

**Product number/ REF:**  
10-501

**Manufacturer:**  
Icentia Inc. 2750, Einstein, Quebec, QC Canada G1P 4R1

## Description and Instructions for use

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The EART analysis concept is based on a 2D colour-coded ECG representation scheme allowing the user to visualize a large number of QRS complexes - in the tens of thousands - representing several hours of ECG recording in one static view. The number of QRS complexes and the ECG duration which can be displayed in a single screen view vary depending on the heart rate of the recording and the screen resolution.

When compared to the classic ECG representation (in mV over a time scale in seconds), the EART representation is more compact and meaningful, hence it significantly improves the ability of the user to clearly visualize and identify rhythm-based abnormalities. With such a representation, the user can efficiently annotate large portions of the recording with specific attributes such as: atrial fibrillation/flutter, noise and more. Atrial and ventricular premature complexes (SVE & VE) are also clearly identifiable and can be annotated by the user.

A prerequisite of the color view is the annotation of beats in the EART file prior to its import by the software. The beats are detected by Icentia's beat detection algorithm which has demonstrated performances for sensitivity and positive predictivity of above 98% on required databases from PhysioNet.

## Product safety information

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The product complies with the requirements of standard:

IEC 60601-2-47 Medical electrical equipment — Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems.