pacing since last follow-up [%]	metric	n.a.

14.3 Treatment of Missing and Spurious Data

See general definitions in chapter 5.4.

14.4 Exclusion of Particular Information

See general definitions in chapter 5.5.

14.5 Descriptive Analyses

See general definitions in chapter 5.1 and notes previous variable tables.

14.6 Hypotheses & Statistical Tests

There are no pre-specified hypotheses.

15 Abbreviations

ADE	Adverse Device Effect
AE	Adverse Event
AF	Atrial Fibrillation
CDMS	Clinical Data Management System
CI	Confidence Interval
CIP	Clinical Investigation Plan
CIR	Clinical Investigation Report
CRF	Case listing Form
FU	Follow-up
SADE	Serious Adverse Device Event
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SAR	Statistical Analysis Report
SOP	Standard Operating Procedure
SD	Standard Deviation