

Project file Module M21: 10.1 Instruction for use (IFU)

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| title | | 10.1 Instruction for use (IFU) | |
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1. Instruction for use of Medical device

1.1. Declaration of conformity

- A declaration of conformity according to R&TTE will be inserted to each instruction for use of the Medical device which uses the Module M21.

1.2. General items

- M21 Reader Module is an integrated part within Draeger Medical devices. The antennas are permanently connected to the M21 via connectors.
- M21 Reader Module has an operational manual. The programming of the Draeger Medical device is based on this document. There is no user interface to the module.

1.3. Mandatory text

- Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment
- The intended use of the M21 will be explained within each instruction for use of the Medical device which uses the Module M21.
- Following text has to be content of the device IFU:
This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.