



July 08, 2019

Re: Philips FCO86201863

To whom it may concern:

The Field Safety Notice (FSN) for FCO86201863 was revised several times prior to this final version. The Revision C draft of the Field Safety Notice explains the relationship of Revision Band C to the initial notice. For Revision C, at the request of the FDA, Philips edited the opening statement to clarify that the more recent notices refer to additional issues related to battery use and makes changes to the "Actions to be taken by the customer" section. Revision C was created specifically to address the concern stated in our discussion with FDA on May 9, 2019 that users may be unclear as to which directions to follow as between the original notice and revision B.

The attached FSN for FCO86201863 reflects the final version, which now also includes a reply card.

Sincerely,

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