

Hørsholm, Denmark, Monday February 26th 2018

URGENT FIELD SAFETY NOTICE

For all users of XO dental units XO 4 and XO FLEX

Dear customer

We hereby wish to inform you of a situation regarding suction hoses for the above-mentioned XO units. These suction hoses, each containing a small magnet, 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.

The suction hose on XO 4 and XO FLEX units 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.)

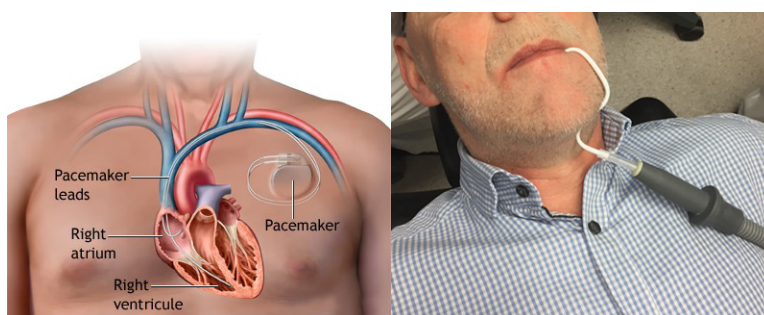


Fig 1. The typical placement of pacemaker and suction hose during treatment

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 A/S want to empathize that XO 4 and XO Flex during the years – with more than 75 MIO estimated treatments – have no reported injuries as a result of this issue.

Product correction forward

XO CARE has designed a new suction hose which contains a warning in the tip of the suction hose nipple warning about magnetic field radiated from the tip of the suction hose. This part is made available to you via your distributor from week 14, 2018. The motivation of this redesign has to be found in XO CARE A/S desire to act responsibly, furthermore to be foreseen regarding future upcoming implant devices sensitive to magnetic fields.

Measures to be taken by customer/user

You may continue to use the system following these instructions:

- 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 such that the suction nipple is minimum 2,5 cm above the patient. Usage of a folded towel will be sufficient.
- In general, you have to consider and treat the magnet in the suction hose equally to magnets and magnet fields you know from mobile phones and other household electronics.
- Pay attention if any acoustic signal occurs from the pacemaker, move the suction hose nipple immediately until the acoustic signal warning tone stops. Potential risk is hereby eliminated.

Instruct relevant professional staff within the organization.

XO CARE has reported the issue and the incident to the relevant authorities.

If you have any questions or concerns regarding this notification, please contact your local distributor or service representative.

With best regards,



Holger Wentzel Olsen,
Managing Director - XO CARE A/S



FSN Acknowledgment Form

With reference to FSN of Monday February 26th 2018.

Please complete this acknowledgment form confirming receipt of the information and send back to:

[Distributor name]

[Street address 1]

[Street address 2]

[City]

[Zip code]

Or via e-mail to: [Distributor contact e-mail address]

Unit serial number	
Clinic	
Address	
Form completed by	
Title/role	
Date	

