Hørsholm Thursday October 26th 2017

XO CARE A/S

Safety notice

For all users of XO Units XO 4 and XO FLEX Unit

Dear customer

We hereby wish to inform you of a newly identified situation regarding suction hoses for the above-mentioned XO Units. These suction hoses, containing magnets, have the potential to negatively impact implanted pacemakers and implanted defibrillators (ICDs). In this context, we wish to inform you about the corrective actions XO CARE as responsible manufacturer have initiated, as well as the actions we recommend you as a user of the XO 4 and/or XO FLEX to take.

What is the situation and what are the risks potentially associated with this:

Implanted cardiac pacemakers and defibrillators are working to treat cardiac arrhythmias by delivering electrical impulses to the heart muscle. The implanted device is usually placed under the skin, often on the left side of the chest, immediately below the clavicle. From this position, it is further connected to the heart through electrodes inserted into the heart muscle.

The correct function of pacemakers and defibrillators are in principle life-saving and a disturbance of the function, therefore in principle, potentially life-threatening.
Pacemakers and implanted defibrillators are delicate electronic devices that are sensitive to magnetic exposure.

A magnetic field may thus impede the normal functioning of the device temporarily or permanently. Implanted cardiac pacemakers are designed to withstand an impact of a magnetic field with a strength of up to 1 mT (mili Tesla) without affecting the device's function, while a magnetic field exceeding 50 mT has the potential to interfere with the device's functionality permanently[1]. Between these extremes i.e. from 1 – 50 mT the magnetic field may temporarily affect the functionality of the pacemaker.

The suction hose on XO-4 and XO FLEX unit is fitted with a magnet built into the dark grey nipple at the distal end of the suction hose, where it connects to the suction catheter. The function of the magnet is to control a contact that stops the suction action when the hose is placed in the cradle and automatically enable suction when the hose is lifted from the cradle. These nipples are often placed on the patient's chest during treatment, in the immediate vicinity of any implanted pacemaker. (fig 1.)

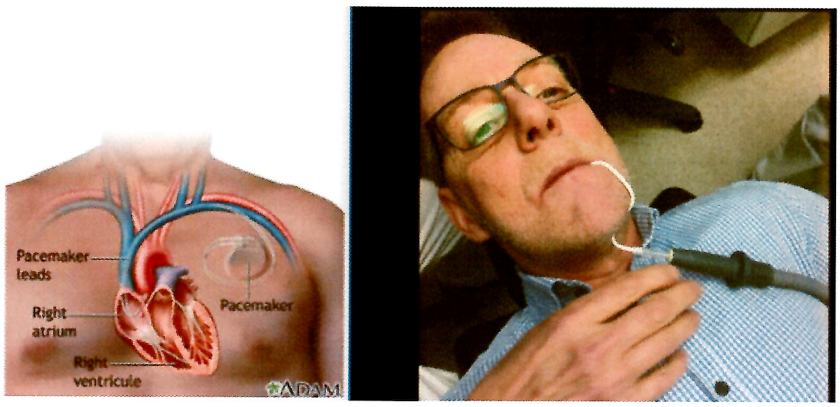

Fig 1. The typical placement of pacemaker and suction hose during treatment

XO CARE has been made aware of a single case, in which an implanted defibrillator made a warning tone in connection with positioning an XO suction hose immediately above an implanted defibrillator. By moving the suction hose from this position, the alert sound was discontinued. The presence of the alert sound indicates that the defibrillator has sensed a magnetic field from the magnet in the suction hose, with a potential for impacting the functionality of the device as long as the magnetic field would remain in the immediate vicinity of the defibrillator.

XO CARE notes that no damage to pacemakers and ICDs or patients have ever been reported to the company. XO CARE further notes that more than 5.000 similar suction systems currently are in use on a daily basis. The product has been on the market in the past 14 years. With an average number of treatments of more than 10 per day we can estimate more than 50.000 daily treatments are conducted without any reported damage to pacemakers or patients.

What activities have XO CARE initiated to mitigate magnetic impact on the pacemaker:

XO CARE has conducted tests at a third-party testing lab, measuring the magnetic field's strength and extent in both large and small XO suction hoses.
The results of the tests have shown that the magnetic field decreases sharply with the distance from the suction hose nipple. The magnetic field at a distance from the hose nipple of ≥ 2.5 cm is reduced to a force of less than 1 mT, which means that a pacemaker localized more than 2.5 cm from the suction hose nipple should not be affected at all by the magnetic field of the suction hose.

If the distance to the suction hose nipple is 0 mm, i.e. same distance as if the suction hose nipple is placed directly on top of the pacemaker, without any skin and clothes in between, the magnetic field is measured as less than 50mT. This indicates that the suction hose magnet, even in a worst-case scenario in which the suction hose is placed directly on the pacemaker, should not be able to permanently disturb the device's function.

The placement of the suction hose directly over the implanted pacemaker is, however, able to temporarily affect the appliance, which XO CARE finds unacceptable.

XO CARE have therefore launched a number of initiatives to mitigate the situation.

Design modification:

- All XO suction hoses and suction hose associated electronics will onwards be produced with a modified design that eliminates the magnet in the suction hose

Alertness and mitigate advice:

- For all existing suction hoses, the user shall be instructed in the situation that can occur and how to prevent it from happening
- XO CARE has reported the problem and the incident to the relevant authorities

Alertness and mitigating advice for existing units:

- Be aware if your patient carries an implanted pacemaker or defibrillator
- Ask the patient about the pacemaker's position
- Ensure not to place the suction hose nipple in proximity of the implanted pacemaker
- If possible place a folded towel or similar over the location of the pacemaker
- Pay attention if any acoustic signal occurs from the pacemaker, move the suction hose nipple immediately until the acoustic signal warning tone stops
- As in any case at which a patient experiences unexplained discomfort during treatment, the treatment should be paused and proper attention paid to a potential medical situation

Conclusion:

XO CARE has - until the current episode - during the 10 years that XO-4 and XO FLEX units have been fitted with magnets built into the suction hoses, received no reports of problems in connection with pacemakers or IDCs. This has to be seen in the context of millions of treatments. We therefore consider the risk for the patients as extremely small.

With best regards

XO CARE A/S 26/10-2017

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References

1. A 45502-2-2 Active implantable medical devices – party 2-2: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (includes implantable defibrillators)