

Customer Bulletin

HeartSine AEDs conformance to IEC 60601-1-2:2014 (Edition 4.0)

26 October 2018

Dear Valued Customer,

This brief communication is to inform you that we are in the process of transitioning across to the manufacture of AEDs which will conform to the latest test specifications for **IEC 60601-1-2:2014 (Edition 4.0) Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance**. All manufacturers of AEDs who wish to market AEDs within the EU must comply with this test specification by the end of 2018.

AEDs are increasingly being used in non-EMC (electromagnetic compatibility) controlled public environments in the ten years since this test specification has been updated. With the increased presence of electromagnetic radiating devices in these spaces (such as mobile phones, Wi-Fi® networks, etc.), this revised test standard has been updated to enhance the immunity of AEDs from possible electromagnetic interference during operation.

All HeartSine AEDs shipped from the Belfast manufacturing site (to EU countries) will be compliant to this test standard before 31 December 2018. There will be change to the outward appearance of HeartSine AEDs during as a result. The devices will be identifiable by the literature shipped with the AED where:

- All HeartSine AEDs will be shipped with a combined user manual for SAM 350P/360P/500P
- The Emergency User Guide will be replaced by an Emergency Use Hangtag - which can be fixed to the carry case.

This does not affect the use or sale of AEDs currently installed in the market or in the possession of our distributors.

Thank you for your continued support of HeartSine AEDs.

Yours sincerely,



Dr Peter O'Hare

**Global Product Manager
HeartSine AEDs**