

Specificația completată

Modelul: ECOSound Producător: Medical Econet GmbH, Țara: Germania

Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină propusă de către autoritatea ofertantă
Doppler fetal portabil Măsoară ritmul cardiac la făt Display LCD color, ≥ 1.5 inch Frecvența ultrasunetului de lucru 1 MHz, $\pm 5\%$ Posibilitatea de a auzi bătăile inimii fătului de la 10 săptămâni da Mod de lucru Doppler pulsatoriu Rata de ritm cardiac fetal: $\geq 50-210$ batai / min Putere de ieșire audio: ≥ 1 W Acuratețea $\pm 1\%$ sau ± 2 bpm Alimentarea, baterii reîncărcabile Da, incluse în set Timp de functionare de pe barie min 5 ore Gel de contact Flacon 250ml – 2 buc. Încărcător pentru baterii Da, de la rețea 220V	Doppler fetal portabil DA Măsoară ritmul cardiac la făt DA Display LCD color, - 1.5 inch DA Frecvența ultrasunetului de lucru 2 MHz, $\pm 5\%$ DA Posibilitatea de a auzi bătăile inimii fătului de la 10 săptămâni DA Mod de lucru Doppler pulsatoriu DA Rata de ritm cardiac fetal: 40-240 batai / min DA Putere de ieșire audio: 1.2 W DA Acuratețea $\pm 2\%$ sau ± 1 bpm DA Alimentarea, baterii reîncărcabile DA , incluse în set Timp de functionare de pe barie min 5 ore DA Gel de contact Flacon 250ml – 2 buc. DA Încărcător pentru baterii , de la rețea 220V DA



medical **ECONET**
GERMANY

ECOsound

Easy-to-use pocket size fetal doppler



User-friendly hand-held fetal doppler

ECOsound fetal doppler of medical ECONET securely accompany women through all stages of their pregnancy.

ECOsound is a pocket-size Ultrasound Doppler irradiates ultrasound wave to the abdomen of a pregnant woman to detect the Doppler frequency signal and analyze, and displays the heart rate on the LCD screen. The device also provides the heart sound from the heart of the fetus through a built-in speaker. By measuring the fetal heart rate(FHR), you are able to predict fetal well-being.

It is designed for the professional uses with 2 MHz of Sensitivity which provides better penetration and early detection of heart signal. Also, active Noise reduction technology and separate Ultrasound probe allow optimize sound quality.

Features and Benefits

- Clear LCD with backlight battery status
- Ultra sensitive 2 MHz transducer
- Suitable for clinical and home use
- User-friendly design
- Audio output for headphones
- Easy to handle
- Compact size and light weight
- Increase sensitivity after 10~12th weeks
- LCD display: battery status and heart rate
- Heart Rate Range: 50-240 bpm
- Easy to detect fetal heartbeat
- 1.2 W integrated loudspeaker with stepless volume control
- Battery Life up to 360 minutes for continuous measurement
- Ultra-sensitive 2 MHz transducer with approx. 1,5 m cable
- Active noise reduction to optimize signal quality
- Automatic shutdown after 5 minutes
- Waterproof probe (IPX7)
- Equipped with sound card as a PC interface
- Supplied with bag, ultrasound gel and 2 AA batteries

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Application of ECOsound

Usually, during pregnancy women regularly counts their baby's movements to make sure it's alright and spend a lot of time and energy worrying about its well-being. ECOsound is the simplest and easiest way to check the health of the fetus. The device can be used by medical personnel in clinics or pregnant women's homes, as well as by users who have not trained.



Main functions of ECOsound

- Compact-sized and lightweight devices enable the user to take fetal doppler where you need it.
- 2MHz ultrasound sensitivity helps the user to confirm the well-being of fetal.
- The device can operate up to 360 minutes on two AA batteries.
- It has IPX7 waterproof probes which withstands up to 1 meter of water for over 30 minutes.
- A large LCD screen displays users to see battery consumption and FHR.



ECOsound

Easy-to-use pocket size fetal doppler

Specifications

Dimension

Main unit:	75 (W) x 26 (D) x 128 (H) mm
Probe:	25 (W) x 25 (D) x 131 (H) mm
Weight:	190 g

Fetal Heart Rate

Ultrasound frequency:	2 MHz
Range:	50 bpm to 240 bpm
Accuracy:	± 2%
Resolution:	1 bpm
Intensity:	< 10 mW/cm ²
Sensitivity:	10 ~ 12 weeks onward

Audio Output

Output:	1.2 W
Earphone jack:	3.5 mm

Auto shut off

Sound off:	1 min
Power off:	5 min

Power

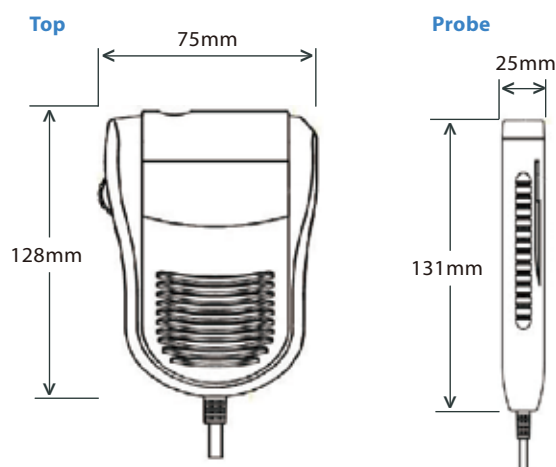
Battery:	1.5 V x 2ea, AA type
Operating time:	360 min

Environmental Conditions

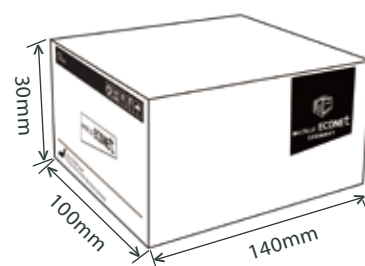
Operating temperature:	10 °C to 40 °C (50 °F to 104°F)
Operating humidity:	30% to 85%, non-condensing
Storage temperature:	-10 °C to 60 °C (14 °F to 131°F)
Storage humidity:	20% to 95%, non-condensing

Accessory

Standard	Carrying pouch	1 ea
	Ultrasound gel	1 ea
	AA Battery	2 ea



Packaging



Approx. 200 g





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Guide

Cleaning and Disinfection

As influenza and epidemics become more frequent around the world than before, demands to prevent nosocomial infections are becoming important. In particular, Cleaning and disinfecting medical devices are the most fundamental way to prevent infections. We provide these guides to ensure our clients, patients, and clinicians to stay safe and to mitigate infections.

Fetal



ECOTwin LED / ECOTwin LCD / ECOsound / Smart 1 / Smart 3

ECG



Cardio M / Cardio M Plus / PHYSIO PORT
Cardio M-Holter LZ EKG / Cardio E3 / Cardio M-PC

Patient Monitor



COMPACT 5/7/9



PROVIEW 10/12



M10

Cleaning and disinfection should be done in appropriate ways and agents. If medical devices exposed to unapproved agents, it could occur medical-related infections or damage to the device of plastic components. Therefore, we recommend several agents to ensure safe disinfection and cleaning. Please note the devices listed, and find the proper disinfectants as below.

BDM



Excellus / Primus / inus D
inus S

Recommended cleaners and disinfectants for medical ECONET devices

To reduce possibility of device damage and the spread of pathogens, we recommend the following wipe and liquid products. All of these wipes are ready-to-use and alcohol-free products. So they can be used to disinfect the surfaces of alcohol-sensitive medical devices simply and efficiently. And the liquid products are supplied as a concentrate. Therefore, the concentration should be properly adjusted according to the intended use. Also these products can be used with cloths or wipes.

Wipes

MyClean® Wipes DS OA

80.10-5521

Mikrobac® Tissues

80.10-5521

CLEANISEPT® WIPES

80.10-5521

Liquid



HIMID® SinAlc sensitive

46.20-5141

Optisept®

80.10-5521

Mikrobac® forte

80.10-5521





Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)

(Devices in Class IIa, IIb or III)

No. G1 056586 0013 Rev. 00

Manufacturer:

Medical Econet GmbH

Im Erlengrund 20
46149 Oberhausen
GERMANY

Facility(ies):

Medical Econet GmbH
Im Erlengrund 20, 46149 Oberhausen, GERMANY

**Product Category(ies): ECG Recorders, Patient Monitors,
Fetal Monitors, Medical Diagnostic
Software, Mobile X-ray Generators,
Bone Densitometers**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

713146223

Valid from:

2018-12-05

Valid until:

2023-12-04

Date,

2018-12-04

Stefan Preiß

EC Declaration of Conformity

According to Annex II of MDD

93/42/ECC dated 14th of June 1993

we,

Medical ECONET GmbH

Im Erlengrund 20
46149 Oberhausen
Germany

declare in own responsibility, that following products

Product name:

Ultrasound Fetal Doppler System: "ECOsound"

Medical Device Class: IIa

UMDNS: 11-696

are manufactured according to guideline 93/42/EEC and fulfil the essential requirements according Annex I of above mentioned guideline. The technical documentation will be kept under above mentioned address.

Applied standards are quoted in the list of documents.

CE 0123

TÜV SÜD PRODUCT SERVICE GmbH, Ridlerstrasse 65, 80339 München

This declaration is valid for all deliveries after the date of issue, until the next change of the product, but no longer than until the expiration of the certificate with the No. G1 056586 0013 Rev. 00, on 04.12.2023

Oberhausen, 05.12.2018

.....
(date and place of issuing)

.....

(General Management)



ECOsound

Einfach zu bedienender fetaler
Taschendoppler

großes LCD Display für die Anzeige der Herzrate
und des Batteriezustands

hochsensible 2 MHz Sonde, wasserfest

integrierter Lautsprecher

Audio Ausgang für Kopfhörer

Rauschunterdrückung für optimale Signalqualität

ca. 6 Stunden Betriebszeit bei durchgehender Messung

Automatische Abschaltung



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Technische Spezifikationen

Modell	ECOsound
Display	LCD Display mit Batterieanzeige
Messbereich der Herzrate	50-240 bpm
Genauigkeit	± 2 %
Ultraschallfrequenz	2 MHz
Ultraschallintensität	<10mW/cm2
Lautsprecher	1.2 W integrierter Lautsprecher
Audio Ausgang für Kopfhörer	ja
Automatische Abschaltung	nach 5 Minuten
Stromversorgung	2 x AA Batterien, 1.5V
Empfindlichkeit	ab der 10ten Schwangerschaftswoche



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f: +49 (0)208 / 377 890 - 55 www.medical-econet.com

Fachhändler

*Änderungen vorbehalten



Certificate

No. Q5 056586 0014 Rev. 00

Holder of Certificate:**Medical Econet GmbH**

Im Erlengrund 20
46149 Oberhausen
GERMANY

Facility(ies):

Medical Econet GmbH
Im Erlengrund 20, 46149 Oberhausen, GERMANY

See Scope of Certificate

Certification Mark:**Scope of Certificate:**

Design and development, production, sales and service of active monitoring systems, medical diagnostic software, mobile X-ray generators, bone densitometers, as well as sales and service of medical products

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:

www.tuvsud.com/ps-cert?q=cert:Q5 056586 0014 Rev. 00

Report No.:

713184133

Valid from:

2021-02-16

Valid until:

2024-02-15

Date,

2021-02-16

Christoph Dicks

Head of Certification/Notified Body