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# Table of Content



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# 0. Change History

Version 1.0: Initial document.

Version 2.0: General document improvement.

[redacted]

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# 1. Introduction

## 1.1. Aim

The aim of this document is to provide detailed instructions on descriptive statistical analyses for the Clinical Investigation Report (CIR). There are no pre-specified inferential analyses which are mandatory to be reported in the CIR.

## 1.2. 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 specification 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 7.

Descriptive and inferential 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.

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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" or event-specific record_ID); additionally, a new data file ("data_SAR") might be generated by merging all relevant data from the original CDMS data files and generating derived variables (e.g. BMI from weight and height or date of first AE episode)
- Notes — Information whether data has to be presented with descriptive methods as defined in the following sub-chapter, data for listings, or data needed for generating of derived variables only
- 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), 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, identifier patient_display_id_full | Notes | Variable name | Variable label | Variable level | Nominal values |
|---|---|---|---|---|---|

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# 2. Objectives

CIP chapter 7.1 Objectives

*The objective is to build a library of surface ECG signals from patient groups with different forms of diagnosed arrhythmias and/or specific ECG characteristics from heart diseases. The signals will be used to support the development and improvement of algorithms for the accurate detection and sensing of rhythm anomalies.*

# 3. Investigational Device

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

*This study will not investigate a medical device or medicinal product. This exploratory investigation aims to collect clinical real-life data of different heart conditions which can be observed via Holter ECG recordings.*

*Therefore no investigational device is defined.*

# 4. Study Design

## 4.1. Overview

CIP chapter 9.1 Overview

*The following study related procedures (Table 9-1) apply and have to be documented in the respective electronic case report form (CRF) for each patient enrolled.*

**Table 9-1**: Overview of study procedures.

| Investigations | Enrollment/ Baseline | ECG Recording (0 to 14 days) | | Termination |
|---|---|---|---|---|
| | | 3-Patch (EPS) | 10-Patch (non-EPS) | |
| Patient informed consent | x | | | |
| Demographic data | x | | | |
| NYHA class | x | | | |
| ECG history prior to enrollment | x | | | |
| Medical history | x | | | |
| ECG during EPS | | x | | |
| Body Motion Test | | | x | |
| Daily Living Observation (24-hour ECG) | | (x) | x | |
| Patient diary | | (x)[1] | x | |
| Return of Holter ECG device | | | | x |
| Adverse event reporting | x | x | x | x |
| CRF completion | x | x | x | x |

EPS = electrophysiological study

(x) = optional, (x)[1] = optional, only during 24 h ECG, x = if applicable

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## 4.2. CDMS

Datasets to be analyzed

| Dataset name | Data rows, unique identifier | Data rows unique type | Relevant for SAP and SAR | Parent CRF In case of embedded log | Notes |
|---|---|---|---|---|---|
| adverse_event | record_id | Event | Yes | n.a. | |
| baseline_general | record_id, patient_id patient_display_id_full | Patient | Yes | n.a. | |
| cardiac_diagnostics | record_id, patient_id patient_display_id_full | Patient | Yes | n.a. | |
| ecg_recording | record_id, patient_id patient_display_id_full | Patient | Yes | n.a. | |
| enrollment | record_id, patient_id patient_display_id_full | Patient | Yes | n.a. | |
| internal_evaluation | record_id, patient_id patient_display_id_full | Patient[1] | Yes | n.a. | |
| medical_history | record_id, patient_id patient_display_id_full | Patient | Yes | n.a. | |
| termination | record_id, patient_id patient_display_id_full | Patient | Yes | n.a. | |

Other Datasets

| Dataset name | Data rows, unique identifier | Data rows unique type | Relevant for SAP and SAR | Parent CRF In case of embedded log | Notes |
|---|---|---|---|---|---|
| deviation_form_bio_log | record_id, site ID | Site | No | n.a. | Log per Site- for deviation_form_bio |
| deviation_form_bio | record_id | Event | No | n.a. | |
| deviation_form_site | record_id | Event | No | n.a. | Might be related to another CRF via parent_record_id |
| hospitalization_log | record_id, patient_id patient_display_id_full | Event | No | adverse_event | |
| monitor_evaluation | record_id, patient_id patient_display_id_full | Patient[2] | No | n.a. | |

[1] Has to be checked during Blind Review, because technically multiple entries per patient are possible

[2] Technically multiple entries per patient are possible

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# 5. General Statistical Procedures

## 5.1. Descriptive analyses

*CIP chapter 11.1 Statistical design, method and analytical procedures*

*Exploratory data analysis will be used to describe the patient population....*

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

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

Nominal – dichotomous data

| Variable (N total = 10) | Category | N non-missing | Absolute frequency | Relative frequency [%] |
|---|---|---|---|---|
| Gender | Female | 9 | 3 | 33.3 |
| History of atrial fibrillation | Yes | 8 | 4 | 50.0 |

| Variable (N total = 10) | Category | Group Type of recording | N non-missing | Absolute frequency | Relative frequency [%] |
|---|---|---|---|---|---|
| Gender | Female | 3-Patch Holter (N group = 4) | 4 | 1 | 25.0 |
| | | 10-Patch Holter (N group = 4) | 4 | 2 | 50.0 |
| | | All | 9 | 3 | 33.3 |
| History of atrial fibrillation | Yes | 3-Patch Holter | 4 | 2 | 50.0 |
| | | 10-Patch Holter | 4 | 2 | 50.0 |
| | | All | 8 | 4 | 50.0 |

Nominal data – more than two categories

| Variable (N total = 10) | N non-missing | AV block I N(%) | AV block II N(%) | AV block III N(%) |
|---|---|---|---|---|
| Type of AV block | 8 | 3 (37.5%) | 3 (37.5%) | 2 (25.0%) |

| Variable (N total = 10) | Group Type of recording | N non-missing | AV block I N(%) | AV block II N(%) | AV block III N(%) |
|---|---|---|---|---|---|
| Type of AV block | 3-Patch Holter (N group = 4) | 3 | 1 (33.3%) | 1 (33.3%) | 1 (33.3%) |
| | 10-Patch Holter (N group = 4) | 4 | 2 (50.0%) | 1 (25.0%) | 1 (25.0%) |
| | All | 8 | 3 (37.5%) | 3 (37.5%) | 2 (25.0%) |

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Scale / metric data

| Variable (N total = 10) | N non-missing | Mean | SD | Min | Lower quartile | Median | Upper quartile | Max |
|---|---|---|---|---|---|---|---|---|
| Age [years] | 9 | 56.1 | 15.9 | 25.0 | 50.0 | 60.0 | 66.0 | 77.0 |
| Weight [kg] | 8 | 78.5 | 13.9 | 55.0 | 69.5 | 78.5 | 89.0 | 99.0 |

| Variable (N total = 10) | Group Type of recording | N non-missing | Mean | SD | Min | Lower quartile | Median | Upper quartile | Max |
|---|---|---|---|---|---|---|---|---|---|
| Age [years] | 3-Patch Holter (N group = 4) | 4 | 61.8 | 11.2 | 50.0 | 55.0 | 60.0 | 68.5 | 77.0 |
| | 10-Patch Holter (N group = 4) | 4 | 50.3 | 21.5 | 25.0 | 32.5 | 53.0 | 68.0 | 70.0 |
| | All | 9 | 56.1 | 15.9 | 25.0 | 50.0 | 60.0 | 66.0 | 77.0 |
| Weight [kg] | 3-Patch Holter | 3 | 85.0 | 7.0 | 77.0 | 77.0 | 88.0 | 90.0 | 90.0 |
| | 10-Patch Holter | 4 | 76.0 | 18.5 | 55.0 | 62.5 | 75.0 | 89.5 | 99.0 |
| | All | 8 | 78.5 | 13.9 | 55.0 | 69.5 | 78.5 | 89.0 | 99.0 |

Ordinal data

Identical tables as for metric data but without mean and SD

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## 5.2. Inferential analyses

*CIP chapter 11.2 Sample Size*

*For this study, no statistical hypotheses can be formulated.*

## 5.3. Significance level

A two-sided P value < 0.05 is considered to indicate statistical significance. No adjustment for multiple testing is foreseen. All analyses except are considered to be exploratory.

## 5.4. Missing Data

*CIP chapter 11.10 Handling of missing, unused and spurious data*

*Missing or spurious data will not be imputed.*

Missing 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*

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

## 5.6. Subgroups

*CIP chapter 11.8 Specification of subgroups*

*There are no pre-defined sub-groups.*

## 5.7. Interim analyses

*CIP chapter 11.5 Provision for an interim analysis*

*As there is no hypothesis to test, no comprehensive interim analysis is planned at a certain point in time. The acquired data will be continuously forwarded to the technical department for analysis.*

## 5.8. Software

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

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# 6. Specific Study Dates

## 6.1. Enrollment date

*CIP chapter 8.3.5 Point of enrollment 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 | Patient: Date of informed consent signature | date | n.a. |

## 6.2. Date of baseline assessment

*CIP chapter 9.2 Enrollment/Baseline visit*

*After a subject has been enrolled, the following data have to be collected and entered in the respective CRF:*

- *Date of baseline assessment*

| Data file, identifier patient_display_id_full | Variable name | Variable label | Variable level | Nominal values |
|---|---|---|---|---|
| baseline | SVBLDT | Date of baseline assessment | date | n.a. |

## 6.3. Termination date

*CIP chapter 8.3.5 Point of enrollment and study termination*

*The patient's study participation ends regularly at the moment when the last study procedure according to protocol has been completed. The point of non-regular study termination can be the following:*

- *Date of withdrawal of consent*
- *Date of patient death*
- *If patient is a drop-out, the date of last patient related patient contact.*

*Study related procedures and data collection must end at the day of study termination.*

| Data file, identifier patient_display_id_full | Variable name | Variable label | Variable level | Nominal values |
|---|---|---|---|---|
| termination | DSTRDT | Date of study termination | date | n.a. |

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# 7. Analysis Sets

## 7.1. Analysis Set: Enrolled patients

All patients with valid informed consent are included in the analysis set of all enrolled patients

| Data file, identifier patient_display_id_full | Variable name | Variable label | Variable level | Nominal values |
|---|---|---|---|---|
| enrollment | DMICDT | Patient: Date of informed consent signature | date | n.a. |
| enrollment | DMSUBSPS | Patient signed the informed consent personally | nominal | ○ Yes ○ No |
| enrollment | DMRPRSPS | A legally authorized representative signed the informed consent | nominal | ○ Yes ○ No |
| enrollment | DMSUBDPS | Patient dated the informed consent personally | nominal | ○ Yes ○ No |
| enrollment | DMRPRDPS | A legally authorized representative dated the informed consent | nominal | ○ Yes ○ No |
| data_SAR | analysis_set_enrol_SAR[3] | Analysis set of all enrolled patients | nominal | ○ Yes ○ No |

[redacted]

## 7.2. Analysis Set: Enrolled Patients with any ECG

All patients from the analysis set of enrolled patients with any documented ECG are included in the analysis set of enrolled patients with ECG.

| Data file, identifier patient_display_id_full | Variable name | Variable label | Variable level | Nominal values |
|---|---|---|---|---|
| ecg_recording | EGEPSSDT | Start Date and Time EPS ECG | date | n.a. |
| | EGEPSEDT | End Date and Time EPS ECG | date | n.a. |
| | EGEPDOSD | Start Date and Time EPS DLO-ECG | date | n.a. |
| | EGEPDOED | End Date and Time EPS DLO-ECG | date | n.a. |
| | EGBMTSDT | Start Date and Time BMT ECG | date | n.a. |
| | EGBMTEDT | End Date and Time BMT ECG | date | n.a. |
| | EGBMDOSD | Start Date and Time BMT DLO-ECG | date | n.a. |
| | EGBMDOED | End Date and Time BMT DLO-ECG | date | n.a. |
| data_SAR | analysis_set_ecg_SAR[4] | Analysis set of all enrolled patients compliant with all in- and exclusion criteria and with any ECG data available | nominal | ○ Yes ○ No |

[redacted]

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# 8. Data for a CONSORT diagram

All analyses are performed for the analysis set of all enrolled patients[5].

## 8.1. Enrollment

- Date of First-Patient-In
- Date of Last-Patient-In
- Number of patients
- Number of patients per site

Inclusion criteria

| Data file, identifier patient_ display_id_full | Notes | Variable name | Variable label | Variable level | Nominal values |
|---|---|---|---|---|---|
| enrollment | descriptive | TIINCL01 | Patient is able to understand the nature of the study and willing to provide written informed consent | nominal | ○ Yes ○ No |
| | | TIINCL02 | Patient is willing and able to attend Holter ECG procedure following a visit | nominal | ○ Yes ○ No |
| | | TIINCL03 | Patient with pacemaker or ICD and ventricular stimulation > 30% or | nominal | ○ Yes ○ No |
| | | TIINCL04 | Frequent Ventricular Extrasystoles (VES) (incl. Bigeminus) or | nominal | ○ Yes ○ No |
| | | TIINCL05 | Atrioventricular Reentrant Tachycardia (AVRT) / Wolff-Parkinson-White (WPW) syndrome or | nominal | ○ Yes ○ No |
| | | TIINCL06 | Atrioventricular Nodal Reentrant Tachycardia (AVNRT) or | nominal | ○ Yes ○ No |
| | | TIINCL07 | Sinus Tachycardia at rest or | nominal | ○ Yes ○ No |
| | | TIINCL08 | Atrial Flutter or | nominal | ○ Yes ○ No |
| | | TIINCL09 | Any form of Ventricular Tachycardia (VT) or | nominal | ○ Yes ○ No |
| | | TIINCL10 | Silent / paroxysmal / persistent / permanent AF or | nominal | ○ Yes ○ No |
| | | TIINCL11 | Brugada syndrome or | nominal | ○ Yes ○ No |
| | | TIINCL12 | Long QT syndrome or | nominal | ○ Yes ○ No |
| | | TIINCL13 | Right Bundle Branch Block (RBBB) or | nominal | ○ Yes ○ No |
| | | TIINCL14 | Left Bundle Branch Block (LBBB) or | nominal | ○ Yes ○ No |
| | | TIINCL15 | Myocardial Ischemia / Acute Myocardial Infarction or | nominal | ○ Yes ○ No |
| | | TIINCL16 | Other abnormal QRS(T) complex, ST segment or T-wave morphology | nominal | ○ Yes ○ No |

Exclusion criteria

| Data file, identifier patient_ display_id_full | Notes | Variable name | Variable label | Variable level | Nominal values |
|---|---|---|---|---|---|
| enrollment | descriptive | TIEXCL01 | Any condition which precludes the patient's ability to comply with the study requirements. | nominal | ○ Yes ○ No |
| | | TIEXCL02 | Known allergy to patch electrodes | nominal | ○ Yes ○ No |
| | | TIEXCL03 | Pregnant or breast feeding | nominal | ○ Yes ○ No |
| | | TIEXCL04 | Less than 18 years old | nominal | ○ Yes ○ No |
| | | TIEXCL05 | Participating in another interventional clinical investigation according to the definition | nominal | ○ Yes ○ No |

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## 8.2. Termination

- Date of First-Patient-Out
- Date of Last-Patient-Out

| Data file: Identifier patient_display_id_full | Notes | Variable name | Variable label | Variable level | Nominal values |
|---|---|---|---|---|---|
| termination | descriptive | DSRTRM | Regular study termination | nominal | ○ Yes<br>○ No |
| termination | Descriptive for DSRTRM= Yes | DSETRREA | Reason for early study termination | nominal | ○ Patient moved away from investigational center<br>○ Patient withdrew consent to study participation<br>○ Patient death<br>○ Drop-out according to protocol<br>○ Enrollment failure<br>○ Other |

| Data file: Identifier patient_display_id_full | Notes | Variable name | Variable label | Variable level | Nominal values |
|---|---|---|---|---|---|
| enrollment | Case listings for DSRTRM = Yes | DMSUBIC | Date of informed consent | date | n.a. |
| termination | | DSTRDT | Date of study termination | date | n.a. |
| | | DSRTRM | Regular study termination | nominal | ○ Yes<br>○ No |
| | | DSETRREA | Reason for early study termination | nominal | ○ Patient moved away from investigational center<br>○ Patient withdrew consent to study participation<br>○ Patient death<br>○ Drop-out according to protocol<br>○ Enrollment failure<br>○ Other |
| | | COETRREA | Please specify reason for early termination | text | … |

| Data file: Identifier patient_display_id_full | Notes | Variable name | Variable label | Variable level | Nominal values |
|---|---|---|---|---|---|
| data_SAR | descriptive | FU_duration_SAR[6] | Days from enrollment to termination | scale | n.a |

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| Data file: Identifier patient_display_id_full | Notes | Variable name | Variable label | Variable level | Nominal values |
|---|---|---|---|---|---|
| enrollment | Case listings for DSETRREA = | DMSUBIC | Date of informed consent | date | n.a. |
| termination | Drop-out according to protocol | DSTRDT | Date of study termination | date | n.a. |
| | | DSRTRM | Regular study termination | nominal | ○ Yes<br>○ No |
| | | DSETRREA | Reason for early study termination | nominal | ○ Patient moved away from investigational center<br>○ Patient withdrew consent to study participation<br>○ Patient death<br>○ Drop-out according to protocol<br>○ Enrollment failure<br>○ Other |
| | | DSDRPPRO | Please specify reason for early termination | nominal | ○ Patient is unable or unwilling to proceed with the Holter ECG recording due to discomfort when wearing the electrodes.<br>○ Patient is unable or unwilling to proceed with the Holter ECG recording due to discomfort or dizziness during the Body Motion Test.<br>○ Holter ECG recording does not take place for any reasons within 14 days after enrollment.<br>○ For 10-Patch Holter ECG recording: DLO does not take place for any reasons within 14 days after BMT<br>○ Other |
| | | CODRPPRO | Please specify "Drop-out according to protocol- Other" | text | … |

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# 9. Data of interest

*CIP chapter 7.3 Further data of interest*

- *Demographic data, medical history, ECG diagnosis*
- *Adverse Events related to the study procedure*
- *Optional: chest x-ray, only if already available and part of a procedure (e.g. implantation) that occurred prior to enrollment*

## 9.1. Analysis set

All analyses are performed for the analysis set of all enrolled patients[7].

## 9.2. Variables

Baseline / Demographic data

| Data file, identifier patient_ display_id_full | Notes | Variable name | Variable label | Variable level | Nominal values |
|---|---|---|---|---|---|
| baseline | descriptive | DMSEX | Gender | nominal | ○ Male<br>○ Female |
| | descriptive | DMAGE | Age [Years] | scale | n.a. |

Baseline / Physical examination

| Data file, identifier patient_ display_id_full | Notes | Variable name | Variable label | Variable level | Nominal values |
|---|---|---|---|---|---|
| baseline | descriptive | VSHGHT | Height [cm] | scale | n.a. |
| | descriptive | VSWGHT | Weight [kg] | scale | n.a. |

Baseline / Physical examination / device

| Data file, identifier patient_ display_id_full | Notes | Variable name | Variable label | Variable level | Nominal values |
|---|---|---|---|---|---|
| baseline | descriptive | PRIMDVTY | Type of implanted device | nominal | ○ Single Chamber ICD<br>○ VR-T DX System<br>○ Dual Chamber ICD<br>○ Single Chamber PM<br>○ Dual Chamber PM<br>○ Implantable Loop Recorder<br>○ No device |

Chest X-Ray

| Data file, identifier patient_ display_id_full | Notes | Variable name | Variable label | Variable level | Nominal values |
|---|---|---|---|---|---|
| Baseline | descriptive for PRIMDVTY = No device | PRCHXR | Chest X-ray of original procedure available | nominal | ○ Yes<br>○ No |

[redacted]

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## Cardiac diagnostic / ECG history

| 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 | EGPRI | PR interval [ms] | scale | n.a. |
| | descriptive | EGQRS | QRS width (intrinsic) [ms] | scale | n.a. |
| | descriptive | EGQRSM | QRS morpholgy | nominal | ○ Normal<br>○ LBBB<br>○ RBBB<br>○ Indeterminate |
| | descriptive | CVEGARH | Atrial rhythm during ECG recording | nominal | ○ Sinus rhythm<br>○ Atrial fibrillation<br>○ Atrial flutter/other SVT<br>○ Atrial paced rhythm<br>○ Other |
| | Case listings for CVEGARH = Other | COEGARH | Specification of other atrial rhythm during ECG recording | text | … |
| | descriptive | CVEGVRH | Ventricular rhythm during ECG | nominal | ○ Intrinsic - atrial conducted<br>○ Intrinsic - escape rhythm<br>○ Ventricular paced rhythm<br>○ Other |
| | Case listings for CVEGARH = Other | COEGVRH | Specification of other ventricular rhythm during ECG recording | text | … |

## Cardiac diagnostic / LVEF

| Data file, identifier patient_ display_id_full | Notes | Variable name | Variable label | Variable level | Nominal values |
|---|---|---|---|---|---|
| cardiac_diagnostic | descriptive | EHLVEF | Left ventricular ejection fraction [%] | scale | n.a. |

## Medical history / Coronary Artery Disease

| Data file, Identifier patient_ display_id_full | Notes | Variable name | Variable label | Variable level | Nominal values |
|---|---|---|---|---|---|
| medical_history | descriptive | MHCAD | History of coronary artery disease | nominal | ○ Yes ○ No |
| | descriptive for MHCAD = Yes | MHUANG | Prior acute coronary syndrome (any type) | nominal | ○ Yes ○ No |
| | | MHMI | Prior myocardial infarction | nominal | ○ Yes ○ No |
| | | PRRVC | Prior revascularization (PCI or CABG) | nominal | ○ Yes ○ No |

## Medical history / brady- and tachyarrhythmias

| Data file, identifier patient_ display_id_full | Notes | Variable name | Variable label | Variable level | Nominal values |
|---|---|---|---|---|---|
| medical_history | descriptive | MHSSS | History of sick sinus syndrome | nominal | ○ Yes ○ No |

| Data file, identifier patient_ display_id_full | Notes | Variable name | Variable label | Variable level | Nominal values |
|---|---|---|---|---|---|
| medical_history | descriptive | MHAVB | History of AV block | nominal | ○ Yes ○ No |
| | descriptive for MHAVB = Yes | MHAVBTYP | Type of AV block | nominal | ○ AV block I°<br>○ AV block II°<br>○ AV block III° |

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| Data file, identifier patient_ display_id_full | Notes | Variable name | Variable label | Variable level | Nominal values |
|---|---|---|---|---|---|
| medical_history | descriptive | MHBBB | History of bundle branch block | nominal | ○ Yes ○ No |
| | descriptive for MHBBB = Yes | MHBBBTYP | Type of bundle branch block | nominal | ○ LBBB<br>○ RBBB<br>○ Other |
| | Case listings for MHBBBTYP=Other | COBBBTYP | Specification of other type of bundle branch block | text | … |

| Data file, Identifier patient_ display_id_full | Notes | Variable name | Variable label | Variable level | Nominal values |
|---|---|---|---|---|---|
| medical_history | descriptive | MHAFB | History of atrial fibrillation | nominal | ○ Yes ○ No |
| | descriptive for MHAFB = Yes | CVAFBTYP | Type of atrial fibrillation | nominal | ○ Paroxysmal<br>○ Persistent<br>○ Long-standing persistent<br>○ Permanent |
| | descriptive | MHAVA | History of other atrial/ supraventricular arrhythmias | nominal | ○ Yes ○ No |
| | descriptive for MHAVA = Yes | MHAFL | History of atrial flutter | nominal | ○ Yes ○ No |
| | | MHAT | History of atrial tachycardia | nominal | ○ Yes ○ No |
| | | MHSVT | History of supraventricular tachycardia | nominal | ○ Yes ○ No |
| | | MHAVAOTH | History of other type of atrial/ supraventricular arrhythmias | nominal | ○ Yes ○ No |
| | Case listings for MHAVAOTH = Yes | COAVAOTH | Specification of other type of atrial/supraventricular arrhythmia | text | … |

| Data file, Identifier patient_ display_id_full | Notes | Variable name | Variable label | Variable level | Nominal values |
|---|---|---|---|---|---|
| medical_history | descriptive | MHVA | History of ventricular arrhythmia | nominal | ○ Yes ○ No |
| | descriptive for MHVA = Yes | MHNSUVT | Non-sustained ventricular tachycardia | nominal | ○ Yes ○ No |
| | | MHSUVT | Sustained ventricular tachycardia | nominal | ○ Yes ○ No |
| | | MHVFB | Ventricular fibrillation | nominal | ○ Yes ○ No |
| | | MHVAOTH | History of other ventricular arrhythmia | nominal | ○ Yes ○ No |
| | Case listings for MHVAOTH = Yes | COVAOTH | Specification of history of other ventricular arrhythmia | text | … |

## 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 for MHHF = Yes | CVNYHA | Current NYHA classification | nominal | ○ I<br>○ II<br>○ III<br>○ IV |

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Adverse Events related to the study procedure

| Data file, Identifier record_id | Notes | Variable name | Variable label | Variable level | Nominal values |
|---|---|---|---|---|---|
| adverse_event | No reporting | AERELSPR | AE is related to an additional study procedure | nominal | ○ Not related<br>○ Unlikely<br>○ Possible<br>○ Probable<br>○ Causal relationship |
| | Case listing for all AEs except AERELSPR = not related | 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 |
| | | CORELCM | Please specify | text | … |
| adverse_event_SAR | | SAE_SAR[8] | Serious Adverse Event | nominal | ○ Yes ○ No |

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| Data file, Identifier patient_display_id_full | Notes | Variable name | Variable label | Variable level | Nominal values |
|---|---|---|---|---|---|
| data_SAR | descriptive | any_AE_procedure_unlikely_SAR[9] | Any (S)AE classified as unlikely to be related to an additional study procedure | nominal | ○ Yes ○ No |
| data_SAR | descriptive | any_AE_procedure_possible_SAR[10] | Any (S)AE classified as possible to be related to an additional study procedure | nominal | ○ Yes ○ No |
| data_SAR | descriptive | any_AE_procedure_probable_SAR[11] | Any (S)AE classified as probable to be related to an additional study procedure | nominal | ○ Yes ○ No |
| data_SAR | descriptive | any_AE_procedure_causal_SAR[12] | Any (S)AE classified as causal relationship to an additional study procedure | nominal | ○ Yes ○ No |
| data_SAR | descriptive | any_SAE_procedure_unlikely_SAR[13] | Any SAE classified as unlikely to be related to an additional study procedure | nominal | ○ Yes ○ No |
| data_SAR | descriptive | any_SAE_procedure_possible_SAR[14] | Any SAE classified as possible to be related to an additional study procedure | nominal | ○ Yes ○ No |
| data_SAR | descriptive | any_SAE_procedure_probable_SAR[15] | Any SAE classified as probable to be related to an additional study procedure | nominal | ○ Yes ○ No |
| data_SAR | descriptive | any_SAE_procedure_causal_SAR[16] | Any SAE classified as causal relationship to an additional study procedure | nominal | ○ Yes ○ No |

[redacted]

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## 9.3. Treatment of Missing and Spurious Data

See general definitions in chapter 5.4.

## 9.4. Exclusion of Particular Information

See general definitions in chapter 5.5.
No data are excluded from the analysis from the above analysis set and variables.

## 9.5. Descriptive Analyses

See general definitions in chapter 5.1 and notes in each table.

## 9.6. Hypotheses & Statistical Tests

*CIP chapter 7.2 Endpoints and hypotheses*
*There are no predefined hypotheses.*

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# 10. Endpoints

*CIP chapter 7.2 Endpoints and hypotheses*

*As described in section 11.2, the number of successful ECGs per condition stated in the inclusion criteria (section 8.3.2) was chosen as an endpoint, whereat each condition shall be included at least six times and at most ten times; with the exception of 'Any form of Ventricular Tachycardia (VT)' being included at least twelve times or more.*

*CIP chapter 8.3.2 Inclusion criteria*

*History of at least one of the following conditions (established via ECG prior to enrollment):*

*(A)Patient with pacemaker/ICD and*

*1. Ventricular stimulation > 30 % or*

*(B)Patient either without pacemaker/ICD or with pacemaker/ICD, but without significant atrial and ventricular stimulation and at least one of the following:*

*2. Frequent Ventricular Extrasystoles (VES) (incl. Bigeminus) or*

*3. Atrioventricular Reentrant Tachycardia (AVRT)/Wolff-Parkinson-White (WPW) syndrome or*

*4. Atrioventricular Nodal Reentrant Tachycardia (AVNRT) or*

*5. Sinus Tachycardia at rest or*

*6. Atrial Flutter or*

*7. Any form of Ventricular Tachycardia (VT) or*

*8. Silent/Paroxysmal/persistent/permanent AF or*

*9. Brugada syndrome or*

*10. Long QT syndrome or*

*11. Right Bundle Branch Block (RBBB) or*

*12. Left Bundle Branch Block (LBBB) or*

*13. Myocardial Ischemia/Acute Myocardial Infarction or*

*14. Other abnormal QRS(T) complex, ST segment or T-wave morphology, i.e. any other*

- *QRS anomaly*
- *ST segment elevation*
- *ST segment depression*
- *T wave changes*

## 10.1. Analysis set

All analyses are performed for the analysis set of enrolled patients with any ECG[17].

[redacted]

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## 10.2. Variables

History of arrhythmia

| Data file, identifier patient_ display_ id_full | Notes | Variable name | Variable label | Variable level | Nominal values |
|---|---|---|---|---|---|
| enrollment | descriptive | TIINCL03 | Patient with pacemaker or ICD and ventricular stimulation > 30% or | nominal | ○ Yes ○ No |
| | | TIINCL04 | Frequent Ventricular Extrasystoles (VES) (incl. Bigeminus) or | nominal | ○ Yes ○ No |
| | | TIINCL05 | Atrioventricular Reentrant Tachycardia (AVRT) / Wolff-Parkinson-White (WPW) syndrome or | nominal | ○ Yes ○ No |
| | | TIINCL06 | Atrioventricular Nodal Reentrant Tachycardia (AVNRT) or | nominal | ○ Yes ○ No |
| | | TIINCL07 | Sinus Tachycardia at rest or | nominal | ○ Yes ○ No |
| | | TIINCL08 | Atrial Flutter or | nominal | ○ Yes ○ No |
| | | TIINCL09 | Any form of Ventricular Tachycardia (VT) or | nominal | ○ Yes ○ No |
| | | TIINCL10 | Silent / paroxysmal / persistent / permanent AF or | nominal | ○ Yes ○ No |
| | | TIINCL11 | Brugada syndrome or | nominal | ○ Yes ○ No |
| | | TIINCL12 | Long QT syndrome or | nominal | ○ Yes ○ No |
| | | TIINCL13 | Right Bundle Branch Block (RBBB) or | nominal | ○ Yes ○ No |
| | | TIINCL14 | Left Bundle Branch Block (LBBB) or | nominal | ○ Yes ○ No |
| | | TIINCL15 | Myocardial Ischemia / Acute Myocardial Infarction or | nominal | ○ Yes ○ No |
| | | TIINCL16 | Other abnormal QRS(T) complex, ST segment or T-wave morphology | nominal | ○ Yes ○ No |

Main internal evaluation

| Data file, identifier patient_ display_ id_full | Notes | Variable name | Variable label | Variable level | Nominal values |
|---|---|---|---|---|---|
| Internal_ evaluation | Descriptive for intern_ evaluation_ 2nd = False | intern_ evaluation | Internal Evaluation | nominal | ○ Patient with pacemaker/ICD and ventricular stimulation > 30%<br>○ Frequent Ventricular Extrasystoles (VES) (incl. Bigeminus)<br>○ Atrioventricular Reentrant Tachycardia (AVRT) / Wolff-Parkinson-White (WPW) syndrome<br>○ Atrioventricular Nodal Reentrant Tachycardia (AVNRT)<br>○ Sinus Tachycardia at rest<br>○ Atrial Flutter<br>○ Any form of Ventricular Tachycardia (VT)<br>○ Silent / paroxysmal / persistent /permanent AF<br>○ Brugada syndrome<br>○ Long QT syndrome<br>○ Right Bundle Branch Block (RBBB)<br>○ Left Bundle Branch Block (LBBB)<br>○ Myocardial Ischemia/Acute Myocardial Infarction<br>○ Other abnormal QRS(T) complex, ST segment or T-wave morphology |

The main internal evaluation for each patient is given for intern_evaluation_2$^{nd}$ = False.

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All internal evaluations

| Data file, identifier patient_ display_ id_full | Notes | Variable name | Variable label | Variable level | Nominal values |
|---|---|---|---|---|---|
| SAR | descriptive | any_intern_eval_incl03_SAR[18] | Any evaluation: Patient with pacemaker/ICD and ventricular stimulation > 30% | nominal | ○Yes ○No |
| | see above | any_intern_eval_incl04_SAR | Any evaluation: Frequent Ventricular Extrasystoles (VES) (incl. Bigeminus) | nominal | ○Yes ○No |
| | | any_intern_eval_incl05_SAR | Any evaluation: o Atrioventricular Reentrant Tachycardia (AVRT) / Wolff-Parkinson-White (WPW) syndrome | nominal | ○Yes ○No |
| | | any_intern_eval_incl06_SAR | Any evaluation: Atrioventricular Nodal Reentrant Tachycardia (AVNRT) | nominal | ○Yes ○No |
| | | any_intern_eval_incl07_SAR | Any evaluation: Sinus Tachycardia at rest | nominal | ○Yes ○No |
| | | any_intern_eval_incl08_SAR | Any evaluation:Atrial Flutter | nominal | ○Yes ○No |
| | | any_intern_eval_incl09_SAR | Any evaluation: Any form of Ventricular Tachycardia (VT) | nominal | ○Yes ○No |
| | | any_intern_eval_incl10_SAR | Any evaluation: Silent / paroxysmal / persistent /permanent AF | nominal | ○Yes ○No |
| | | any_intern_eval_incl11_SAR | Any evaluation: Brugada syndrome | nominal | ○Yes ○No |
| | | any_intern_eval_incl12_SAR | Any evaluation: Long QT syndrome | nominal | ○Yes ○No |
| | | any_intern_eval_incl13_SAR | Any evaluation: Right Bundle Branch Block (RBBB) | nominal | ○Yes ○No |
| | | any_intern_eval_incl14_SAR | Any evaluation: Left Bundle Branch Block (LBBB) | nominal | ○Yes ○No |
| | | any_intern_eval_incl15_SAR | Any evaluation: Myocardial Ischemia/Acute Myocardial Infarction | nominal | ○Yes ○No |
| | | any_intern_eval_incl16_SAR | Any evaluation: Other abnormal QRS(T) complex, ST segment or T-wave morphology | nominal | ○Yes ○No |
| | descriptive | sum_intern_eval_incl03_SAR[19] | Sum evaluations: Patient with pacemaker/ICD and ventricular stimulation > 30% | as ordinal | n.a. |
| | see above | sum_intern_eval_incl04_SAR | Sum evaluations: Frequent Ventricular Extrasystoles (VES) (incl. Bigeminus) | as ordinal | n.a. |
| | | sum_intern_eval_incl05_SAR | Sum evaluations: Patient o Atrioventricular Reentrant Tachycardia (AVRT) / Wolff-Parkinson-White (WPW) syndrome | as ordinal | n.a. |
| | | sum_intern_eval_incl06_SAR | Sum evaluations: Atrioventricular Nodal Reentrant Tachycardia (AVNRT) | as ordinal | n.a. |
| | | sum_intern_eval_incl07_SAR | Sum evaluations: Sinus Tachycardia at rest | as ordinal | n.a. |
| | | sum_intern_eval_incl08_SAR | Sum evaluations: Atrial Flutter | as ordinal | n.a. |
| | | sum_intern_eval_incl09_SAR | Sum evaluations: Any form of Ventricular Tachycardia (VT) | as ordinal | n.a. |
| | | sum_intern_eval_incl10_SAR | Sum evaluations:Silent / paroxysmal / persistent /permanent AF | as ordinal | n.a. |
| | | sum_intern_eval_incl11_SAR | Sum evaluations: Brugada syndrome | as ordinal | n.a. |
| | | sum_intern_eval_incl12_SAR | Sum evaluations: Long QT syndrome | as ordinal | n.a. |
| | | sum_intern_eval_incl13_SAR | Sum evaluations: Right Bundle Branch Block (RBBB) | as ordinal | n.a. |
| | | sum_intern_eval_incl14_SAR | Sum evaluations: Left Bundle Branch Block (LBBB) | as ordinal | n.a. |
| | | sum_intern_eval_incl15_SAR | Sum evaluations: Myocardial Ischemia/Acute Myocardial Infarction% | as ordinal | n.a. |
| | | sum_intern_eval_incl16_SAR | Sum evaluations: Other abnormal QRS(T) complex, ST segment or T-wave morphology | as ordinal | n.a. |

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ECG type

| Data file, identifier patient_ display_id_full | Notes | Variable name | Variable label | Variable level | Nominal values |
|---|---|---|---|---|---|
| ecg_ recording | no report | EGEPSEDT | End Date and Time EPS ECG | date | n.a. |
| | | EGEPDOSD | Start Date and Time EPS DLO-ECG | date | n.a. |
| | | EGEPDOED | End Date and Time EPS DLO-ECG | date | n.a. |
| | | EGBMTSDT | Start Date and Time BMT ECG | date | n.a. |
| | | EGBMTEDT | End Date and Time BMT ECG | date | n.a. |
| | | EGBMDOSD | Start Date and Time BMT DLO-ECG | date | n.a. |
| | | EGBMDOED | End Date and Time BMT DLO-ECG | date | n.a. |
| | descriptive | EGRTYP | Type of Recording | nominal | ○ 3-Patch Holter<br>○ 10-Patch Holter |

Successful ECG recording

| Data file, identifier patient_ display_id_full | Notes | Variable name | Variable label | Variable level | Nominal values |
|---|---|---|---|---|---|
| data_SAR | descriptive | ecg_3patch_SAR[20] | 3-patch ECG during electrophysiology study | nominal | ○ Yes<br>○ No |
| | | ecg_3patch_24h_SAR[21] | 3-patch 24h ECG after electrophysiology study | nominal | ○ Yes<br>○ No |
| | | ecg_3patch_24h_min12h_ SAR[22] | 3-patch 24h ECG after electrophysiology study for min 12h | nominal | ○ Yes<br>○ No |
| | | ecg_10patch_SAR[23] | 10-patch ECG during Body Motion Test | nominal | ○ Yes<br>○ No |
| | | ecg_10patch_24h_SAR[24] | 10-patch 24h ECG after Body Motion Test | nominal | ○ Yes<br>○ No |
| | | ecg_10patch_24h_min12h_ SAR[25] | 10-patch 24h ECG after Body Motion Test for min 12h | nominal | ○ Yes<br>○ No |
| | descr. for all pts. and each category of intern_evaluation | ecg_successful_SAR[26] | Successful ECG recording | nominal | ○ Yes<br>○ No |

[redacted]

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## Body Motion Test

| Data file, identifier patient_ display_id_full | Notes | Variable name | Variable label | Variable level | Nominal values |
|---|---|---|---|---|---|
| ecg_recording | descriptive | EGBMTCMP | Patient completed all BMT activities | nominal | ○ Yes ○ No |

## Body position

| Data file, identifier patient_ display_ id_full | Notes | Variable name | Variable label | Variable level | Nominal values |
|---|---|---|---|---|---|
| ecg_ recording | descriptive for EGBMTCMP = No | EG1POS | Body position: Supine | nominal | ○ True ○ False |
| | | EG2POS | Body position: Prone | nominal | ○ True ○ False |
| | | EG3POS | Body position: Standing with arms stretched out frontward | nominal | ○ True ○ False |
| | | EG4POS | Body position: Right lateral | nominal | ○ True ○ False |
| | | EG5POS | Body position: Seated | nominal | ○ True ○ False |
| | | EG6POS | Body position: Standing with arms extended out to sides | nominal | ○ True ○ False |
| | | EG7POS | Body position: Left lateral | nominal | ○ True ○ False |
| | | EG8POS | Body position: Standing | nominal | ○ True ○ False |
| | | EG9POS | Body position: Standing with arms above the head | nominal | ○ True ○ False |

## Tension movement

| Data file, identifier patient_ display_ id_full | Notes | Variable name | Variable label | Variable level | Nominal values |
|---|---|---|---|---|---|
| ecg_ recording | descriptive for EGBMTCMP = No | EG1TMOV | Tension movements: Alternating arm movements | nominal | ○ True ○ False |
| | | EG2TMOV | Tension movements: Rubber band under feet, flexing arms up and down | nominal | ○ True ○ False |
| | | EG3TMOV | Tension movements: Flexing arms to sides and back | nominal | ○ True ○ False |
| | | EG4TMOV | Tension movements: Flexing arms above head | nominal | ○ True ○ False |
| | | EG5TMOV | Tension movements: Pressing hands in front of chest | nominal | ○ True ○ False |

## Activity

| Data file, identifier patient_ display_ id_full | Notes | Variable name | Variable label | Variable level | Nominal values |
|---|---|---|---|---|---|
| ecg_ recording | descriptive for EGBMTCMP = No | EG1ACT | Activity: Slow walking | nominal | ○ True ○ False |
| | | EG2ACT | Activity: Slow stair climbing | nominal | ○ True ○ False |
| | | EG3ACT | Activity: Faster walking | nominal | ○ True ○ False |
| | | EG4ACT | Activity: Resting for one minute | nominal | ○ True ○ False |

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## 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
No data are excluded from the analysis from the above analysis set and variables.

## 10.5. Descriptive Analyses

See general definitions in chapter 5.1 and notes in each table.

## 10.6. Hypotheses & Statistical Tests

*CIP chapter 7.2 Endpoints and hypotheses*
*There are no predefined hypotheses.*

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# Abbreviations

| | |
|---|---|
| ADE | Adverse Device Effect |
| AE | Adverse Event |
| AF | Atrial Fibrillation |
| BMT | Body Motion Test |
| CDMS | Clinical Data Management System |
| CI | Confidence Interval |
| CIP | Clinical Investigation Plan |
| CIR | Clinical Investigation Report |
| CRF | Case Report Form |
| ECG | Electrocardiogram |
| EPS | Electrophysiology Study |
| FU | Follow-up |
| SAE | Serious Adverse Event |
| SAP | Statistical Analysis Plan |
| SAR | Statistical Analysis Report |
| SOP | Standard Operating Procedure |
| SD | Standard Deviation |

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