# REVEAL XT PERFORMANCE TRIAL

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Primary objective 1To quantify the 24-hour AF burden accuracy in patients with more than 1% AF burden. Primary objective 2To quantify the detection accuracy of non-arrhythmia in patients with 1% or less AF burden.

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Cardiac arrhythmias |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON31279

**Source**
ToetsingOnline

**Brief title**
XPECT

### Condition

- Cardiac arrhythmias

**Synonym**
AF detection algoritm

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Medtronic SQDM
**Source(s) of monetary or material Support:** MEDTRONIC SQDM

### Intervention

**Keyword:** AF Detection, Looprecorder, Reveal XT

## Outcome measures

### Primary outcome

The primary endpoint is:

- the AF burden determined from the subcutaneous ECG.

Secondary endpoints are:

- R-wave sensing performance parameters, AF performance parameters, and

adverse events.

### Secondary outcome

Secondary endpoints are:

- R-wave sensing performance parameters,

- AF performance parameters,

- and adverse events.

# Study description

### Background summary

The study will demonstrate the AF burden accuracy of the Reveal® XT, compared to 2-day Holter recordings. The correct detection of non-arrhythmia segments (specificity) is equally important clinically and will also be quantified. In addition, the R-wave sensing performance and the overall system performance will be quantified, user feedback obtained, and device safety data collected.
Two patient groups will be enrolled in the study. The first eligible patient group will have had or be scheduled for pulmonary vein ablation or surgical rhythm control intervention. Long term continuous arrhythmia monitoring is expected to disclose AF recurrences post AF ablation and be helpful in making informed therapeutic decisions in these patients.
The second eligible patient group will be patients with difficult to treat paroxysmal AF with frequent symptoms. Arrhythmia monitoring is expected to reveal the true AF burden for therapy management in this group.

## Study objective

Primary objective 1

To quantify the 24-hour AF burden accuracy in patients with more than 1% AF burden.

Primary objective 2

To quantify the detection accuracy of non-arrhythmia in patients with 1% or less AF burden.

## Study design

The study is a prospective, non-randomized, multi-center international post-market study.
The primary study objectives will be assessed using a continuous recording of the subcutaneous ECG and the marker channel from the Reveal® XT, which are uplinked to the Holter and stored on the Holter*s memory card synchronously with a conventional surface ECG. The Reveal® XT can be programmed to continuously upload the subcutaneous ECG and the marker channel for up to 46 hours.

## Study burden and risks

5.2.1 Potential risks and discomforts

The implantation of the Reveal® XT device is not part of the study. Standard risks associated with the medical device are listed in the Reveal® XT 9529 Clinician Manual. This study is considered to entail minimal risk. The potential risks to a subject are expected to be the same as those encountered during standard ECG testing or Holter recording. Therefore the risks involved include but are not limited to irritation of the skin or an allergic reaction to the ECG electrodes or the adhesive plaster or tape used to secure the electrodes or leads to the skin.
There may be additional risks related to study participation that are unknown at this time.To minimize the risks, the center personnel will be well trained on the study procedures and the patients will be closely observed and monitored during the study visits.

5.2.2 Potential benefits

There are no direct personal benefits for participating subjects.
Participation in the study will contribute to a better understanding of the performance of a new medical device, which will be important for future

developments and future treatments.

## Contacts

**Public**
Medtronic SQDM

P.O. Box 5227
6802 EE
Nederland
**Scientific**
Medtronic SQDM

P.O. Box 5227
6802 EE
Nederland

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

### Inclusion criteria

• Patient is willing and able to provide his/her informed consent
• Patient has been implanted with a Reveal® XT
• Patient fulfills at least one of the following three additional requirements
1. is scheduled for PV ablation or surgical rhythm control intervention, and the PV ablation or surgical intervention can be deferred until study completion or
2. has documented frequent AF or frequent symptoms attributable to AF or
3. has undergone PV ablation within the last 6 months and still has symptoms attributable to AF

### Exclusion criteria

- Patient has an implanted pacemaker or ICD
- Patient has persistent or permanent AF
- Patient is allergic to adhesive ECG electrodes
- The study will interfere with a therapeutic or diagnostic procedure which is planned or expected during the study period
- Patient is participating in another study that is expected to compromise the results of this study
- Patient is a minor, legally incompetent, or does not meet other local requirements for participation in a clinical study
- Patient is pregnant

## Study design

### Design

**Study type:** Observational non invasive

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Diagnostic |

### Recruitment

NL

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|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-06-2007 |
| Enrollment: | 50 |
| Type: | Anticipated |

## Ethics review

Approved WMO

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|---|---|
| Date: | 31-08-2007 |
| Application type: | First submission |
| Review commission: | METC Noord-Holland (Alkmaar) |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
| --- | --- |
| CCMO | NL18217.094.07 |