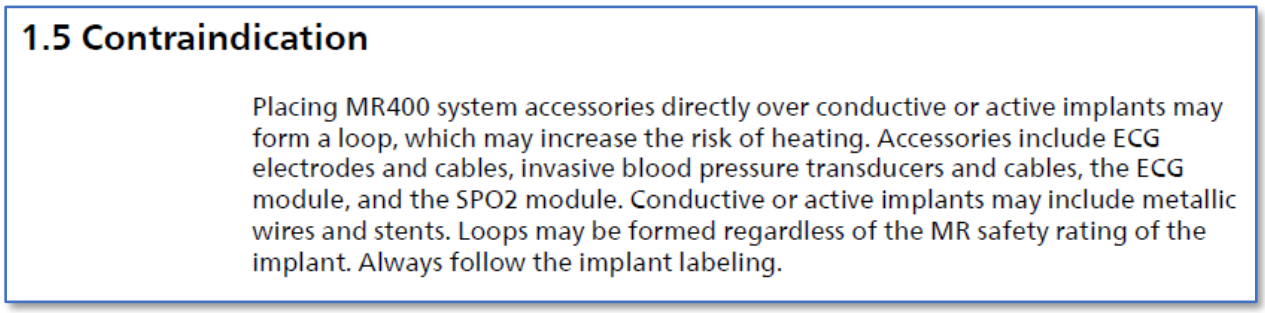
PHILIPS

Subject: New MR400 Instructions for Use Released Date: June 2, 2025

Dear Valued Customer,

Philips understands that you have questions regarding the contraindication and warning concerning implants and pacemakers in the Expression MR400 MRI Patient Monitoring System Instructions for Use (IFU). Beginning June 2025, Philips released a revised IFU that improves readability and clarity surrounding our contraindication and warning. Please refer to the (English) IFU, part number 453665150021 Revision A, released in June 2025.

The revised contraindication states:



1.5 Contraindication

Placing MR400 system accessories directly over conductive or active implants may form a loop, which may increase the risk of heating. Accessories include ECG electrodes and cables, invasive blood pressure transducers and cables, the ECG module, and the SPO2 module. Conductive or active implants may include metallic wires and stents. Loops may be formed regardless of the MR safety rating of the implant. Always follow the implant labeling.

Figure 1: Expression MR400 Instructions for Use, part number 453665150021, revision A, page 2.

There is a general potential risk of radio frequency (RF) induced heating that is present in the MR environment when any conductive or active implants are present, regardless of the MR Patient Monitor in use. MR systems require the use of RF pulses to create the MR signal. When conducting materials are

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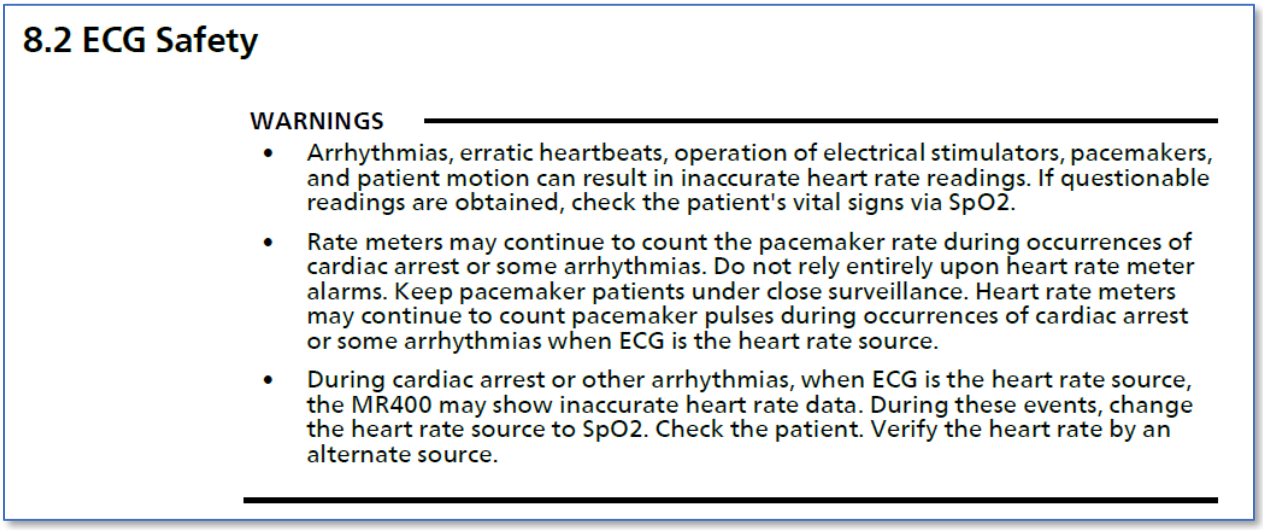
placed within the RF field, the result may be a concentration of electrical currents sufficient to cause excessive heating and tissue damage.

The MR400 Instructions for Use, Chapters 8-13 regarding monitoring the parameters, provides proper placement instructions of all accessories with respect to the patient and the MRI system.

The MR400 Instructions for Use, Chapter 8 “Monitoring ECG”, includes warnings regarding use of the MR400 with patients that have pacemakers or electrical stimulators. This warning is related to the ECG technology which may treat pacer pulses as MRI gradient noise. In this case, the MR400 gradient filtering may remove the pacer waveform while removing the MRI gradient noise that also appears as high frequency pulse-shaped waveforms. For this reason, it is recommended that SpO2 be used as the heart rate source.

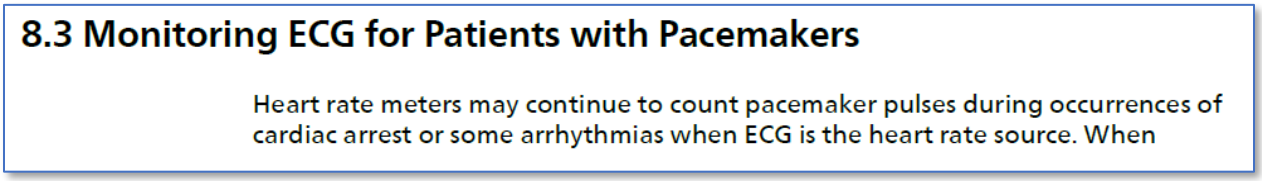


8.2 ECG Safety

WARNINGS

- Arrhythmias, erratic heartbeats, operation of electrical stimulators, pacemakers, and patient motion can result in inaccurate heart rate readings. If questionable readings are obtained, check the patient's vital signs via SpO2.
- Rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon heart rate meter alarms. Keep pacemaker patients under close surveillance. Heart rate meters may continue to count pacemaker pulses during occurrences of cardiac arrest or some arrhythmias when ECG is the heart rate source.
- During cardiac arrest or other arrhythmias, when ECG is the heart rate source, the MR400 may show inaccurate heart rate data. During these events, change the heart rate source to SpO2. Check the patient. Verify the heart rate by an alternate source.

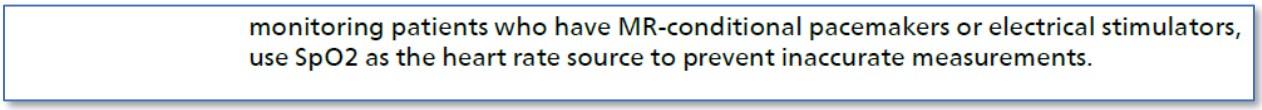
Figure 2: Expression MR400 Instructions for Use, part number 453665150021, revision A, page 87.



8.3 Monitoring ECG for Patients with Pacemakers

Heart rate meters may continue to count pacemaker pulses during occurrences of cardiac arrest or some arrhythmias when ECG is the heart rate source. When

Figure 3: Expression MR400 Instructions for Use, part number 453665150021, revision A, page 87.



monitoring patients who have MR-conditional pacemakers or electrical stimulators, use SpO2 as the heart rate source to prevent inaccurate measurements.

Figure 4: Expression MR400 Instructions for Use, part number 453665150021, revision A, page 88.

Sincerely,

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MR Patient Care

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