SmartCardia

SmartWearable® Medical Device with Artificial Intelligence (AI)

A Unique Clinical Offering

- Uses Artificial Intelligence (AI) for **Predictive Data Analysis** of live collated data.
- **Low incidence of False Alarms** - Uses unique signal processing methods with data fusion.
- **Patient Specific Automatic Calibration** – Sensors adapt to device location, skin colour and body build.
- **Clinically validated** – Several clinical trials successfully performed across. Europe, United States (US) and Asia.
- **7 International patent applications** (2 granted in the US) that includes:
  - signal processing under noise;
  - AI for abnormality detection;
  - heart rate variability method;
  - device and patch;
  - blood oxygen saturation (SpO2) method.

5 years of Research and Development (R&D) from top signal processing and machine-learning teams at Ecole Polytechnique Fédérale de Lausanne (EPFL) Switzerland.

SmartCardia Clinical Trials

1

SmartHealthy – Switzerland, Completed
No. of Enrolled Patients: 30 Healthy participants with an emphasis on Wellbeing in different Age Spectrums

Primary Outcome of the study: Clinical Validation for Accuracy, Safety and Efficacy

2

SmartCor2 – Cardiocentro University Hospital at Lugano Switzerland /Completed

No. of Enrolled Patients: 60 CVD patients with an emphasis on Cardiovascular Medicine Major " Incidents", such as Heart Failure (different stages)

3

SmartCor_ICVDV – Kamenica Institute of CVD University Hospital at Novi Sad / Serbia / Ongoing

No. of Enrolled Patients: 500 CVD patients with an emphasis on Cardiovascular Medicine Major " Incidents", such as Heart Failure (different stages)

4

SmartCor1 – Ramon Cajal University Hospital on Madrid / Ongoing
1st Phase completed with Holter Analysis (=30 patients)

No. of Enrolled Patients: 150 CVD patients with an emphasis on Heart Failure (different stages)

5

SmartCor3 – Sengupta Sengupta Institute of Clinical Medicine and Research / Nagpur / India / Ongoing

No. of Enrolled Patients: 150 CVD & Sepsis patients with an emphasis on Cardiovascular Medicine Major "Incidents", such as Heart Failure and Sepsis (different stages)

6

SmartSomnus – University Hospital at Kragujevac / Serbia Completed

No. of Enrolled Patients: 50 Sleep Disorder patients with an emphasis on Polygraphy (Sleep apnoea)

7

PaSME – Metropoloitan Hospital, Greece/ Ongoing

No. of Enrolled Patients: 30 Chronic Pain Disorder patients with an emphasis on Myoskeletal Disorders (different stages)

8

ANAPNEO – University of Thessaloniki Medical School, Greece, Ongoing

No. of Enrolled Patients: 30 x 2 (Control of themselves within three month period) Sleep Disorder patients with an emphasis on Polysomnography / Polygraphy / CPAP Titration (different stages)

9

SmartSomnus_Tracking – Kamenica Institute of Pulmonary Medicine University Hospital at Novi Sad / Serbia / Ongoing

No. of Enrolled Patients: 200 Sleep Disorder patients with an emphasis on Polysomnography / Polygraphy / CPAP Titration (different stages) divided into three groups

10

SmartCor_ShockRoom – Belgrade Medical School & University Hospital / Serbia

No. of Enrolled Patients: 100 ICU patients with an emphasis on Intensive Care Medicine - Medicine Major "Incidents" such as Sepsis (diferent stages)

11

SmartFit – Newcastle Medical School / UK / Approved & Ongoing

No. of Enrolled Patients: 150 CVD / Metabolic Disorders and Healthy Subjects with an emphasis on Stress Tests and Exercise & Rest Testing and (different stages)

12

SmartCor_4 – Queen Elisabeth University Hospital at Birmingham / UK / Approved & To be commenced

No. of Enrolled Patients: 30 CVD ICU patients

13

PaSME – Serbia Institute of G.I. Medicine Kragujevac University Hospital / Kragujevac / Serbia / Approved & Ongoing

No. of Enrolled Patients: 100 Chronic Pain Disorder vs. 100 Acute G.I Pain Disorder patients (different stages)

14

SmartCor_ICVDV – University Hospital at Novi Sad / Serbia /Approved & Ongoing

No. of Enrolled Patients: 100 Arrhythmic patients with an emphasis on AFib (different stages).
Validation Tool for AFib in CVD Medicine and Therapeutics

15

SmartCor_ShockRoom – Bezanijska Kosa Hospital Institute of Clinical Medicine and Research / Belgrade Medical School & University Hospital / Serbia / Yet to commence

No. of Enrolled Patients: 100 ICU patients - Infection and Inflammation

16

SmartCor_Dredinje_AFib – Institute of CVD University Hospital at Belgrade / Serbia Approved and Ongoing

No. of Enrolled patients: 100 Arrhythmic patients with an emphasis on AF (different stages)

17

SmartSomnus_Tracking – Manipal Institute of Pulmonary Medicine University Hospital of Manipal / India / Approved, yet to commence

No. of Enrolled Patients: 150 Polysomnography monitoring

18

SmartCor_ShockRoom – Manipal Institute of Clinical Medicine and Research / Manipal Medical School & University Hospital at Manipal /India/ Approved, yet to commence

No. of Enrolled patients: 150 patients ICU and infected patients study

References:
SmartCardia SA. Medical Wearable with Artificial Intelligence for Clinical Insights (Slide Deck_GS_May 2018).

SmartCardia

SmartCardia Clinical Trials

- **Performed in 14 hospitals:** 11 in Europe (e.g. Switzerland, Spain, Germany, UK), one in the US and two in India.
- **Validation** against **hospital gold standards** in all trials (i.e. ICU monitors, polysomnography devices, Holter recorders, etc.).
- **Completed data collation of 1,000 patients, 16,000 patient hours** – simultaneous arm and chest monitoring.
- 2,300 patients enrolled in trials that covered areas of:
  * Cardiovascular disease
  * Arrhythmia
  * Atrial fibrillation (AF)
  * Sleep apnoea
  * Infection & sepsis detection
  * Pain monitoring
  * Health & Wellness data collation
- **Sleep:** Multi-centred trial with 200+ patients completed, sleep apnoea, real-time detection.
- **Atrial fibrillation and Arrhythmia:** 300+ patients completed, real-time detection. Meets CE/ FDA standards.

Apnoea episodes, micro-arousals during sleep

Avista

Predictive Early Warning for Cardiovascular Deterioration

CARDIOCENTROTICINO

Hospital Universitario Ramón y Cajal

Sengupta

Pain

METROPOLITAN HOSPITAL

Newcastle University

AF and Stroke

SCHÖN KLINIK

IKVBV

Sepsis

IKVBV

Hospital Universitario Ramón y Cajal

MADE IN SWITZERLAND

SmartCardia SA
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Switzerland

SmartCardia SA is a Swiss medical device company with focus on clinical quality data and validation. They are an ISO 13485 and ISO 9001 certified medical device manufacturer and meet strict quality control standards for their solutions. The company is also ISO 27001 certified for data security and privacy. Moreover, the SmartWearable® device is CE-marked as Class IIa medical device.

ISO 13485 · ISO 9001:2015 · ISO 27001

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KIARA Innovating Healthcare

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