
Urgent Field Safety Notice

Commercial name of the affected product: AngelSounds JPD-100S4 Fetal Doppler

FSCA-identifier: QS7111

Type of action: Field Safety Notice (Update to Instructions For Use)

Date: 20th of September 2018

Dear Customer,

Shenzhen Jumper Medical Equipment Co. Ltd. are contacting you regarding a safety issue identified with one of our products. This notice contains urgent safety information intended for users of the AngelSounds Fetal Doppler (JPD-100S4).

Identification of medical devices concerned:



This action affects all AngelSounds Fetal Doppler - JPD-100S4 devices (as pictured above).

Reason for the issue of the notice:

The Instructions For Use (IFU) for this device are being updated as they **did not** contain clear warnings indicating this device cannot replace a professional fetal monitor.

If an abnormal fetal heart rate is detected, you cannot find the fetal heart or cannot feel fetal movement, seek medical attention **immediately**.

If you have bought other JUMPER products, you can also contact the Manufacturer contact person below to obtain the latest version of the instructions for use.

The following cautions have been added to the IFU:

- Please read the User Manual carefully to make sure safe and proper use of this Fetal Doppler, Please read and fully understand the Safety Precautions before use.
- It cannot replace the professional fetal monitor, when the fetal heart rate is abnormal, or can not find the fetal heart, can not feel the fetal movement, pregnant woman's should immediately go to the hospital to seek the doctor's help.

An indication of a normal fetal heart range has also been added

Advise on action to be taken by the user:

1. Read this notice and the accompanying User Manual/IFU carefully.
2. Only use the device as instructed by the User manual/IFU.
3. Report any issues or concerns regarding to this device to the manufacturer or your local national competent authority.
4. Contact the Manufacturer to confirm receipt of this FSN and the accompanying updated IFU.
5. End users can also download the latest user manual from JUMPER's official website (<http://www.jumper-medical.com/enindex.php/service>).

Transmission of this Field Safety Notice:

If you are no longer in possession of this device and have given it to a third party, please pass on a copy of this Field Safety Notice to them without delay. Please keep this Field Safety Notice and the updated IFU with your device.

Manufacturer Contact:

Company Name	Shenzhen Jumper Medical Equipment Co., Ltd.
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