

**Intraoperative testing of the circuit during defibrillator enclosure
replacements.
“T-DEF”**

**INTERVENTIONAL RESEARCH PROTOCOL WITH
MINIMAL RISKS AND LIMITATIONS**

GENERAL INFORMATION

PROTOCOL REFERENCES

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PROTOCOL SIGNATURE PAGE

Study Title: Intraoperative circuit testing during defibrillator enclosure replacements.

Protocol code: 2019/08

Version: V2.0 dated 09/28/2020

This protocol was read and approved on the date noted below.

The parties agree to conduct the research in accordance with the protocol, good clinical practices, and applicable laws and regulations.

FOR THE SPONSOR

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1. ABBREVIATIONS

ANSM: French National Agency for Medicines and Health Products Safety ARC:

Clinical Research Associate

Stroke: Cerebrovascular Accident

GCP: Good Clinical Practice MHC:

Medical-Surgical Center

CNIL: National Commission for Information Technology and Civil

Liberties CPP: Committee for the Protection of Persons

CRF: Standardized Data Collection Form

ICD: Implantable Cardioverter Defibrillator AF:

Atrial Fibrillation

MR: Reference Methodology

GDPR: General Data Protection Regulation RICAP:

Research and Innovation at the Ambroise Paré Medical-

Surgical Center TD: Defibrillation Test

2. SCIENTIFIC JUSTIFICATION AND GENERAL DESCRIPTION OF THE RESEARCH

2.1. Study Context

Over the years, advances in technology and knowledge, as well as evolving clinical practices, have led to the routine discontinuation of the defibrillation test (DT) during the implantation of an implantable cardioverter-defibrillator (ICD). Furthermore, improved monitoring through telemetry has enhanced patient safety by enabling the early detection of chronic lead malfunctions.

While this approach is logical during the initial implantation of a defibrillator and has been demonstrated by numerous studies, the question of whether to perform this test during device replacement remains open. Indeed, the leads are older at that point, potentially more fragile, and handling the connectors exposes them to an increased risk of wear ¹.

The defibrillation lead remains the weak link in a defibrillation system: its design is complex, and it is subjected to constant mechanical stress from the surrounding tissues. The overall operational rate of a defibrillation lead is 89% at 5 years, but this rate decreases ² rapidly thereafter, reaching 60% at 8 years ^{2,3}. Certain general characteristics (female gender, young patient) and the venous access route (subclavian) appear to increase the risk of lead wear.

When replacing the housing, handling the lead—which involves using an electrosurgical knife in close proximity to dissect the tissue and expose the connectors encased in fibrosis, as well as applying gentle traction to release the lead from the connector and reconnect it—requires meticulous technique ⁴, especially since older leads are more fragile ⁵. Some studies have reported a dysfunction rate of 3.5% one year after the housing replacement ⁶. Furthermore, the occurrence of technological failures in certain catheters (Fidelis, Riata) necessitated increased monitoring of these devices, which provided a better understanding of the impact of the hush on failures. Thus, it has been reported that these failures occurred at rates comparable to those of “control” leads without recall ⁷, but more rapidly over time. For the Fidelis lead, there also appears to be a peak within 3 months after lead system replacement ⁸.

In light of these findings, the TD during housing changes requires further study before it can be discontinued. This is the aim of this study.

2.2. Research Objective

The objective of this study is to demonstrate that the TD during defibrillator enclosure replacement enables the early detection of potential defibrillation circuit failures.

2.3. Summary of the benefits, if any, and the foreseeable and known risks for research participants

2.3.1. Expected benefits for the patient

Testing the defibrillation circuit, by enabling early detection of potential lead abnormalities, would lead to their replacement, thereby reducing the risk of inappropriate shocks and failure to treat serious arrhythmias.

2.3.2. Foreseeable and known risks

The risks associated with a defibrillation test are low. However, they must be weighed against the expected benefits. The largest registries suggest that the risk of major complications, including stroke, pulmonary embolism, cardiogenic shock, or

hypotension requiring resuscitation, have an estimated incidence of 0.17–0.4%, and that the risk of mortality is estimated at 0.016–0.07%^{9,10}.

A recent update of data on defibrillation testing suggests that this practice is no longer warranted during the initial implantation of a defibrillator, but should be reserved for specific cases and certain patient populations¹¹.

For all the reasons outlined in the scientific rationale for our protocol, we believe that defibrillator replacement procedures fall into this category of specific cases, due to the potential fragility of the older lead compared to that encountered during initial implantation.

Furthermore, the data above pertain to the defibrillation test involving the induction of ventricular fibrillation, as was conventionally performed in the past, whereas in our study we propose prioritizing a QRS-synchronized shock, which has the advantage of not disrupting the patient's hemodynamics. Finally, we chose to exclude patients at high risk of undergoing this test. These various reasons allow us to avoid the complications described above.

2.4. Description of the study population

Adult patients scheduled for an ICD lead replacement.

3. RESEARCH OBJECTIVES

3.1. Primary objective

The primary objective of the study is to demonstrate a non-zero failure rate of the defibrillation circuit during a device replacement.

3.2. Secondary Objectives

The secondary objectives are to:

1. Determine the failure rates of defibrillation leads 3 and 12 months after the implantable device replacement.
2. Identify clinical variables that may be associated with a risk of failure.
3. Identify potential catheters at risk of failure.

4. EVALUATION CRITERIA

4.1. Primary endpoint

The primary endpoint is the intraoperative catheter failure rate based on an abnormal shock impedance value (as defined by the manufacturer in Appendix 1).

4.2. Secondary endpoints

In relation to secondary objective 1:

Probe malfunction rate at the follow-up visit at M3 and M12 based on an abnormal impedance value (stimulation circuit and shock impedance) recorded during probe parameter testing.

In relation to secondary objectives 2 and 3:

Correlation between the probe malfunction rate and probe type and patient clinical variables.

5. SELECTION OF RESEARCH PARTICIPANTS

5.1. Inclusion Criteria

The following patients will be included:

- Over 18 years of age,
- Who have a VVI, DDD, or BiV defibrillator implanted and require a device replacement due to battery wear,
- Who have given their consent to participate in accordance with regulations,
- Currently enrolled in a social security program or eligible for coverage.

5.2. Exclusion criteria

Patients meeting the following criteria will not be included:

- Atrial fibrillation (AF) without effective anticoagulation for a shock,
- Severe aortic stenosis,
- Stroke occurring within the month prior to enrollment,
- Hemodynamic instability contraindicating shock therapy,
- Contraindication to anesthesia,
- Pregnant or breastfeeding women,
- Inability to understand the information provided,
- Under guardianship, conservatorship, or judicial protection.

5.3. Exclusion criteria

No exclusion criteria.

5.4. Recruitment Criteria

All patients scheduled for a defibrillator enclosure replacement who meet the eligibility criteria will be offered the opportunity to participate in the study. They will be informed during the pre-procedure cardiology consultation. Informed consent will be obtained after taking the time to verify that the information provided has been fully understood. Patients unable to understand the content of the information provided will not be included in the study.

5.5. Simultaneous Participation in Another Study, Exclusion Period

Patients may participate in another study simultaneously provided that the inclusion and exclusion criteria are met. There is no exclusion period for participants in this study.

6. RESEARCH METHODOLOGY

6.1. Study Type

Interventional, multicenter, prospective, non-randomized, open-label study.

6.2. Study Protocol

6.2.1. Inclusion

The patient will be informed of the protocol by an investigator during the pre-procedure cardiology consultation. Clear and honest information will be provided to the patient both verbally and in writing (see information sheet). The physician will verify the inclusion and exclusion criteria.

If the patient agrees to participate in the study after a cooling-off period that he or she considers sufficient, a consent form will be provided. This form must then be dated and signed by the investigator and the patient.

6.2.2. In the operating room

The procedure will be performed under general anesthesia or sedation, at the physician's discretion.

a) Before replacing the defibrillator's housing

Testing the lead parameters on the old defibrillator case

b) Replacement of the defibrillator housing

Replacement of the defibrillator housing and visual inspection of the connectors, following standard procedure.

After replacing the defibrillator housing

- Testing of probe parameters before and after connection to the new housing.
- Testing the defibrillation circuit:

Either via the standard defibrillation test, which involves inducing a ventricular arrhythmia through electrical cardiac stimulation and verifying the quality of its detection and the effectiveness of defibrillation.

Or via a high-energy synchronized shock; the test involves delivering a high-energy electrical shock synchronized with the QRS complex, in accordance with each manufacturer's standard guidelines (Appendix 1).

Important points:

- The use of an electrosurgical unit during surgery must be specified by the investigator, as its use may increase the risk of damaging the probe.
- If a malfunction of the defibrillation lead is detected during surgery, it will be replaced during the same procedure.

6.2.3. In the post-operative monitoring room / On the ward

Recording of any complications

6.2.4. Follow-up at 3 months and 1 year post-procedure

A standard follow-up visit to check the defibrillator is scheduled 3 months (\pm 3 months) and 12 months (\pm 3 months) after the procedure. This follow-up involves testing the lead's standard parameters (sensitivity, pacing threshold, pacing impedance, and defibrillation impedance), as well as downloading the device's memory to ensure there have been no abnormal signals from the lead since the procedure.

6.3. Study Design

Steps	Inclusion Visit	In the operating room	3 months post-procedure (± 3 months)	12 months post-surgery (± 3 months)
	Pre-procedure Pre-procedure cardiology visit			
Information	R			
Consent	R			
Verification of criteria inclusion and non-inclusion	R			
Testing the probe settings on the old housing		R		
Replacing the defibrillator		S		
Visual inspection of the connectors		S		
Testing the probe parameters before and after connecting to the new housing		S		
Testing the defibrillation circuit on the new unit		R		
Test of probe parameters at 3 months (± 3 months) and 12 months (± 3 months) post-procedure			S	S
Recording of any complications		S	S	S

R: Procedures, processes, and treatments added by the research;

S: Procedures, processes, and treatments related to care

6.4. Expected duration of participant involvement, description of the timeline and duration of the study

The study for a patient begins when the patient and the investigator sign the consent form and ends at the 12±3-month visit. For each patient, the duration of the study will therefore be 12 months (± 3 months).

The planned enrollment period is 24 months. The study is expected to take 39 months to complete, starting from the date of the first enrollment.

6.5. Identification of Participants

For this study, participants will be identified as follows:

Upon signing the consent form, the investigator will log into the eCRF and create a patient record. The presence of inclusion criteria and the absence of exclusion criteria will be verified on the site prior to assigning an enrollment number in order to minimize the possibility of selection bias. The alphanumeric “patient identifier” enrollment number will then be automatically generated by the application. It consists of the center number followed by a sequential enrollment number and the patient’s initials (first letter of the last name and first letter of the first name). This unique identifier will be retained for the duration of the study.

The principal investigator establishes and maintains a list of patients enrolled in the study. This list allows for the unambiguous association of the patient’s identity with their enrollment number.

6.6. Description of measures taken to reduce or avoid bias

6.6.1. Patient selection

To avoid any selection bias, this study will be offered to all patients scheduled for a defibrillator device replacement who meet the inclusion and exclusion criteria assessed during the pre-procedure cardiology consultation. For eligible patients who are not included, the reason for exclusion will be noted.

6.6.2. Blinding procedures, measures implemented to maintain blinding, and procedures for unblinding, if applicable

N/A

6.7. Description of the rules for permanent or temporary withdrawal of a person's participation in the research, procedures for monitoring these individuals, and procedures for replacing these subjects, if applicable

Any subject included in the study may at any time decide to withdraw their consent to participate, for any reason, without having to provide explanations or justifications and without this affecting the care they are receiving or will receive. The investigator must indicate in the patient's eCRF the date and, if applicable, the reason for discontinuation of participation in the research. Withdrawal of consent prohibits the use of medical data obtained after the withdrawal of consent. Data already collected regarding the subject may be used, unless the patient objects.

The investigator may temporarily or permanently discontinue a subject's participation in the study for any reason that affects the subject's safety and in the best interests of the patient. Data already collected regarding the subject may be used in the analysis of the study results.

A subject's withdrawal from the study will not affect their usual care.

A patient who withdraws prematurely from the study will be replaced, and a study withdrawal form will be completed, including, if possible, the reason for withdrawal (Consort flow diagram).

Once the protocol-specified sample size is reached, the investigator must halt recruitment for the study. However, patients who have already signed a consent form may still be included in the study.

6.8. Identification of all data collected directly in the study's eCRF and for which no other source documents exist

NA

7. SAFETY ASSESSMENT

In the context of interventional research involving minimal risk and constraints, the medical procedures or strategies that are the subject of the research are part of standard practice and are used in accordance with their indications. Potential incidents or adverse events are therefore those related to the patient's routine care (care-related) and do not require a specific report from the research manager.

These events must follow the standard reporting procedure established by current regulations and implemented at the facility:

- Adverse effects that may be related to a medication, to be reported to the Regional Pharmacovigilance Center,

- Incidents or potential incidents resulting from the use of a medical device to be reported to the local medical device vigilance liaison,
- Others (reporting of nosocomial infections).

These reports are mandatory for all physicians (or other relevant healthcare professionals), both within the context of this research and outside of it.

8. STATISTICAL

8.1. Description of planned statistical methods

Study population

All included subjects will be included in the analyses, which will be conducted according to the ITT principle.

Statistical analyses

An initial analysis of the data will provide a description of the overall population. The normality of the distribution of quantitative variables will be assessed using the Shapiro-Wilks normality test. Statistical results will be presented as means \pm standard deviations for quantitative variables with a Gaussian distribution, and as medians and interquartile ranges for other variables. For qualitative variables, frequencies and associated percentages will be presented. Qualitative variables will be compared using a chi-square test. If the conditions for conducting this test are not met, Fisher's exact test will be used. Quantitative variables will be compared between the two groups: for normally distributed variables, using a Student's t-test or an analysis of variance; for non-normally distributed variables, using a Wilcoxon-Mann-Whitney test.

Analysis of the primary outcome measure

Dysfunction rates will be estimated as point estimates and 95% confidence intervals.

Analysis of Secondary Endpoints

Depending on the rates of dysfunction observed, logistic regression will be used to estimate the variables associated with the risk of dysfunction. If the rate is too low for such modeling, descriptive analyses will be performed.

Modeling of dysfunction times over time may be performed using a Kaplan-Meier model. A Cox regression may be adjusted to determine the associated variables.

8.2. Expected number of participants to be included in the study, with statistical justification

Since the primary objective is to detect a non-zero rate of probe malfunction at the time of the procedure, we base the calculation of the sample size on the binomial distribution and the probability of observing no malfunctions in a sample of size n . Assuming a minimum malfunction rate of 1%, a study of 299 subjects yields a probability of observing no malfunctions that is less than an alpha risk of 5%. To account for unusable data and withdrawals of consent, we propose including a total of $N=330$ subjects in this study.

8.3. Expected significance level

A significance threshold of 5% will be used in the analyses.

8.4. Statistical criteria for study termination

No interim analysis is planned that could lead to the study being halted.

8.5. Method for handling missing, unused, or invalid data

No specific method for imputing missing data is planned.

8.6. Management of changes to the initial statistical plan

Any modification to this plan will be documented in writing, stating the reasons for the changes. The analysis plan and, if applicable, the document(s) modifying the initial statistical analysis plan will be appended to the analysis report.

9. DATA PROTECTION RIGHTS AND SOURCE DOCUMENTS

9.1. Data Protection

The processing of personal data for this research falls within the scope of Articles 53 through 61 of Law No. 78-17 of January 6, 1978, as amended, relating to information technology, files, and civil liberties; and the General Data Protection Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016, on the protection of individuals.

In accordance with the requirements of the CNIL (Law on Information Technology, Data Files, and Civil Liberties) and the European General Data Protection Regulation (GDPR), participants in this research will be informed, via the information notice and the consent form, of the following rights:

- the nature and purpose of the data collected as part of the research, as well as the retention period for such data.
- the possibility of withdrawing from the study at any time and the retention, by the sponsor, of the information collected (unless otherwise indicated by the data subject).
- their rights of access, rectification, objection, restriction, erasure, and data portability with respect to the data collected as part of the research. These rights may be exercised at any time during the study either by submitting a request to the physician overseeing the participants in the study (who will contact the sponsor) or by submitting a request to the sponsor's Data Protection Officer.
- the option, in the event of a problem or disagreement, to file a complaint with the CNIL.

The sponsor (through the TEC or the investigators) undertakes to respond to any request for access to data within a maximum of one month. Furthermore, only personnel authorized by the sponsor (investigators, ARC, TEC) and representatives of health authorities may have access to this information.

9.2. Access to Data

The sponsor has obtained the agreement of all parties involved in the research to ensure direct access to all research sites, source data, source documents, and reports for the purpose of quality control and audit by the sponsor and/or the competent authorities.

Investigators shall make the individual documents and data strictly necessary for the monitoring, quality control, and audit of the research available to persons authorized by the sponsor in accordance with applicable laws and regulations (Articles L.1121-3 and R.5121-13 of the Public Health Code).

9.3. Source documents

Source documents are defined as any original document or item that serves as proof of the existence or accuracy of data or facts recorded during the research. They will be retained for 15 years by the healthcare facility where the research was conducted, in accordance with regulations.

9.4. Data Confidentiality

In accordance with the provisions regarding the confidentiality of data to which persons responsible for quality control of research involving human subjects have access (Article L.1121-3 of the Public Health Code), and in accordance with the provisions regarding the confidentiality of information concerning, in particular, the nature of investigational drugs, trials, the participants, and the results obtained (Article R. 5121-13 of the Public Health Code), individuals with direct access to this data shall take all necessary precautions to ensure the confidentiality of information regarding the participants, particularly with respect to their identity, as well as the results obtained. Those responsible for quality control, just like the investigators themselves, are bound by professional secrecy (under the conditions defined by Articles 226-13 and 226-14 of the Penal Code).

During the course of the research or upon its completion, the data collected on the participants and transmitted to the sponsor by the investigators (or any other specialized personnel) will be anonymized. Patients will be identified only by an identification number containing the center number, their study entry number, and their initials. These details are recorded in the observation log. The collected data are strictly confidential. They are accessed only by the medical team, persons duly authorized by the study sponsor, and, if necessary, by representatives of the competent health and judicial authorities. The identity of participants will not be disclosed in any report or publication resulting from this study.

The sponsor will ensure that each research participant has provided written consent for the access and use of their personal data, which is strictly necessary for the quality control of the research.

The sponsor declares that it will process the study data in accordance with CNIL reference methodology MR-001.

9.5. Registration in the national registry of individuals participating in human research

This registration is not required for this research.

10. QUALITY CONTROL AND ASSURANCE

10.1. Quality Control

The sponsor appoints a Clinical Research Associate (CRA) to conduct monitoring visits, who will ensure that:

- the rights, safety, and protection of research participants are ensured,
- the critical elements necessary for analyzing the primary and secondary objectives are present,
- the reported data are accurate, complete, and consistent with the source documents,
- the research is conducted in accordance with the protocol, the Sponsor's Standard Operating Procedures, Good Clinical Practice (GCP), and applicable laws and regulations.

Quality control for the trial is conducted under the sponsor's responsibility in accordance with its Standard Operating Procedures and in compliance with Good Clinical Practice (GCP), the latest revision of the Declaration of Helsinki, and applicable laws and regulations.

The investigator and members of his or her team agree to make themselves available during visits conducted by the ARC.

During these visits, the following items will be reviewed:

- Written informed consent;
- Compliance with the research protocol and the technical procedures defined therein;
- Quality of data recorded in the observation log: accuracy, missing data, consistency of data with "source" documents (medical records, appointment logs, original laboratory results, etc.).

10.2. Quality assurance

Quality control of the trial is carried out under the responsibility of the Ambroise Paré Clinical Research Center. An audit may be conducted at any time by individuals appointed by the sponsor and independent of the research leaders. Except in special cases, the investigator is informed sufficiently in advance of the planned audit. The same applies to an inspection conducted by the Competent Authority. The purpose of these procedures is to ensure the quality of the research, the validity of its results, and compliance with applicable laws and regulations.

Those who direct and oversee the research agree to comply with the requirements of the sponsor and the Competent Authority regarding an audit or inspection of the research.

11. ETHICAL CONSIDERATIONS

11.1. Statement indicating that the research will be conducted in accordance with the protocol, good clinical practice, and applicable laws and regulations

The protocol complies with the ethical principles established by the^{18th}World Medical Assembly (Helsinki 1964) and by the amendments established at the^{29th}(Tokyo 1975),^{35th}(Venice 1983),^{41st} (Hong Kong 1989),^{48th}(Somerset West 1996),^{52nd}(Edinburgh 2000),^{53rd}(Washington 2002),^{55th}(Tokyo), 59th (Seoul), and revised at the 64thth World Medical Assembly (Fortaleza, Brazil, October 2013) . It will be conducted in accordance with the ICH guidelines on Good Clinical Practice.

11.2. Procedures for Informing and Obtaining Consent from Research Participants

No interventional research may be performed on a person without their free and informed consent, obtained in writing after all relevant information has been provided to them orally and in writing and prior to any procedure specified in the protocol and related to the research.

The research is presented orally to the patient by an investigator during the pre-procedure cardiology consultation. During this visit, patients receive information in understandable terms regarding the study's objectives and constraints, potential risks involved, necessary monitoring and safety measures, their right to refuse to participate in the study, and the possibility of withdrawing at any time without this affecting the care they receive. An information sheet corresponding to the information provided to the patient is given to the patient. After answering any questions the patient may have, and after ensuring that the patient has had sufficient time to reflect, the investigator obtains the patient's consent before enrolling the patient in the study.

A copy of the consent form, dated and signed by the person participating in the research as well as by the investigator, is provided to the person prior to their participation in the research. The investigator retains the original copy of the person's dated and signed consent form.

Changes to the protocol that result in an amendment shall be reflected by corresponding changes in the informed consent form and the information provided verbally to the patient.

11.3. Compensation for Participants

No compensation is provided for patients in this study.

11.4. Legal obligations

11.4.1. Roles of the Sponsor

The CMC Ambroise Paré is the sponsor of this research and is responsible for its conduct. The sponsor reserves the right to discontinue the research at any time for medical or administrative reasons; except in cases of force majeure, the investigator's opinion on this decision will be obtained and recorded in the trial documentation.

11.4.2. Approval of the protocol and amendments

Prior to the start of the study, the protocol, the information sheet, the informed consent form, and any other relevant documents will be submitted to the Institutional Review Board (IRB) for review. Notification of the HPC's favorable opinion will be forwarded to the study sponsor. This document must include a list of the HPC members who were present on the day the opinion was issued, along with their positions and qualifications.

The sponsor will notify the French National Agency for Medicines and Health Products Safety (ANSM) of the study.

The study may only be initiated after the sponsor has received all documents required from an ethical and regulatory standpoint, and in particular the favorable opinion of the CPP.

Any substantial modification to the protocol concerning the study's objectives, design, study population, or significant administrative aspects will require the approval of the coordinating investigator and the sponsor, as well as a favorable opinion from the CPP.

11.4.3. Commitment to Compliance with "Reference Methodology" MR-001

This study falls within the scope of the CNIL's Reference Methodology MR-001 for the following reasons:

- the collection of health data for research purposes
- obtaining the opinion of an IRB prior to commencing the research
- the use of anonymized data (identified by the inclusion number)
- providing information and obtaining individual consent from the participants
- access to data limited to healthcare and research professionals involved in the study under the responsibility of the investigators or the sponsor.

The Ambroise Paré Clinical Research Center, the study sponsor, has signed a commitment to comply with the "Reference Methodology" MR-001.

Patient data confidentiality will be ensured by using enrollment numbers and initials on the documents required for the research, or by appropriately redacting personally identifiable information from copies of source documents needed for research documentation. Only coded data will be accessible to the Sponsor.

The identity of participants will not be disclosed in any report or publication resulting from this study.

In accordance with the Law of March 4, 2004, on patients' rights, and if they so request of their investigator, participants in this study may be informed of the study's results once it has been completed.

11.4.4. Final Research Report

The final research report is prepared and signed by the sponsor and the coordinating investigator. A summary of the report, drafted in accordance with the Competent Authority's reference template, must be submitted to the Competent Authority and to the CPP within one year of the end of the research, corresponding to the end of the participation of the last person enrolled in the study.

12. DATA PROCESSING AND RETENTION OF DOCUMENTS AND DATA RELATED TO THE RESEARCH

12.1. Electronic Case Report Form (eCRF)

All information required by the protocol will be recorded in an electronic case report form (eCRF), with data hosted on a central, secure server at the CMC Ambroise Paré. Data will be collected as it is obtained by the investigator and/or personnel designated by the investigator.

12.2. Data Entry and Processing

The data required to conduct the study are listed in the table below, which specifies, for each document, its format, processing, and content.

	Format	Processing	Content
Consent form	Paper	Document completed by the patient and filed: - by the investigator's site in a secure location.	It contains proof of the patient's information and consent.
Inclusion form	Digital	Document completed by the site and used to notify the sponsor of a new patient's inclusion in the study.	This form contains the but not the patient's identity.
List of included patients	Paper	Confidential document retained by each investigator.	Document containing identifying data available only to the investigator; it allows the patient to be contacted if necessary. It also allows the study-specific enrollment number to be linked to the patient's medical record
Data collected by the investigator	Electronic	e-CRF	This data does not contain any information that would allow identify the patient.

12.3. Archiving

In accordance with the decree of August 11, 2008, establishing the retention period for documents and data related to biomedical research other than that involving medicinal products for human use, to be maintained by the sponsor and the investigator, upon completion of the research:

- all documents (various versions of the protocol, case report forms, investigator's file, consent forms, correspondence, etc.) in paper form will be archived at the center and at the sponsor's premises for 15 years.
- Data in electronic format will be retained until the final research report is completed and then archived for 15 years.

12.4. Ownership of Data

The CMC Ambroise Paré is the owner of the data, and no use or transfer to a third party may be made without its prior written consent.

12.5. Identification of all data to be collected in the observation log

Preoperative data:

- Age
- Gender
- Height
- Weight
- Medical history
- Data on first implantation

Intraoperative data:

- Result of probe parameter test
- Defibrillation circuit test result
- ICD impedance
- Any complications

Postoperative data:

- Results of the lead parameter test

13.FINANCING AND INSURANCE

13.1. Study funding

The costs associated with conducting this research are the responsibility of the sponsor.

13.2. Insurance

The Sponsor has taken out insurance for the entire duration of the study (under policy number BARCLT18496 with Lloyd's) covering its own civil liability as well as that of the investigators responsible for directing and supervising the conduct of the study on behalf of the Insured, and of any other party involved in this study on behalf of the Insured. This insurance policy, in accordance with Article L.1121-10 of the Public Health Code, is taken out with **Lloyd's**, 8/10 rue Lamennais, 75008 Paris, France.

14. PUBLICATION RULES

The study will be registered on the ClinicalTrials.gov website.

This study will be published in the form of presentations and original articles. The order of authorship will be determined by Dr. Caroline GRIMARD, the principal investigator.

The CMC Ambroise Paré must be cited as the sponsor of the research and as a source of funding, if applicable.

15. REFERENCES

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16. APPENDICES

Appendix 1: Defibrillation circuit testing using synchronized high-energy shocks by manufacturer.

APPENDIX 1: TEST OF THE SYNCHRONOUS HIGH-ENERGY SHOCK DEFIBRILLATION CIRCUIT BY MANUFACTURER.

AED	Defibrillation Circuit Test	Expected impedance value
MEDTRONIC	Delivery of a synchronized shock to a spontaneous QRS (cardioversion) at a maximum energy of 35 J. In the event of a circuit break, the ICD will protect itself and will not deliver a shock. <i>In the case of a pacemaker-dependent patient, the ICD cannot perform cardioversion (no synchronization possible on a Vs), it must then choose a defibrillation at 35J.</i>	< 150 Ω
SJM/ABBOTT	Delivery of a synchronized shock on a spontaneous QRS with a recommended energy of 36 J. Retrieval of the shock impedance by re-querying the defibrillator.	20–120 Ω
BIOTRONIK	Delivery of a manual R-wave shock at 40 J.	50–150 Ω
BOSTON SCIENTIFIC	Delivery of two synchronized shocks triggered by the R-wave. A first shock at 1.1 J, followed by a ^{second} verification shock at 41 J. Only the combination of these two tests can truly confirm the integrity of the system, particularly the leads.	15 – 120 Ω
MICROPORT	Delivery of a 42 J shock (maximum energy) <i>Program therapies in advance, which allows the ICD, in the event of arrhythmia induction, to diagnose and treat the triggered arrhythmia.</i>	30–60 Ω (dual-coil probe) 50–10 Ω (single-coil probe)