SCHILLER MEDICAL
4, rue Louis Pasteur
67160 Wissembourg – France

**Safety notice reference: IM00888**
**April 2025**

# Safety notice
# MAGLIFE RT-1 monitor

For the attention of users of MAGLIFE RT-1 monitors

| Local contact |
|---|
| **Customer assistance:** |

| 1. Device information |
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| 1. Type |
| MAGLIFE RT-1 |
| 2. Trade names |
| MAGLIFE RT-1 |
| 3. Main clinical use of device |
| Monitoring in MRI environments |
| 4. Models concerned by the notice |
| All MAGLIFE RT-1 devices |

| 2 Reason for safety notice |
|---|
| 1. Description of problem |
| The MAGLIFE RT-1 monitor uses radio frequency communication links to report monitoring information to a remote screen, and for some links with sensors connected to the patient. Wireless communication losses have been reported in MAGLIFE RT-1 devices when they are used in an MRI environment. |
| 2. Risk |
| May lead to interruptions in patient monitoring during an MRI examination |
| 3. Source of the problem |
| Instability in radio communication. |

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## 3. Action to mitigate the risk

**Corrective action**

Schiller Medical is developing a new software version that optimises radio frequency communication between the device and its peripheral equipment.
The **SOFT04B01L01** software version is available from your Schiller distributor and must be installed on all your MAGLIFE RT-1 devices.

| | |
|---|---|
| 1. Response required from the user<br>Please see the modalities in the letter from your distributor | YES |

## 4. General information

| | | |
|---|---|---|
| 4. | 1. Type of notice | Initial |
| | Additional information expected while monitoring the FSN? | No |
| | 2. The competent (regulatory) authority of your country has been informed of this notice to customers. | |
| | 3. Surname/signature | Alain Weissinger<br>Quality and Regulatory Affairs Director |

## Circulation of this safety notice

This notice is to be passed on to all those who need to be informed within your organisation or any other organisation to which devices that are potentially concerned have been transferred.