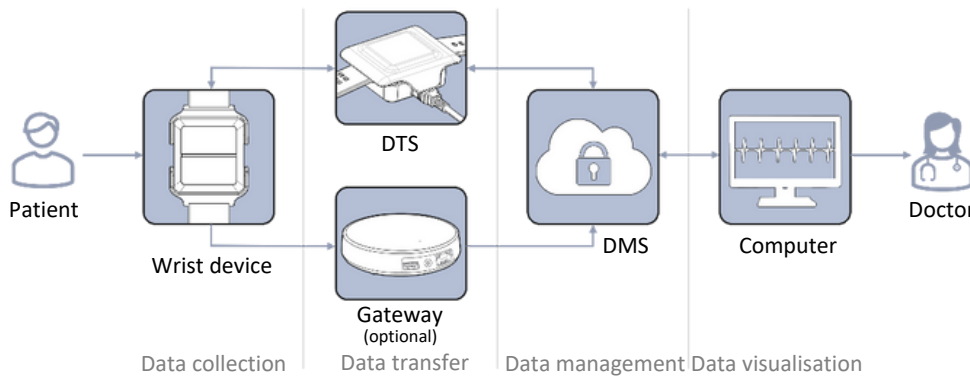# Data Sheet

PulseOn Arrhythmia Monitor System (AMS-1)

The Solution

The PulseOn Arrhythmia Monitor System is used to assist in the diagnosis, screening, and monitoring of cardiac arrhythmias. It consists of a wrist device, a data management service (DMS), and a data transfer software (DTS). An optional compatible gateway can be used with it for remote data transfer.

Specifications

PulseOn Arrhythmia Monitor AM-1 (wrist device)			
Length (strap size L)	250.4 mm	Length (strap size S)	215.5 mm
Width	39 mm	Depth	13 mm
Weight (with strap size L)	45 g	Ingress protection classification	IP57
Operating conditions	Temperature +5°C to +38°C Humidity 5% to 90% Pressure 700 to 1060 hPA	Storage/transport conditions	Temperature -20°C to +60°C Humidity 5% to 90% (non-condensing) Pressure 500 to 1060 hPA
Battery type	Li-ion polymer rechargeable battery, 350 mAh Nominal voltage 3.70V Integrated safety circuit	Operating time	More than 7 days without recharging (with full battery)
Internal memory	128 MB flash memory (can store 1 month of data)	Sensors	ECG, PPG, 3-axis accelerometer
Indicators	LED lights (green, white and red), vibration motor	Connectivity	Bluetooth (micro USB in charging dock)
Materials	Device: ABS plastic, polycarbonate and stainless steel Straps: Silicone and stainless steel	Measurement details	ECG sample rate: 512 Hz ECG measurement resolution: 1 µV ECG measurement bandwidth*: - high-pass cut-off frequency < 0.6 Hz - low-pass cut-off frequency > 150 Hz *bandwidth tests apply for raw filter configuration in DMS PPG peak wavelength: 590 nm

Authorized Distributor:

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Always consult the complete User Guide (ref. AMS-1-UG-EN) before use.

Supported web browsers

Data Management Service supports the following web browsers on a PC:
   • Microsoft Edge, Google Chrome, Mozilla Firefox

Workstation requirements

It is recommended that Windows 10 or newer with relatively modern hardware be used with the Data Management Service. Minimum recommended setup:
- Processor: 1.5 gigahertz (GHz) or faster processor
- RAM: 4 GB
- Graphics card: DirectX 9 or later with WDDM 1.0 driver
- Display: 1920x1080 pixels
- USB port

Performance

Optical atrial fibrillation detection performance

- The PulseOn Arrhythmia Monitor has the following performance in detecting atrial fibrillation in Caucasian over-50-year-olds when evaluated in 5-minute segments: sensitivity > 95 %, specificity > 99 % (disregarding the segments of undetermined rhythm, ~46 %)

ECG analysis algorithm performance

- The ECG analysis algorithm has achieved the following performance for atrial fibrillation detection in a large-scale clinical trial* with a different measurement device but based on the same approach, i.e. short Lead I ECG measurements between the hands: sensitivity 92.4%, specificity 94.4% as reported by the *Possible arrhythmia* label in the ECG measurement.

   *E. Svennberg, M. Stridh, J. Engdahl, F. Al-Khalili, L. Friberg, V. Frykman, M. Rosenqvist. Safe automatic one-lead electrocardiogram analysis in screening for atrial fibrillation. *EP Europace* 19: 9,1 (2017) pp. 1449–1453, https://doi.org/10.1093/europace/euw286

Benefits

- Long-term monitoring (weeks, months, years)
- 24/7, beat by beat arrhythmia detection, especially AFib.
- Detects also challenging, rare, and short arrhythmia episodes, even asymptomatic.
- Easy to use - notifies the patient to record ECG at the right time.
- Does not affect patients' quality of life, can be worn for extended periods.
- Enables remote patient monitoring.
- Efficient cloud service for fast diagnosis.

Manufacturer

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