

Specificație Tehnică Completată

Anexa 4 Monitor Holter pentru tensiunea arterială

Model: BR-102 PLUS Reg. SDM: DM000708728

Producător: SCHILLER AG

Țara: Elvetia

Specificarea tehnică deplină solicitată, Standarde de referință	Specificația tehnică propusă de ofertant
Perioade de măsurare a TA: 24 -48 și 51(opțional) ore; Metoda de măsurare: Deflație oscilometrică în trepte; Capacitate de măsurare: minim 300 măsurări; Precizie: ± 3 mmHg sau 2% din valoarea măsurată; Manșete aplicabile: Mici, standard și mari; Afișaj: Ecran; Transmitere informații către PC: Da; Masa cu baterii: ≤ 300 g sau masa fără baterii ≤ 200 g; Conform cu standardele internaționale (ex. BHS, AAMI, ESH -IP) Pile electrice format AA de 1,5 V, pile electrice reîncărcabile tip AA de 1,2 V	Perioade de măsurare a TA: 24 -48; DA, Technical data_BR-102 Metoda de măsurare: Deflație oscilometrică în trepte; DA, Technical data_BR-102 De asemenea există și alt regim „Auscultator (Korotkoff/Riva-Rocci) împreună cu oscilometric. Capacitate de măsurare: 400 măsurări; DA, Technical data_BR-102 Precizie: ± 3 mmHg din valoarea măsurată; Measuring range Blood pressure 25 to 300 mmHg (± 3 mmHg) DA, pag. 59 din User manual_BR-102 Manșete aplicabile: Mici, standard și mari; DA, Technical data_BR-102 Afișaj: Ecran; DA, Prezentare BR-102. În plus sunt 2 butoane pentru navigare. Transmitere informații către PC: Da, Prezentare BR-102 Există program Darwin 2. Sunt 4 ferestre exclusiv pentru măsurarea și analiza măsurătorilor tensiune arterială: BP trend, BP histogram, BP statistics, Print. BP trend: HR, Systolic, Diastolic, MAP, PP, RPP; BP histogram: Systolic BP, Diastolic BP, Mean BP(MAP), PP (pulse pressure), Heart rate, RPP (rate pressure product) BP Statistics: Period, Duration, Measurements, SYS Limit, DIA Limit, Systolic, Diastolic, MAP, HR, PP, BP Load, BP Load, Asleep Dip, Asleep Dip, BP Classification, RPP Index Masa cu baterii: 200 g cu baterii DA, Technical data_BR-102 Conform cu standardele internaționale (ex. BHS, AAMI, ESH -IP) Da, Prezentare BR-102 Acumulator reîncărcabile, 2 unități DA, Technical data_BR-102 În plus se oferă Stație de încărcare pentru acumulator.



Technical Data

BR-102 plus

System

Device

Dimensions: 100 x 68 x 28 mm (l/w/h)

Weight: 200 grams (including batteries)

Ambient condition

Temperature

- Operation: 10 to 40 °C
- Transport/storage: -10 to 50 °C

Humidity

- Operation: 15 to 95 % non-condensing
- Transport/storage: 10 to 95 % non-condensing

Pressure

- Operation: 700 to 1060 hPa
- Transport/storage: 500 to 1060 hPa

Electrical data

Power: 2 rechargeable NiMH batteries (≥ 2700 mAh), type "AA"¹

Display: Colour OLED display with multi-language menu

Interface: USB interface for data transfer

PC Requirements: USB port

Data Storage: Flash memory and microSD card stores up to 400 readings and 30 s of voice recording

Blood pressure module

Programming: Menu guidance; 2 buttons

Measurement duration: 24 hours or 48 hours

BP Technique: Auscultatory (Korotkoff / Riva-Rocci) and oscillometric or only oscillometric, both with linear adjustable deflation

BP Range: 25 – 300 mmHg

HR Range: 25 – 300 bpm

Deflation Speed: 2 – 9 mmHg/s or automatic (3 mm/Hg per beat)

Recording programs: 4 programs with max. 8 modifiable measurements cycles

Measurement intervals: 5 – 120 min

Manual measurement: the patient can trigger an additional measurement at any time during a recording.

¹ We recommend using SCHILLER batteries exclusively, as their capacity and quality has been tested. Care should always be taken that the batteries capacity equals or exceeds 2700 mAh.

Accessories

Standard

Schiller cuff (Size Adult M)

4 NiMH rechargeable batteries

Battery charger

Carrying pouch, patient belt and shoulder strap

USB interface cable

DARWIN2 Software

User guide

Optional

SCHILLER Cuff

- **XS:** (14 – 20 cm) / 2.120063 (only oscilometric)

- **S:** (18 – 24 cm) / 2.120064

- **M:** (25 – 35 cm) / 2.120065

- **L:** (30 – 36 cm) / 2.120066

- **XL:** (35 – 46 cm) / 2.120067

SCHILLER Cuff D-ring

- **S:** cuff D-ring Small / 2.120076

- **M:** cuff D-ring Medium / 2.120077

- **S:** cuff D-ring Large / 2.120078

SCHILLER Comfort sleeve

- **XS:** 2.120068

- **S:** 2.120069

- **M:** 2.120070

- **L:** 2.120071

- **XL:** 2.120072

Single use pouches (50 pieces) 2.156086

Carry case 2.156079

Warranty

See general terms of condition on www.schiller.ch

Standards

Certification

Safety Standards: IEC 60601-1; IEC 80601-2-30; ISO 81060-1; IEC 1060-3; IEC 60601-1-2

Protection Class: Internal power supply

Applied Part: BF according to IEC/EN 60601-1

Conformity: CE according to Annex II 93/42/EEC (medical devices)

Classification: IIa according to MDD 93/42/EEC

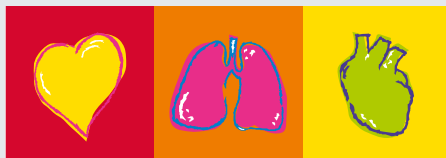
Notified body: CE⁰¹²³





BR-102 plus

SCHILLER's Ambulatory Blood Pressure Monitoring System combines outstanding accuracy and comfort



SCHILLER
The Art of Diagnostics

BR-102 plus

A must-have for ambulatory blood pressure monitoring

The latest version of our established BR-102 plus device results from over 30 years' experience and close collaboration with renowned experts. Ambulatory blood pressure monitoring (ABPM) is considered the gold standard for blood pressure measurement by physicians worldwide. This method provides valuable diagnostic information that stationary hospital or home equipment is unable to provide, such as BP variability, nocturnal BP, as well as nocturnal BP fall and morning BP surge.

SCHILLER's ambulatory blood pressure monitoring system combines two measurement techniques – the auscultatory and the oscillometric – in one: both are used in parallel! This reliable combination ensures correct readings every time.

Furthermore, since the cuff will only inflate as much as necessary, it is hardly possible to hear or feel the BR-102 plus anymore. This added comfort leads to extremely accurate results that can be processed and analysed properly by the evaluation software DARWIN2 ABPM.



Accuracy you can rely on

The BR-102 plus is clinically validated and meets all four internationally recognised standards:

- British Hypertension Society (BHS)¹
- European Society of Hypertension International Protocol (ESH)¹
- Association for the Advancement of Medical Instrumentation (AAMI) SP10
- Recommended by dabl® Educational Trust

¹ Test in progress

Optimal patient comfort for precise results

- Motion-tolerant technology prevents re-inflation and failed readings
- Dynamic inflation to 30 mmHg above the previous systolic reading reduces measurement time
- Built-in pump, and thus almost silent
- Five cuff sizes, from the pediatric to the XL adult size, guarantee optimal measurement accuracy and maximum comfort

DARWIN2 ABPM

Analysis, interpretation and reporting

DARWIN2 ABPM is a user-friendly, Windows®-based program that allows maximum flexibility for configuration, analysis, interpretation and ABPM reporting. Comprehensive and professional reports can be generated in no time.

Interpretive summary

Automated analysis of ABPM levels for normality and nocturnal fall according to the AHA¹, ESH² or JNC7³ guidelines.

White-coat analysis

The first-hour data is compared to the full 24-hour results. The software indicates whether the patient presents with a white-coat hypertension.

One-page report

The one-page report includes ABPM graph, interpretive summary, nocturnal BP fall analysis, and statistics with selected patient data.

Clear presentation of statistical results

Statistics are provided for awake and asleep phases as well as for all other phases, and include average blood pressure, heart rate, pulse pressure, mean arterial pressure and BP load.

¹ Recommendations for blood pressure measurement in humans, American Heart Association, 2005.

² ESH/ESC Guidelines for the management of arterial hypertension, 2013.

³ Seventh report of the joint national committee on prevention, detection, evaluation, and treatment of high blood pressure, 2003.

An ultramodern and versatile device

- Light and compact design
- Simple to set up and operate
- Intended use: white-coat hypertension, drug-resistant hypertension, masked hypertension, hypotensive symptoms with antihypertensive medications



Create clear reports quickly and easily using the DARWIN2 modular reporting system. The level of detail and appearance of reports can be customized at will.



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