

Tel-O-Graph<sup>®</sup> Tel-O-Graph<sup>®</sup>GSM plus (030100010)

Technical Datasheet 2.2\_2024-03-06

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Technical data

# 1 Technical data

Scope of the document

Product family Tel-O-Graph<sup>®</sup>

Product registration Tel-O-Graph<sup>®</sup> GSM plus (030100010)

## **General Performance**

Measurement principle	Oscillometric principle Single blood pressure measurement with automatic transmission
Advanced comfort	IGI (Initially Gradual Inflation): Pressure setting for a gentle measurement SST (Soft Slope Technology): Time adaption of measurement according to cuff (S-XL))
	<ul> <li>AF<sup>®</sup> Logic (Auto-Feedback-Logic): Faster and most convenient measurements</li> <li>First measurement: Step-up / Step-down technology</li> <li>From the second measurement: Auto-Feedback-Logic - AF<sup>®</sup> (significantly better night sleep and comfort for the patients through individualized cuff inflation algorithm*)</li> </ul>
PWA functionality	Calculation via license system Key A: Central blood pressure Key B: Full Pulse Wave Analysis Key C: Central blood pressure + Augmentation index @75
Communication	GSM/LTE Infrared
Measurement range	Systolic (SYS): 60 to 290 [mmHg] Diastolic (DIA): 30 to 195 [mmHg] Pulse: 30 to 240 beats per minute
Static pressure range	0 to 300 mmHg
Pressure accuracy	±2 % or ±3 mmHg (whichever value is higher)
NIBP accuracy (non invasive blood pressure measure- ment)	validated according to: ISO 81060-2, BHS (A/A Grading)
Automatic transmis- sion	after each measurement
Power supply	Internal power supply 6 V: Batteries 4 x LR6 or HR6, Size: AA 1,5 V
Operation and control	Display: LCD (70 x 72 mm) Acoustic: Beeper Panel: 1 Multifunction button
Memory	350 measurements 150 measurements Blood Pressure and Pulse Wave Analysis

#### Technical data

Battery capacity	Approx. 500 measurements (in the case of 2 measurements per day with M cuff and high-grade batteries*)
Transport tempera- ture	-25 °C to +70 °C
Transport humidity	15 % to 93 % relative humidity, non-condensing
Operation tempera- ture	+5 °C to +40 °C
Operation humidity	15 % to 93 % relative humidity, non-condensing
Storage temperature	-25 °C to +70 °C
Storage humidity	15 % to 93 % relative humidity, non-condensing
Atmospheric Pres- sure	700 to 1060 hPa
IP Rating	IP 20
Weight	Approx. 355 g (without batteries)
Dimensions	151 x 108 x 57 mm
Material (housing)	ABS (acrylnitrile-butadiene-styrene)
Material (cuff)	Polyester
Expected operational life of the device	5 years
Expected operational life of the cuff	6 months
Product classification	The Tel-O-Graph <sup>®</sup> GSM plus incorporates a Class B software product in ac- cordance with IEC 62304.

#### Performance data of the wireless connections

GSM LTE			
GSM chip	Quectel BG95-M3		
Internet Access	Default for APN, User, Password and DNS released by IEM		

#### **Maintenance Service**

- Remote Service: debugging, transmission status
- Data Synchronisation: ADR (Acknowledgment for data receipt by the database) data integrity (100 % service level)
- Infrared interface: calibration for blood pressure module

#### Cuff sizes

The blood pressure monitor is suitable for people with an arm circumference of 20-55 cm (7.9-21.7 in) when the appropriate size of blood pressure cuff is used.

Arm circumference in cm	Size of blood pressure cuff
20 – 24 cm (7.9 – 9.5 in)	S
24 - 32 cm (9.5 - 12.6 in)	Μ

Arm circumference in cm	Size of blood pressure cuff
32 – 38 cm (12.6 – 15.0 in)	L
38 – 55 cm (15.0 – 21.7 in)	XL

### **Applicable Standards and Directives**

- Directive 93/42/EEC (MDD)
- Directive 2014/53/EU (RED)
- Directive 2011/65/EU (RoHS)
- IEC 60601-1: 2020, IEC 60601-1-2: 2020, IEC 60601-1-6: 2020, IEC 60601-1-11: 2020
- IEC 80601-2-30: 2018
- FCC 47 CFR Part 2, Part 15, Part 22, Part 24, Part 27, Part 90
- FCC KDB 971168 D01 v03r01
- IEEE/ANSI C63.26:2015
- IEEE/ANSI C63.27-2017
- ACMA Act 2005

#### Тір

Use only high-quality batteries. If using less efficient batteries IEM cannot guarantee the operating time specified above. Using batteries of poor quality can reduce operating time to 50 %.

\* Convenience of ambulatory blood pressure monitoring: Comparison of different devices BPMJ 2005, Vol 10 No 10:239-242