

DETAILS ABOUT BLUETOOTH CONNECTION AS PER

IEC 60601-1:2005 + A1:2012 + A2:2020,

**for seca scales and for the following seca products:
seca 874 + / seca 874 u+**

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1 Purpose of the PEMS's connection to an IT-NETWORK

- Broadcasting the scale's name to establish the Bluetooth connection with the external system (mobile device)
- Transmitting the weight value of the last measured patient and the scale battery status to an external system (mobile device)

2 Required characteristics of the IT-NETWORK incorporating the PEMS

- The "Bluetooth Low Energy" standard is implemented
- „Body Composition Service“ (BCS) is supported, specification, see: <https://www.bluetooth.com/specifications/specs/body-composition-service-1-0/>
- “Battery service” (BAS) is supported, specification, see: <https://www.bluetooth.com/de/specifications/specs/battery-service-1-0/>

3 Required configuration of the IT-NETWORK incorporating the PEMS

- No configuration required

4 Technical specifications of the network connection of the PEMS including security specifications

- Pairing / bonding of the PEMS is required in order to exchange short term key (STK), long term key (LTK) and identity resolve key (IRK)
- An encrypted connection to the PEMS is required

5 Intended information flow between the PEMS, the IT-NETWORK and other devices on the IT-NETWORK, and the intended routing through the IT-NETWORK

- Information flow PEMS → mobile device
 - Broadcasting of the scale's name
 - Transmission of weight value and the scale battery status

6 List of the HAZARDOUS SITUATIONS resulting from a failure of the IT-NETWORK to provide the characteristics required to meet the purpose of the PEMS connection to the IT-NETWORK

- Bluetooth connection can't be established
 - No transmission of weight value and the scale battery status → no risk for patient, user or third party
- Bluetooth connection breaks off
 - No transmission of weight value and the scale battery status → no risk for patient, user or third party