

### BEDIENUNGSANLEITUNG BLUTDRUCKMESSGERÄTE ANEROID





# XXL Guarantee. You have trusted in us FOR 130 YEARS. Thank you.

Trust must be earned. Through continuity and sustainability. As a fourth generation family company, we at ERKA. stand by our promise of "Quality Made in Germany". Those who choose an ERKA. product are consciously seeking the highest quality and durability. We are convinced of the quality of our products – as demonstrated by the ERKA. XXL Guarantee. Register your product up to 4 weeks after your purchase at www.myerka.de and get an additional warranty of up to five years - free of charge. NO IFS OR BUTS.

# XXL Garantie. Sie vertrauen auf uns SEIT 130 JAHREN. Vielen Dank

Vertrauen muss man sich erarbeiten. Durch Kontinuität und Nachhaltigkeit. Als Familienunternehmen in der vierten Generation stehen wir bei ERKA. zu unserem Versprechen Qualität "Made in Germany". Wer sich für ein FRKA. Produkt entscheidet, sucht bewusst höchste Oualität und Langlebigkeit. Wir sind von der Oualität unserer Produkte überzeuat das beweist die ERKA. XXL Garantie. Registrieren Sie Ihr Produkt nach dem Kauf unter www.myerka.de und sichern Sie sich eine zusätzliche Garantiezeit von bis zu fünf Jahren – zum Nulltarif, OHNE WENN UND ABER.

## 360° SERVICE Global expertise from a single source

Do you have any questions about our products, their use or maintenance?

ERKA. products and services, our expert ERKA. Service Team is happy to provide advice and support at the following phone number +49 8041 8009-0.

For all your needs concerning

or by E-mail to service@erka.org.

\*Our telephone consultation service can be reached on weekdays between 8:00 a.m. and 5:00 p.m.

### 360° SERVICE globale Kompetenz aus einer Hand

Sie haben Fragen zu einem unserer Produkte, zu dessen Anwendung oder Instandhaltung?

Von A wie Auftragserteilung bis Z wie Zertifiziert nach DIN EN ISO 13485 - unser kompetentes ERKA.-Serviceteam berät und unterstützt Sie gerne persönlich unter der Rufnummer +49 8041 8009-0\*

oder per E-mail an service@erka.org.

\*Unsere Telefonberatung ist für Sie werktags von 08:00 bis 17:00 Uhr erreichbar.

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# USER MANUAL ANEROID SPHYGMOMANOMETERS

Register your device at www.myerka.de

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#### EXPLANATION OF SYMBOLS I LÉGENDE I ERKLÄRUNG DER SYMBOLE I EXPLICACIÓN DE SÍMBOLOS I SPIEGAZIONE DEI SIMBOLI:



Please pay attention to the accompanying User Manual.

Veuillez lire le mode d'emploi ci-joint.

Bitte beiliegende Bedienungsanleitung beachten.

Por favor, tenga en cuenta el manual de instrucciones adjunto. Si prega di osservare le allegate istruzioni per l'uso.



This product complies with the Council Directive 93/42/EEC concerning medical devices

> Ce produit est en conformité avec la directive 93/42/CEE du Conseil pour les dispositifs médicaux

Dieses Produkt entspricht der Richtlinie 93/42/EWG

des Rates über Medizinprodukte

Este producto se corresponde con la directiva 93/42/CEE

del Consejo relativa a productos sanitarios.

Questo prodotto è conforme alla Direttiva 93/42/CEE del Consiglio in materia di prodotti medicali.



#### Serial number

You will find the serial numbers of our devices on the front or on the back side of the device. The first two digits correspond to the year of production.

#### Numéro de série

Vous trouverez les numéros de série de nos appareils à l'avant ou à l'arrière de l'appareil. Les deux premiers chiffres correspondent à l'année de production.

#### Seriennummer

Die Seriennummern unserer Geräte finden sie entweder auf der Skala oder auf der Geräterückseite. Die ersten beiden Ziffern geben das Herstellungsjahr wieder.

#### Número de serie

Encontrará los números de serie de nuestros dispositivos en la parte anterior o en la parte posterior del dispositivo. Los primeros dos dígitos corresponden al año de producción.

#### Numero di serie

Troverete i numeri di serie dei nostri dispositivi sul lato anteriore o sul retro del dispositivo. Le prime due cifre corrispondono all'anno di produzione.



Latex free Sans latex

Latexfrei Libre de látex Privo di lattice



PVC free Sans PVC PVC-frei

Libre de PVC Privo di PVC



DEHP free Sans DEHP DEHP-frei Libre de DEHP Senza DEHP





#### LOT number

Thanks to the lot numbers on the bladders the products can be traced.

#### Número de lote

La traçabilité est assurée par le biais du numéro de lot sur les poches.

#### LOT Nummer

Die LOT Nummer ist auf den eingezogenen Blasen der Manschetten zu finden und dient zur Nachverfolgbarkeit

Los números de lote en las cámaras de aire sirven para asegurar la trazabilidad de los productos.

#### Numero di lotto

Grazie al numero di lotto sulle camere d'aria i prodotti possono essere rintracciati.



Catalogue number Numéro de catalogue Katalognummer Número de catálogo Numero di catalogo



Caution Attention Achtung Atención

Attenzione



Fragile: Handle with care! Fragile, à manipuler avec précaution

Zerbrechlich, mit Sorgfalt handhaben Frágil, manipular con cuidado Fragile, manipolare con cura



Temperature threshold Limite de température Temperaturbegrenzung Limitación de la temperatura Limitazione della temperatura



Manufacturer **Fabricant** Hersteller **Fabricante** Produttore



Store in a dry place À stocker dans un endroit sec Trocken aufbewahren Conservar en seco Conservare in luogo asciutto



Humidity threshold Limite d'humidité de l'air Luftfeuchte Begrenzung Limitación de la humedad del aire Limitazione umidità dell'aria



Limb circumference, length, width Circonférence du bras/

de la jambe, longueur, largeur Extremitäten Umfang Spannung, Bereich, Weite Circunferencia del brazo/ de la pierna, longitud, anchura Circonferenza del braccio/ della gamba, lunghezza, larahezza



# USER MANUAL ANEROID SPHYGMOMANOMETERS

#### TABLE OF CONTENTS:

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#### 1 IN GENERAL

Dear Customer,
With this blood pressure cuff, you have purchased a quality product
from ERKA. We are delighted that you have expressed your confidence in ERKA. quality and we thank you for doing so. We have a wide range of blood pressure cuffs in
various models. High quality materials that are suitable to the task guarantee optimal
operation. If you have questions regarding the right choice or the operating of your
blood pressure cuff,

you can direct them to service@erka.org. We would be happy to help you.

Please read this user's manual before use carefully and thoroughly and follow the instructions for maintenance and keep the manual for further use. Important for home users: Consult your doctor at regular intervals. He will tell you your individual values for normal blood pressure, as well as the value at which the level of the blood pressure is considered hazardous.

#### 2 PRODUCT DESCRIPTION

#### PURPOSE

The aneroid sphygmomanometers of ERKA. are used for measuring blood pressure as per the method of auscultation of measurement on healthy skin on the upper arm and/or on the thigh.

#### MEASURING RANGE

The reading scale has a measurement of 0 - 300 mmHg. The accuracy of measurement is  $\pm /-3$  mmHg over the entire measuring range.



#### MEASURING RANGE

The reading scale has a measurement of 0 - 300 mmHg. The accuracy of measurement is +/- 3 mmHg over the entire measuring range.

#### SIDE EFFECTS

No side effects are known so far.

#### BLOOD PRESSURE MONITORS

#### VARIO

Sphygmomanometer with a very large scale (140 mm) for optimum readability. In addition to the model as a desktop device, the Vario also that complies with all the requirements of modern medicine as a rail unit, wall-mounted or stand-mounted device.

#### PERFECT ANEROID Ø 48 MM

The reference in precision and durability with membrane-friendly dual tube technology.

#### PERFECT ANEROID Ø 56 MM

The reference in precision and durability with membrane-friendly dual tube technology with extra large scale.

#### PERFECT ANEROID CLINIC MODEL Ø 48 MM

Specially developed for the sometimes hectic daily hospital routine with protective cap for pressure gauge.

#### PERFECT ANEROID CLINIC MODEL Ø 56 MM

Especially for the sometimes hectic daily hospital routine with protective cap for pressure gauge designed with extra large scale.

#### PROFIØ 48 MM

Precision instrument with membrane-friendly dual-tube technology.



#### PROFIØ 56 MM

Precision instrument with membrane-friendly dual tube-technology and extra large scale.

#### PROFESSIONAL CLINIC MODEL Ø 48 MM

Precision instrument with membrane-friendly dual tube technology and cap, specifically for the needs of the day-to-day routine at the hospital.

#### KOBOLD Ø 48 MM

Robust and reliable measurement instrument for the professional user with single tube technology. The special hardened copper-beryllium diaphragm for long life with consistently high precision.

#### KOBOLD SMART Ø 48 MM

The innovative Smart concept with single tube technology for 100% hygiene in dealing with patients.

#### SWITCH 2.0 COMFORT Ø 56 MM

Functional and convincing in daily use. Meets the requirements for use in an MR space. Sparing resources by changing quickly within seconds of the load cell by the user on site.

#### SWITCH 2.0 SMART Ø 56 MM

Flexible and in function, the SMART SWITCH 2.0 can be transformed with a movement from a right-handed to a left0handed device. Meets the requirements for use in an MR space.

#### SWITCH 2 0 SIMPLEX Ø 56 MM

Maximum innovation characterizes this instrument. Fast and intuitive change of the load cell to be carried out by the user.



#### OVERVIEW OF DEVICES AND CUFFS

VARIO	Green Cuff Superb Rapid, 2 separate tubes Green Cuff Superb Haken, 2 separate tubes Classic Rapid, 2 separate tubes		
PERFEKT ANEROID	Green Cuff Superb Rapid, Double tube Green Cuff Superb Haken, Double tube Classic Rapid, Double tube		
PROFI	Green Cuff Superb Rapid, Double tube Green Cuff Superb Haken, Double tube Classic Rapid, Double tube		
KOBOLD	Green Cuff Superb Rapid, 1 tube Green Cuff Superb Haken, 1 tube Classic Rapid, 1 tube		
KOBOLD SMART	Green Cuff Smart Rapid, 1 tube		
SWITCH 2.0 COMFORT	Green Cuff Superb Rapid, 1 tube Green Cuff Superb Haken, 1 tube Classic Rapid, 1 tube		
SWITCH 2.0 SMART	Green Cuff Smart Rapid, 1 tube		
SWITCH 2.0 SIMPLEX	Green Cuff Superb D-Ring, 1 tube		
ERKATEST	Green Cuff Superb D-Ring, Double toubulure		
SWITCH 2.0 HOMECARE	Green Cuff Superb D-Ring, 1 tube		

#### PUTTING ON THE CUFF

Select appropriate cuff size for the extent of the extremities. The cuff is applied in such a way that the lower edge of the cuff is found about.

 $2\ {\rm to}\ 3\ {\rm cm}$  above the crook of the arm o approx.  $5\ {\rm cm}$  above the knee joint. Note the marking for the location of the artery while doing so.

Do not wrap the cuff too loose and not too tight around the limb and make sure that the edge of the mark is within the permissible range. Close the valve of the air release valve. With a few pumping of the fan of the ball, the necessary pressure (ca. 30 mmHg above the systolic pressure to be expected) is created in the cuff. The valve is opened slowly and speed deflation rate is measured out from 2 to 3 mmHg per second. With the aid of a stethoscope the Korotkoff flow sounds can be auscultated. After the measurement is completed, open the valve for complete deflation of the cuff.

#### TO ENSURE A CORRECT READING

Blood pressure measurement must be taken in sitting position.

- Take a comfortable sitting position
- Do not cross your legs
- During the measurement, sit in a chair with your feet on the floor and your back and arm supported
- Make sure the middle of the cuff is placed at the level of the right atrium
- For measurement in seating position: Be calm. Sit quietly for five minutes before the test begins. Your arm should rest on a table. Be still during the measurement: do not move and do not speak, otherwise measurement results will not be correct.

# RECCOMENDATIONS ON AUSCULTATORY METHOD OF MEASURING BLOOD PRESSURE:

- Adults, mode V (K5)
- Children from 3 to 12 years old, mode IV (K4)
- Pregnant women mode V (K5), except those cases where some sounds appear as the blood pressure cuff is deflated in this case the mode IV (K4) of the Korotkoff sounds must be used.



K5 is the point where the sounds normally heard with the stethoscope are no more audible.

K4 is the point where the sounds heard with the stethoscope change from clear tapping sounds to dull sounds.

#### 4. SELECTION OF THE CUFF SIZE

The following table provides information on the relevant Application:

Size 1	Infant	10.0 to 15.0 cm circumference	Free of PVC, DEHP and latex	
Size 2	Toddler	14.0 to 21.5 cm circumference	Free of PVC, DEHP and latex	
Size 3	Adults Small	20.5 to 28.0 cm circumference	Free of PVC, DEHP and latex	
Size 4	Grown-ups	27.0 to 35.0 cm circumference	Free of PVC, DEHP and latex	
Size 5	Adults Large	34.0 to 43.0 cm circumference	Free of PVC, DEHP and latex	
Size 6	Thigh	42.0 to 54.0 cm circumference	Free of PVC, DEHP and latex	

#### IMPORTANT INFORMATION



Check the aneroid sphygmomanometers before each use as to its proper function. Do not use this product when it shows visible damage.

- The Medical Products Operator Ordinance is applicable for Germany
- It is a preventive healthcare measure, it doesn't substitute the regular monitoring of the blood pressure by healthcare professionals
- The interpretation of the results of the measurement should only be done by qualified persons



- Do not pump up the manometer above 300 mmHg by any means
- Infants have a lower blood pressure than adults, do not pump too strong
- The measurement time should not exceed two minutes
- The cuff should be used with hygiene protective strips or cleaned before it is used for the next patient
- The products should not be placed in a strong magnetic field (except SWITCH 2.0 and SWITCH 2.0 SMART) and used, such as: MRI
- Avoid using your device outdoors or in an ambulance
- Only use original ERKA spare parts
- Avoid unnecessary vibrations of the instrument
- Avoid damaging the rubber parts with sharp or pointed objects
- Changes to the device are not permitted

#### DISPOSAL

The devices must be disposed of in accordance with the regulations in force in your country.

#### SWITCH 2.0: EXCHANGE OF MANOMETER HEAD













#### SWITCH 2.0: ADJUSTMENT FOR LEFTHANDER OR RIGHTHANDER





# MR SUITABILITY OF THE SWITCH 2.0 COMFORT AND SWITCH 2.0 SMART

In combination with the Rapid cuffs, the manometer was tested for operational capability in magnetic resonance space (MR) according to the requirement of ASTM F2052 - 06e1 (Standard Test Method For Measurement Of Magnetically Induced Displacement Force on Medical Devices

In Magnetic Resonance Environment). Both the functionality requirements, as well as electromagnetic attractive force were in an area filled with 3 Tesla. This is indicated by the marking "MR Conditional" on the scale

#### CALIBRATION

On the back of the manometer, there is a square sticker with the words "MTK" and the "year specification", in which the next calibration of the instrument is required. The metrological control (MTK) must be performed every 2 years, according to the latest Medical Devices Operator Ordinance (MPBetreibV). This can be done by the manufacturer or authorized maintenance services.

You can contact the ERKA. service team at +49 8041 8009-0 or by email to service@erka.org.

Even for private use, we recommend that you perform a metrological check in 2-year intervals through the company ERKA.

Please note that instead of MTK in the model SWITCH 2.0, the manometer head is easily replaced by a new one. The manometers of SWITCH2.0 are not designed for a readjustment.



#### 6. MAINTENANCE AND CARE

#### MANOMETER

The manometer is basically maintenance-free. We recommend that you use a damp cotton or microfiber cloth netted with disinfectants, if necessary. Avoid the penetration of liquids into the cabinet.

#### **CUFFS**

CARE INSTRUCTIONS	Green Cuff Superb	Green Cuff Smart	Classic Cuff	
	<ul><li>Rapid</li><li>Hook</li><li>D-Ring</li><li>Home</li></ul>	<ul><li>Rapid</li><li>Rapid</li><li>one piece</li></ul>	● Rapid	
WASHING	After removing the bladder up to 30° C mild detergent	After removing the bladder up to 30° C mild detergent (not Green Cuff Smart Rapid one piece)	After removing the bladder up to 90° C mild detergent	
Fold covers with Rapid stopper before washing, so that the				

Fold covers with Rapid stopper before washing, so that the Velcro tape and the hook tape are closed to each other.

CLEANING BY SPRAY DISINFECTANT OR WIPE DISINFECTANT

We recommend the following cleaning agents and disinfectants:

Mild Soap, Bacillol AF, Meliseptol, Oxivir Plus Spray, Terralin Protect 70% isopropyl alcohol, Fugaten® Spray (Lysoform-Spray)

After cleaning/disinfecting, wipe with clean water to remove any residue and allow to air dry. Please only use soft cotton or microfiber cloths.

Never use autoclaving!



#### **ENVIRONMENTAL CONDITIONS**

- Optimal is a storage/use at temperatures between 0° C and +40° C and a relative humidity of less than 85%.
- Do not expose the cuff and the appliance directly to direct UV irradiation, this is particularly applicable for all plastic parts.

#### 7. XXL-WARRANTY

Those who opt for a ERKA. product, is deliberately seeking the highest quality and durability. We are confident in the quality of our products - as demonstrated by the ERKA. XXL Warranty! Register your product after purchase and ensure an additional warranty period of up to 5 years, apart from the statutory warranty of 2 years - at no cost. An overview about the warranty periods for different blood pressure monitors on our homepage. Each aneroid sphygmomanometer is provided with a unique serial number on the chest piece and should be appropriately registered on our website www.myerka.de.

At our discretion, we shall remove all defects, which refer to the material or manufacturing defects by repairing or exchanging the device free of charge. Parts that have undergone wear and tear as well as damages due to improper treatment/handling are exempted from the warranty. The warranty expires for interventions that were not performed by authorized service partners, as well as while using replacement parts that are not from ERKA. With proper care, there can be a usage far beyond the warranty period.

If you have any questions, one of our friendly staff will be happy to help you at  $+49\,8041\,8009-0$ .

In the event of a warranty claim, please send the complete device with your purchase receipt.









