

# Multi-electrode electro-anatomical mapping using the Ensite HD Grid Catheter: Activation and repolarization characteristics in human with structural normal hearts and substrate related arrhythmias

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(1) Establishing normal values (cut-offs) for bipolar and unipolar voltage mapping during sinus rhythm and pacing. (2) Establish normal values for conduction velocity during sinus rhythm of the 4 chambers. (3) Establish normal values for activation...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Cardiac arrhythmias
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON45581

### Source

ToetsingOnline

### Brief title

Ensite HD Grid Catheter

### Condition

- Cardiac arrhythmias

### Synonym

atrial en ventricular arrhythmias, supraventricular en ventricular rhythm disorders

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Ablation, electroanatomical mapping, HD Ensite Grid, Multi-elektrode

## Outcome measures

### Primary outcome

Main study parameters/endpoints: electrophysiological data, device success, adverse effects and comparability with the current mapping approach and substrate identified by CE-MRI.

### Secondary outcome

Not applicable.

## Study description

### Background summary

Electro-anatomical mapping (EAM) with standard large tip, bipolar catheters is time consuming and provides limited information. Multi-electrode mapping has several advantages, especially if grid electrodes are used with fixed distances and pacing modalities. Bipolar signals can easily be constructed mathematically and local activation pattern, anisotropic conduction properties and fibrosis can be revealed. The latter is likely a key player in arrhythmogenity and identifying areas with abnormal conduction is of importance for substrate based ablation procedures. In this protocol the HD Ensite Grid Catheter will be used for these purposes.

### Study objective

(1) Establishing normal values (cut-offs) for bipolar and unipolar voltage mapping during sinus rhythm and pacing. (2) Establish normal values for conduction velocity during sinus rhythm of the 4 chambers. (3) Establish

normal values for activation recovery intervals as substitute for action potential duration (APD) and APD restitution curves to evaluate local/global dispersion of repolarization. (4) Evaluate the influence of the direction of the activation wavefront on electrogram amplitude, duration and conduction velocity during pacing from 2 orthogonal located pairs at fixed conduction velocity (CL) and during premature extrastimuli (anisotropic conduction). (5) Comparing voltage and activation mapping data obtained with the HD grid catheter with data acquired with a conventional 4mm tip catheter (Ensite). (6) Comparing procedure time required to obtain high density maps with conventional versus HD grid catheters.

In a second step we would like to compare the electrophysiological substrate characteristics of patients with complex arrhythmias with the current gold standard in imaging to detect fibrosis which is contrast enhanced cardiac MR.

## **Study design**

a prospective, single-arm study.

## **Study burden and risks**

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: This is a first-in-man study and therefore no previous clinical experience in human is available for the use of the HD Ensite Grid Catheter. Comparable catheters with the same material are used in clinical practice. This catheter, which is only a diagnostic tool, has a different design compared to existing multielectrode catheters.

## **Contacts**

### **Public**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- Patients who are electively scheduled for a first catheter ablation to treat an atrial or ventricular arrhythmia.
- Patient understands the implications of participating in the study and provides informed consent

### Exclusion criteria

- Previous surgical or catheter ablation of the atria or ventricle
- Patients with uncontrolled heart failure or with NYHA class > II
- Patients with stable/unstable angina or myocardial ischemia
- Patients with infection
- Patients with severe co-morbidity or poor general physical/mental health
- Patients with contra - indications for cardiac MRI

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

## Recruitment

NL  
Recruitment status: Recruiting  
Start date (anticipated): 23-01-2018  
Enrollment: 48  
Type: Actual

## Medical products/devices used

Generic name: HD Ensight Grid Catheter  
Registration: No

## Ethics review

Approved WMO  
Date: 23-06-2017  
Application type: First submission  
Review commission: METC Leiden-Den Haag-Delft (Leiden)  
metc-ldd@lumc.nl

## 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	NL60897.058.17