

BeneHeart R12

Electrocardiograph



Technical Specifications

Physical	
Height:	128 mm
Width:	365 mm
Depth:	305 mm
4. Weight:	4,9 Kg Svoris 4,9 kg
Processing	
21. ECG sampling rate:	1000 samples/second/channel Diskretizacijos dažnis kanalui 1000 Hz
15. Pacer detection sampling rate:	16,000 samples/second/channel Implantuoto elektrokardiostimuliatoriaus impulsų atpažinimas 16 kHz
ECG amplifier:	DC-coupled
Acquisition mode:	Pre- or post-acquisition, provide 10 seconds of instantaneous ECG acquisition
25. Dynamic range:	AC differential ± 10 mV, DC offset ± 600 mV Dinaminis diapozonas
Resolution:	1 μ V/LSB
Frequency response:	-3 dB @ 0.05 to 150 Hz
18. Baseline drift filter:	0.05 Hz, Baseline Drift Removal (BDR) Bazinės linijos dreifo filtras
Artifact filter:	20 Hz, 35 Hz
AC filter:	50/60 Hz
Common mode rejection:	≥ 110 dB (with AC filter switched off)
ADC:	24 bits Įėjimo varža
20. 23. Input impedance:	> 50 M Ω @ 10 Hz, defibrillator protected Apsauga nuo defibriliacijos impulso
24. Time Constant	≥ 3.2 s Laiko pastovioji.
Noise Level	≤ 15 μ V
Patient leakage:	< 10 μ A
27. Heart rate meter:	30 to 300 BPM $\pm 10\%$ or ± 5 BPM, whichever is greater Širdies susitraukimų dažnio registracijos diapozonas nuo 30 iki 300 k/min.
17. Sensitivity/gain:	2.5, 5, 10, 20, L=10 C=5, L=20 C=10 mm/mV, Auto Jautrumas
13. Boot time:	< 7 s Aparato pasiruošimo darbui trukmė < 7 s.
Display Ekranas įstrižainė 20,32cm, spalvotas LCD.	
5. Display type:	8-inch 24-bit color, TFT LCD with LED graphics backlit
Display resolution:	800x480 pixels Ekranas rezoliucija 800 x 480 pikselių
6. Display data:	Patient ID, Patient name, gender, age, heart rate, clock, battery power indicator, waveforms, lead labels, speed, gain, filter settings, warning messages, information messages, network, USB status
Ekrane atvaizduojama informacija filtrų būseną	
Power	
Power supply:	AC input (without external power adaptor) or battery operation
AC Power	
Input voltage:	100 to 240 VAC $\pm 10\%$
Input power:	100 VA
AC frequency:	50/60 Hz ± 3 Hz
Battery	
38.5. Battery type:	Rechargeable Lithium ion battery, 4500 mAh Pakraunama ličio baterija
Charge time:	≤ 6 h to 90% and ≤ 7 h to 100% with device off
30. Battery Capacity:	More than 3.5 hours of continuous operation or 400 ECGs recording Darbo trukmė iš integruoto akumuliatoriaus 400 EKG.

	Writer	
	Writer technology:	Thermal dot array
16.	Writer speed:	5, 12.5, 25, 50 mm/s Rašymo greitis.
	Number of traces:	12 leads
	Writer speed accuracy:	±5%
	Writer amplitude accuracy:	±5%
	Writer resolution:	Horizontal 40 dots/mm @ 25 mm/s, Vertical 8 dots/mm
19.	Paper type:	Thermal Z-fold A4 paper (210 mm x 295 mm) 12 kanalų EKG užrašymas vienu metu, integruotu terminiu spausdintuvu ant A4 formato popieriaus Letter 8.5x11 in (215 mm x 280 mm)
	Software Suaugusių, vaikų ir naujagimių interpretacijos programa, diagnozės nustatymui.	
31.	Measurement and interpretation:	Supports the University of Glasgow 12-lead ECG analysis program for adults and pediatrics
19. 1.	Resting ECG mode:	Records and prints 12-lead resting ECG with 10-second duration as a standard feature Ramybes EKG registravimas Atliekama pagal amžių, lytį ir rasę
31.	Supported patient information:	Name, patient ID, secondary ID, name, age, date of birth, gender, race, medication, class, V3 electrode Placement.
33.1	Internal storage:	800 ECGs in internal memory Vidinė atmintis 800 EKG.
33.2	ECG Storage format:	XML, PDF, Mindray Saugojimo formatai.
	Report Formats:	3x4+1R, 3x4+3R, 6x2, 6x2+1R, 12x1
	Extensional Function	
	Preview and review full ECG report on screen	
	Reanalyze ECG automatically after changing patient's demographics	
5.	Touch screen (Optional)	Lietimui jautrus ekranas
29.	Connect to external printer directly (Optional)	Jungtis išoriniam spausdintuvui.
	Upload XML or PDF reports through FTP protocol (Optional)	
37. 8.	Barcode scanner (Optional)	Barkodų skaitytuvas
36.	Wifi (Optional)	Bevielio ryšio funkcija Wi-Fi.
	USB flash drive storage of PDF and XML outputs (Optional)	
	Accessories	
	ECG patient cable with banana plugs, Limb Clamps, Chest Bulbs (IEC/AHA)	
	ECG cable with Electrode clips (IEC/AHA)	
	ECG patient cable with banana plugs, banana to tab lead adapters, ECG tab electrodes	
	Country-specific power cords	
	Z-fold thermal paper (Letter or A4)	
	Trolley	

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mindray

2.3 Main Unit

2.3.1 Front and Side View



1. Thermal recorder: prints reports.
2. Hard keys: see **Hard Keys and Indicators** below.
3. Indicators: see **Hard Keys and Indicators** below.
4. Display screen: presents waveforms and text.
5. Soft keys: for the equipment configured with a touchscreen. Press the soft keys to select the options.
Soft key labels: for the equipment not configured with a touchscreen.
See **Soft Keys** below.
6. Soft keys: only for equipment not configured with a touchscreen. The soft keys illuminate when the equipment is powered on. Press the soft keys to select the options that appear on the right side of the screen. For the equipment configured with a touchscreen, there are no keys in this area.

34.

7. USB connector: connects USB devices, such as a USB drive, external printer, or barcode reader.

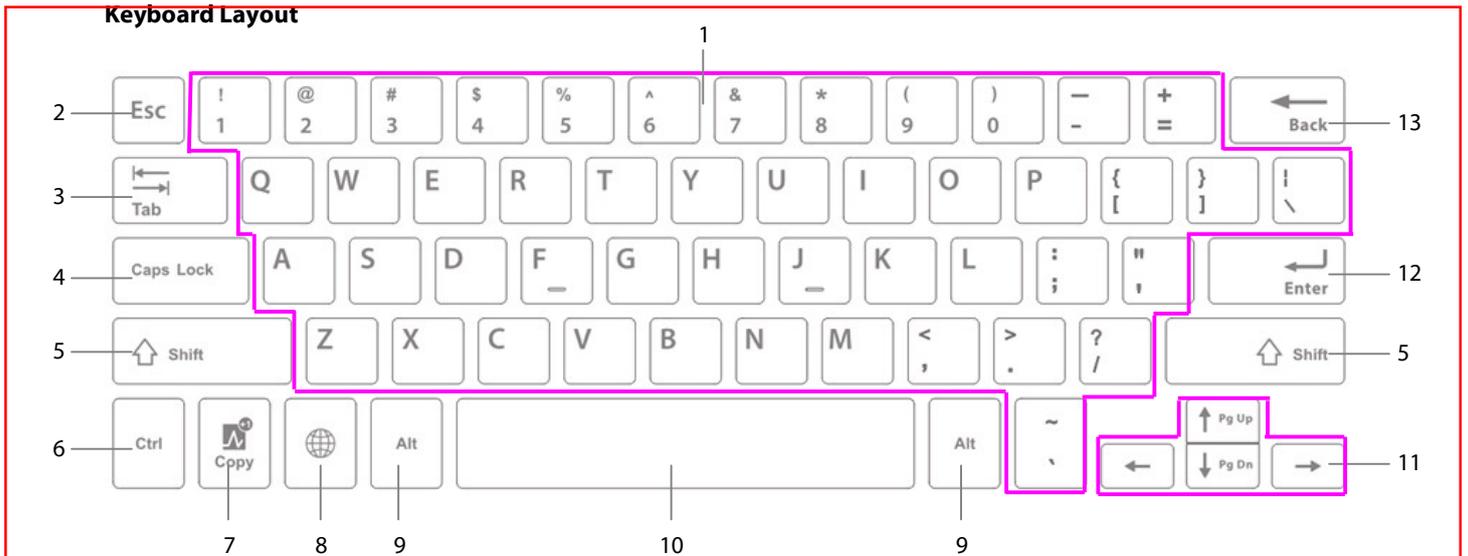
 Integruota USB jungtis.
8. Patient cable connector: connects the patient cable for ECG acquisition.
2.

9. Keyboard: see Keyboard Layout below.
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Hard Keys and Indicators

Key	Function
Power switch 	Turns on the equipment when the equipment is powered off. Turns off the equipment by pressing and holding this key for 0.5 second when the equipment is powered on. Forcefully shuts down the equipment by pressing and holding this key for 10 seconds when it cannot be shut down normally.
Setup key  Setup	Accesses the main menu. Exits a menu and returns to the normal screen when the menu is open.
Leads key  Leads	Switches the format and leads to be displayed. Switches leads to be printed during a manual measurement.
ID key  ID	Enters the [Patient Info] menu.
ECG key  ECG	Starts an auto measurement. Automatinis matavimas pradedamas vieno mygtuko paspaudimu Stops the ongoing auto measurement when the preview option is disabled.
Indicator	Description
Power indicator 	On: when the equipment is powered on. Off: when the equipment is powered off.
Battery indicator 	Green: when the equipment operates on battery power or the battery is being charged. Yellow: when the equipment operates on battery power and the battery is low. Yellow and blink: when the equipment operates on battery power and the battery is depleted. Off: when no battery is installed or the battery is fully charged.
AC indicator 	On: when the AC mains is connected. Off: when the AC mains is not connected.

2.



No.	Key	Description
2. 1	Alphanumeric keys	Enters corresponding letters, digits, and symbols. <i>Pilna raidinē/skaitmeninē klaviatūra</i>
2	Esc key	Returns to the previous screen.
3	Tab key	Moves the cursor to the next item.
4	Caps Lock key	Locks the capital letters and upper case symbols.
5	Shift key	Uses in conjunction with alphanumeric keys to enter the upper case characters. For example, press Shift + a to enter a capital A , and press Shift + = to enter the symbol + .
6	Ctrl key	Not currently used.
7	Copy key	Prints the latest auto or rhythm report.
8	globe key	Switches input method.
9	Alt key	Not currently used.
10	Space bar	Enters a space.
11	Arrow keys	Moves the cursor left, right, up, or down.
12	Enter key	Confirms the selection.
13	Back key	Deletes the character in front of the cursor.

A.5.4 Audio Indicator

Sounder	Gives notification tone, heartbeat tone, and power-on self-check tone
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A.5.5 Recorder

Recorder type	Build-in thermal recorder
3. Number of waveform channels	Max. 12 12 kanalų
Paper speed	5 mm/s, 12.5 mm/s, 25mm/s, 50 mm/s Accuracy: ±5%
Recording paper	Z-fold Paper size: A4 or US Letter
Resolution	Vertical resolution: ≥8 dots/mm Horizontal resolution: 40 dots/mm (with paper speed 25 mm/s)

A.6 System Specifications

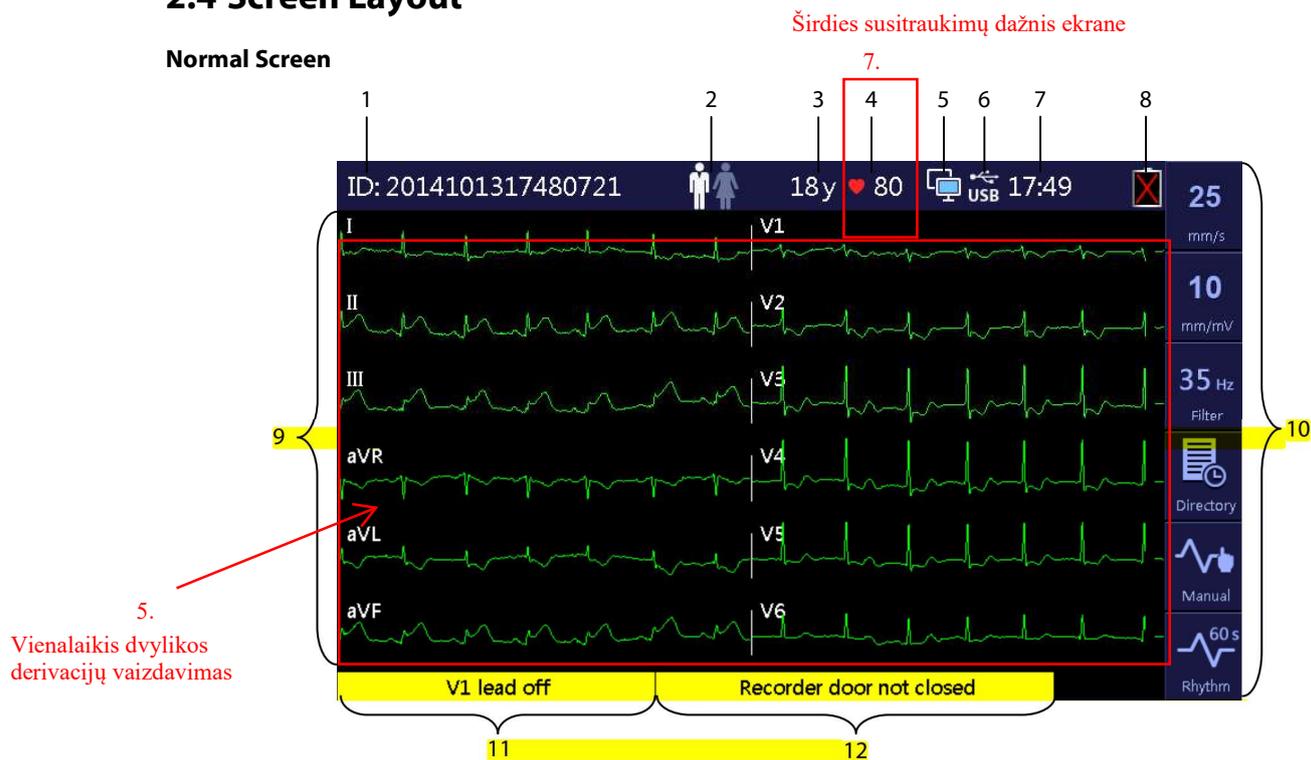
Boot time	≤7 s
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A.7 Measurement Specifications

ECG	
Standards	EC11, IEC 60601-2-51
Measurement mode	Auto, manual, rhythm
Lead type	12-lead
ECG standard	AHA, IEC
ECG size	2.5 mm/mV (× 0.25), 5 mm/mV (× 0.5), 10 mm/mV (× 1), 20 mm/mV (× 2), Auto, L=10 C=5, L=20 C=10 Accuracy: ±5%
Sweep speed	5 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s Accuracy: ≤±5%
Baseline drift removal (BDR)	0.56 Hz
12. Muscle artifact filter	20/35 Hz Raumenų sukeliamų artefaktų filtras.
22. Frequency response	0.05 Hz-150 Hz $\left(\begin{matrix} +0.4dB \\ -3.0dB \end{matrix} \right)$ Dažnių diapazonas.
Accuracy of input signal reproduction	Overall system error is tested using the method described in AAMI EC11 3.2.7.1. Overall system error is ±5%. Frequency response is tested using the method described in AAMI EC11 3.2.7.2 methods A and D.
Common mode rejection ratio	≥110 dB
AC filter	50/60 Hz
ECG sampling rate	1 kHz (A/D) Accuracy: 1 μV/LSB

2.4 Screen Layout

Normal Screen



1. Patient ID: displays the ID of the patient
You can input up to 20 digits. If not inputted, the ID information is left blank.
2. Gender icon: indicates the gender of the patient

If set to **[Male]**,  is displayed. If set to **[Female]**,  is displayed. If not set,  is displayed.
3. Age: displays the age of the patient

The unit can be set to **[Years]**, **[Months]**, or **[Days]**. The input range is 0 to 199 for **[Years]**, 0 to 2400 for **[Months]**, and 1 to 73050 for **[Days]**. If not set, the age area is left blank.
7. 4. **Heart rate: displays the heart rate and heartbeat symbol**  **Širdies susitraukimų dažnis**
5. Network status icon: indicates the current status of network connection
 - ◆  indicates that the equipment is connected to a wire network successfully. -
 - ◆  indicates that the equipment is disconnected from a wire network.
 - ◆  indicates that the equipment is connected to a wireless network successfully.
 - ◆  indicates that the equipment has failed to connect a wireless network.
 - ◆  indicates that the equipment is connected to the CardioVista ECG viewer with a network cable.
 - ◆  indicates that the equipment is connected to the CardioVista ECG viewer via a wireless network.

7.7 Resting 12-lead ECG Analysis

The equipment incorporates the Glasgow algorithm, developed by the University of Glasgow, to provide an interpretation of the resting 12-lead ECG in all situations. The equipment automatically starts analysis at the completion of ECG acquisition.

Resting 12-lead ECG analysis provides:

- Measurements, including:
 - ◆ Vent. Rate (bpm)
 - ◆ PR Interval (ms)
 - ◆ QRS Duration (ms)
 - 32. ◆ QT/QTc Interval (ms) QT ir QTc analizè.
 - ◆ P/QRS/T Axes (°)
 - ◆ RV5/SV1 (mV, available only when [RV5/SV1] is selected)
 - ◆ RV5+SV1 (mV, available only when [RV5/SV1] is selected)
- Critical values, including:
 - ◆ Consider Acute STEMI
 - ◆ Acute MI/Ischemia
 - ◆ Extreme Tachycardia
 - ◆ Extreme Bradycardia
 - ◆ Significant Arrhythmia
 - ◆ Prolonged QTc Interval
- Diagnoses
- Median Complex
 - Gives the median complex of each lead.
- Measurement Matrix
 - Gives 32 measurements of each lead, including:
Pon (ms), Pdur (ms), QRSon (ms), QRSdur (ms), Qdur (ms), Rdur (ms), Sdur (ms), R'dur (ms), S'dur (ms), P+dur (ms), QRSdef (ms), P+amp (μV), P-amp (μV), QRSp2p (μV), Qamp (μV), Ramp (μV), Samp (μV), R'amp (μV), S'amp (μV), STamp (μV), 2/8STT (μV), 3/8STT (μV), T+amp (μV), T-amp (μV), QRSarea (μV*ms), Rnotch, DWconf (%), STslope (deg), Ton (ms), Tdur (ms), T+dur (ms), QTint (ms).

The diagnoses of 12-lead ECG analysis is included on the ECG report by default, see **Report Analysis Setup** in **4.3 Report Setup**.

Resting 12-lead ECG analysis is not intended for the manual measurement and rhythm measurement. Refer to **12-Lead ECG Interpretive Program Physician's Guide** (PN: 046-004817-00) for details.

Menu item	Option	Default	Description
Measurement	Selected, not selected	Selected	Selects whether measurement result is included on the ECG report generated by auto measurement. Measurement result includes Vent. Rate, PR Interval, QRS Duration, QT/QTc Interval, P/QRS/T Axes, RV5/SV1 and RV5+SV1. Note: To include the RV5/SV1 and RV5+SV1 information in the measurement result, both [Measurement] and [RV5/SV1] shall be selected.
Interpretation	Selected, not selected	Selected	Selects whether diagnoses are included on the ECG report generated by auto measurement.
Interpretation Summary	Selected, not selected	Selected	Selects whether interpretation summary is included on the ECG report generated by auto measurement. Note: If the [Interpretation] option is not enabled, interpretation summary is not included on the report even if [Interpretation Summary] is selected.
Tachy	80-130	100	Adjusts tachycardia threshold. Heart rates above the setting are labelled Tachycardia. Only applies to patients whose age exceeds 180 days.
Brady	40-60	50	Adjusts bradycardia threshold. Heart rates below the setting are labelled Bradycardia. Only applies to patients whose age exceeds 2191 days.
QTc Formula	Hodges, Bazett, Fridericia, Framingham	Hodges	Selects QTc formula. Hodges: $QTc = QT + 1.75 \times (HeartRate - 60)$ Bazett: $QTc = QT \times \left(\frac{HeartRate}{60}\right)^{\frac{1}{2}}$ Fridericia: $QTc = QT \times \left(\frac{HeartRate}{60}\right)^{\frac{1}{3}}$ Framingham: $QTc = QT + 154 \times \left(1 - \frac{60}{HeartRate}\right)$
RV5/SV1	Selected, not selected	Not selected	Selects whether the RV5/SV1 and RV5+SV1 information is included on the ECG report generated by auto measurement.

32.

QTc apskaičiavimai pasirinktinai pagal Hodges, Bazett, Fridericia ir Framingham formules

4.4 File Management

Visos elektrokardiogramos peržiūros prieš spausdinant funkcija

Menu item	Option	Default	Description
Preview	Selected, not selected	Not selected	During auto measurement selects whether the ECG report is previewed before being printed.
Auto Send	Selected, not selected	Not selected	During auto measurement selects whether the ECG report is automatically sent out through the network after measurement finished. You can enable Auto Send only when the Preview function is disabled.

10.

Menu item	Option	Default	Description
Send Destination	FTP, CardioVista	FTP	Select the destination of currently generated ECG report. If [Auto Send] is selected, when an ECG report is generated, it will be sent to the selected destination automatically. If [Preview] is selected, you can select [Send] in the preview window to send the generated report to the selected destination.
Auto Save	Selected, not selected	Selected	During auto measurement selects whether the ECG report is automatically saved on the internal storage after measurement finishes.
Auto Delete after Transmission	Selected, not selected	Not selected	Selects whether ECG report is automatically deleted from the internal storage after being sent out through the network.
Delete the Oldest Report	Selected, not selected Saugojimo formatai	Selected	Selects whether the earliest report is deleted when the internal storage is full. If selected, the earliest report is automatically deleted when a new report is saved. If not selected, prompts whether the earliest report is deleted and the current report is saved.
33.2 File Format	MR RAW, FDA XML, PDF, MR XML	PDF	Selects the format of the report sent to the USB drive or the target FTP server. When set to [MR RAW], the report will be sent to the FTP server in MR XML format.
PDF Grid	Selected, not selected	Selected	Select whether there is a grid behind the waveforms when a PDF format report is printed.
Record File List	/	/	Starts printing the Directory List.

4.5 Basic Setup

Menu item	Option	Default	Description
Patient Info Setup	/	/	Enters the [Patient Info Setup] menu.
Date	Year: 2012-2099 Month: 01-12 Day: 01-31	Year: 2012 Month: 01 Day: 01	Sets the current date.
Time	Hour: 00-23 (24 h) 12 am-11 pm (12 h) Minute: 00-59 Second: 00-59	Hour: 00 Minute: 00 Second: 00	Sets the current time.
Date Format	yyyy-mm-dd, mm-dd-yyyy, dd-mm-yyyy	yyyy-mm-dd	Selects the date format.
Time Format	12 h, 24 h	24 h	Selects the time format.
Lead Notation	AHA, IEC	AHA	Sets lead notation.
Institution Name	/	/	Enters the name of the institution.

11.

Menu item	Option	Default	Description
Pre-acquisition	Selected, not selected	Selected	During auto measurement, selects whether the ECG data acquired before pressing the ECG key is recorded. If selected, the equipment records 10 seconds of ECG data acquired before the ECG key is pressed. If less than 10 seconds of data is acquired, the message " ECG Data Insufficient " displays at the bottom of the screen. If not selected, the equipment records 10 seconds of ECG data acquired after the ECG key is pressed.
Extend Record	Selected, not selected	Not selected	Select whether the equipment automatically performs a rhythm measurement and print a rhythm report if critical values " Extreme Tachycardia ", " Extreme Bradycardia ", or " Significant Arrhythmia " are detected at the completion of auto measurement.
Report Analysis Setup	/	/	Enters the [Report Analysis Setup] menu.
Printing Device	Thermal Recorder, External Printer	Thermal Recorder	Selects what printing device is used to output the reports.
Printer Resolution	High Quality, Standard	Standard	Selects the quality of reports produced by the external printer. [Standard]: the printout resolution is 300 dpi. [High Quality]: the printout resolution is 600 dpi.
Printout Grid	Selected, not selected	Selected	Selects whether a grid is printed behind the waveforms on the ECG report produced by the external printer. A grid may make reading ECG waveforms easier.

Report Analysis Setup

26.

Menu item	Option	Default	Description
Median Complex	Selected, not selected	Not selected	Selects whether Median Complex is included on the ECG report generated by auto measurement. Median Complex displays a median complex waveform for each lead and a lead II waveform of 10 seconds in 3x4+1 format.
Measurement Matrix	Selected, not selected	Not selected	Selects whether Measurement Matrix is included on the ECG report generated by auto measurement. EKG charakteristikų (amplitudžių, intervalų, elektrinių ašiu) 32 matavimai 32 measurements for each lead are provided. The measurements are: Pon (ms), Pdur (ms), QRson (ms), QRSdur (ms), Qdur (ms), Rdur (ms), Sdur (ms), R'dur (ms), S'dur (ms), P+dur (ms), QRSdef (ms), P+amp (µV), P-amp (µV), QRSp2p (µV), Qamp (µV), Ramp (µV), Samp (µV), R'amp (µV), S'amp (µV), STamp (µV), 2/8STT (µV), 3/8STT (µV), T+amp (µV), T-amp (µV), QRSarea (µV*ms), Rnotch, DWconf (%), STslope (deg), Ton (ms), Tdur (ms), T+dur (ms), QTint (ms).

7.8 ECG Report

The format and contents of the ECG reports are configurable. Refer to **4.3 Report Setup** for details.

The following is a sample of the standard auto measurement recording with default configuration.

Paciento duomenų spausdinimas.

Datos ir laiko indikacija

28.

1

ID:	012
Name:	long, he
Secondary ID:	00012
DOB:	1987-03-12
Age:	26 Years
Gender:	Male
Race:	Asian
Medication 1:	No Medication
Medication 2:	No Medication
Class 1:	Normal
Class 2:	Normal
Physician:	cheng
Technician:	zhang
Department:	Medicine dept
Room:	10
Bed:	009

11.

2

2013-11-27 16:48:32

Vent. Rate	60 bpm
PR Interval	168 ms
QRS Duration	86 ms
QT/QTc Interval	368/368 ms
P/QRS/T Axes	53/42/51 deg
OTc:Hodges	

3

4

Sinus rhythm
Normal ECG

Unconfirmed Diagnosis



Datos ir laiko indikacija

11.

1. Patient information

2. Time of acquisition

3. Measurements

4. Diagnosis statement

5. Black mark

6. Paper speed

7. Gain

8. Frequency range

9. Institution name

10. System software version/algorithm version

11. Equipment ID

CAUTION

- Do not touch the print head after long-time recording. It might burn the skin.

7.7 Resting 12-lead ECG Analysis

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Resting 12-lead ECG analysis provides:

- Measurements, including:
 - ◆ Vent. Rate (bpm)
 - ◆ PR Interval (ms)
 - ◆ QRS Duration (ms)
 - ◆ QT/QTc Interval (ms)
 - ◆ P/QRS/T Axes (°)
 - ◆ RV5/SV1 (mV, available only when [RV5/SV1] is selected)
 - ◆ RV5+SV1 (mV, available only when [RV5/SV1] is selected)
- Critical values, including:
 - 31. ◆ Consider Acute STEMI STEMI analizè
 - ◆ Acute MI/Ischemia
 - ◆ Extreme Tachycardia
 - ◆ Extreme Bradycardia
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Pon (ms), Pdur (ms), QRSON (ms), QRSdur (ms), Qdur (ms), Rdur (ms), Sdur (ms), R'dur (ms), S'dur (ms), P+dur (ms), QRSdef (ms), P+amp (μV), P-amp (μV), QRSp2p (μV), Qamp (μV), Ramp (μV), Samp (μV), R'amp (μV), S'amp (μV), STamp (μV), 2/8STT (μV), 3/8STT (μV), T+amp (μV), T-amp (μV), QRSarea (μV*ms), Rnotch, DWconf (%), STslope (deg), Ton (ms), Tdur (ms), T+dur (ms), QTint (ms).

The diagnoses of 12-lead ECG analysis is included on the ECG report by default, see **Report Analysis Setup in 4.3 Report Setup**.

Resting 12-lead ECG analysis is not intended for the manual measurement and rhythm measurement. Refer to **12-Lead ECG Interpretive Program Physician's Guide** (PN: 046-004817-00) for details.

Battery

Battery type	Rechargeable lithium-ion battery, 4500 mAh, 11.1 V
Run time	For equipment in standard configure and with default setting, when powered by a new fully-charged battery and at ambient temperature 25 °C±5 °C: ≥400 auto reports, or no less than one hour of continuous paper recording, or no less than 3.5 hours of paperless recording
Charge time	With the equipment power off: ≤6 h to 90% capacity ≤7 h to 100% capacity
Shutdown delay	at least 5 minutes after the low battery message first occurs

A.4 Physical Specifications

Weight	Size (Length × Width × Height)
4.8 kg, including the main unit, battery, and thermal recorder, excluding recording paper and other accessories	305 mm × 365 mm × 128 mm

A.5 Hardware Specifications

A.5.1 Display

Screen type	Color LCD with LED backlight
Screen Size	8 inches
Resolution	800 × 480 pixels

A.5.2 Equipment Connector

Patient cable connector	One, connects patient cable for ECG acquisition
USB connector	Two, connects the USB drive, external printer or barcode reader
Network connector	One standard RJ45 connector for LAN, connects the equipment to the network for data transmission and software upgrade Integruta LAN jungtis
	One standard RJ45 connector for Wi-Fi, connects the equipment to the network for data transmission

34.

A.5.3 Indicators

Power indicator	1 (green)
AC indicator	1 (green)
Battery indicator	1 (two colors: yellow and green)

8.3 Managing the Configuration

Select **Setup** → **[Maintenance]**, enter the required password to enter the **[Maintenance]** menu. You can:

- Select **[Load Configuration]** to load a configuration stored in the USB drive.
- Select **[Export Configuration]** to export the current configuration to the USB drive.
- Select **[Print Configuration]** to print the current configuration.
- Select **[Restore Default Configuration]** to restore the default configuration.

8.4 Sending Files

Kompiuterinė programinė įranga EKG persiuntimui ir peržiūrai

35. The equipment can be connected with the hospital's FTP server or CardioVista ECG viewer through the wired or wireless network to send the patient's ECG reports.

To connect the FTP server or CardioVista ECG viewer:

1. Select **Setup** → **[Maintenance]**, enter the required password to enter the **[Maintenance]** menu.
2. Select **[Network Type]**.
3. If you select **[WLAN]**, set **[Network Name (SSID)]** and **[Password]**.
4. Set the network related information of the equipment:
 - ◆ **[IP Address]**: the IP address of the equipment.
 - ◆ **[Subnet Mask]**: the subnet mask of the equipment.
 - ◆ **[Default Gateway]**: the IP address of the default gateway.
5. Set the destination information:
 - ◆ FTP communication setup, including the IP address, port, user name and password of the FTP server; or,
 - ◆ CardioVista communication setup, namely the CardioVista IP address.

The format of the files sent to the FTP server can be MR XML, FDA XML or PDF. Refer to **[File Format]** as described in **4.4 File Management**.

You can send the patient's reports in either of the following ways:

- Automatically

Select **Setup** → **[File Management]** → **[Auto Send]** and then **[Send Destination]**.

During auto measurement, the equipment automatically sends the current report to the set destination through the network after the measurement is finished.

- Manually

1. Select the **[Directory]** soft key to enter the **[Directory List]**.
2. Select the files to be sent
3. Select the **[Send]** soft key.

Then you can send the selected files to the FTP server or the CardioVista ECG viewer through the network, or send them to the USB drive connected to the equipment.

If you have problems to send out the patient's reports, contact your service personnel.



Electrocardiograph Accessories

Electrocardiograph accessories

- Apply for 12-lead ECG acquisition on electrocardiograph
- Both ECG cable with banana plugs, Limb Clamps, Chest Bulbs and ECG cable with Electrode clips are available
- Both IEC and AHA accessories are available

38.1

For BeneHeart R3/R12

Picture	Model	Part No.	Description	Purchasing Unit
		040-001579-00	12-lead ECG cable, IEC, 04 banana plugs Paciento kabelis	Each



040-001582-00 12-lead ECG cable, AHA, 04 banana plugs

Each

112

38.2

Picture	Model	Part No.	Description	Purchasing Unit
		040-001587-00	Limb clamps, 4/set, IEC Galliniai elektrodai	4 pcs/set



040-001586-00 Limb clamps, 4/set, AHA

4 pcs/set

38.2

Picture	Model	Part No.	Description	Purchasing Unit
		040-001585-00	Chest Bulbs, 6/set Kritiniai elektrodai	6 pcs/set



040-001645-00 12-lead ECG cable, IEC, Clip

Each

040-001643-00

12-lead ECG cable, AHA, Clip

Each



115-024339-00 12-lead ECG cable + Tab adapters + Tab electrode, Adu/ped, IEC

Each

115-024341-00

12-lead ECG cable + Tab adapters + Tab electrode, Adu/ped, AHA

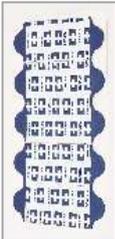
Each

040-001646-00 Tab adapters (use between the cable and tab electrodes)

10 pcs/set

113



Picture	Model	Part No.	Description	Purchasing Unit
		040-001908-00	Table electrode	100 pcs/pkg
		115-024338-00	Carrying bag for R3	Each
		045-001385-00	Trolley for R3, with case and cable arm	Each
		045-001384-00	Trolley for R12, with case and cable arm Transportinis vežimėlis su EKG kabelio laikikliu	Each

38.3

38.4

Defibrillator Accessories



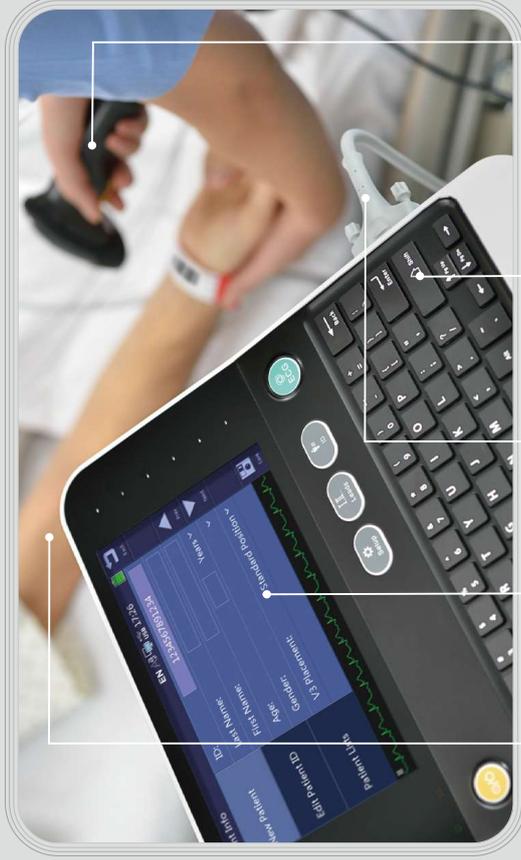
External Paddles and Cables

- Applicable for both adults and pediatric patients, and easy to switch
- Safe for defibrillation energy delivery
- Space-saving spiral cable
- Flexible and durable cables
- Outstanding cable material enduring repeated cleaning and disinfection
- Latex free



Quality and Performance

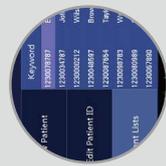
Easy to use technology saves you time



- 8-inch high-resolution colour display
- Optional touchscreen



- User friendly workflow buttons
- Modern designed soft touch hotkeys
- Standard keyboard layout



Patient demographics can be retrieved from the worklist



Anatomically designed cable to minimise tangling and lead reversal

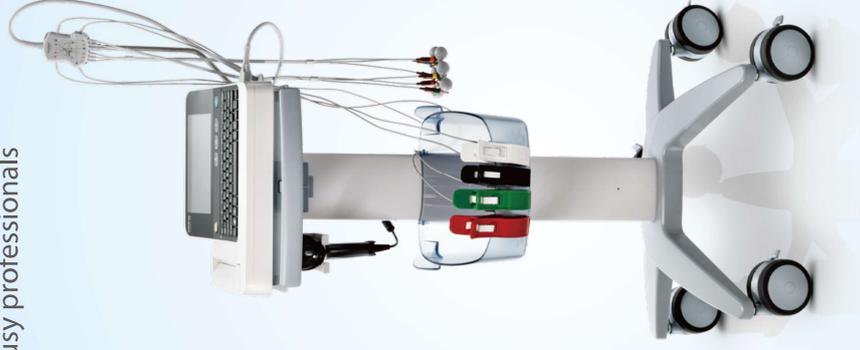


Optional barcode scanner for rapid input of accurate patient demographics

8.

brūkšniški kodų skaitytuvai, skirtas greitai įvesti tikslius pacientų demografinius rodiklius

Intelligent design for busy professionals



- Stable, clean, and accurate ECG waveforms ensure the quality of ECG data and aid faster processing
- Clear view of results helps you focus on diagnosis and care
- Save up to 800 ECG records internally, or use the USB flash drive for offline ECG storage and transmission
- Lithium ion battery powers greater than 3.5 hours of continuous operation or 400-page recording on one charge
- One of the lightest 12-lead electrocardiographs available – only 4.8 kg
- Optional handy and compact trolley for easy mobility and storage

4 System Setup

4.1 Accessing the Main Menu

Press the **Setup** key to access the main menu. To configure the equipment:

- Press the arrow keys on the keyboard to select a menu option.
- Press the **[Prev]** or the **[Next]** soft key to move to the previous or the next menu item.
- Press the **[Back]** soft key or the **[Esc]** key on the keyboard to return to the previous menu.
- Press the **[Select]** or the **[Cancel]** soft key to select or deselect a menu item.
- Press the **[Enter]** soft key or the **Enter** key on the keyboard to confirm the selection.



The settings in the main menu are saved as user defaults and remain effective even after the equipment is turned off and restarted.

4.2 Waveform Setup

14.

Menu item	Option	Default	Description
Muscle Artifact Filter	20 Hz, 35 Hz, Off	35 Hz	<p>Sets the default frequency of muscle artifact filter. Muscle artifact filter attenuates noise in the waveform by restricting the frequencies that are included.</p> <p>The muscle artifact filter is a low-pass filter. That is to say signals that exceed the set frequency are filtered out.</p> <p>[35 Hz]: only signals at 35 Hz or less display. Signals exceeds 35 Hz are attenuated.</p> <p>[20 Hz]: only signals at 20 Hz or less display. Signals exceeds 20 Hz are attenuated.</p> <p>[Off]: signals at 150 Hz or less display.</p>
Raumenų artefaktų filtras	20 Hz, 35 Hz išjungta		

Graina Ltd
Durpyno str.22,
LT-36237 Panevezys,
Lithuania
Tel:037045570605

January 1st, 2022

LETTER OF AUTHORIZATION

To whom it may concern

We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**, (“**Mindray**”), manufacturer of **patient monitors: BeneVision N/ ePM/ uMec/ VS series; Electrocardiograph: R series; Defibrillators: BeneHeart D3/D6, Anesthesia machines: A/ WATO series; Ventilators: SV series**(“**Products**”), hereby certify that we authorize: **Graina Ltd**, with business office at **Durpyno str.22, LT-36237 Panevezys, Lithuania** (“**You**”) as the distributor for sales and service of the above mentioned products in **Lithuania**(“**Territory**”)

As the manufacturer, Mindray guarantees our products against defects in materials and workmanship, and provide services based on the standard terms and conditions of Mindray’s warranty policy.

This authorization of distribution rights is valid from the date of issuance up to **December 31st, 2022**. Mindray reserves the right to terminate the authorization upon fifteen (15) days written notice without any further compensation to You.

Neither this Letter of Authorization nor any further extension, will impose any obligation or grant any rights regarding further distribution of Product, nor allow any party to seek compensation for goodwill developed during the term of Letter of Authorization or any further extension.

Best regards,



Tu Haitao
General Manager of Sales and Marketing Department, Northeast Europe
Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

Vertimas iš anglų kalbos

EU-GJLA202201050011

Graina LTD

Durpyno g. 22

LT-36237 Panevėžys, Lietuva

Tel: 037045570605

2022 m. sausio 1 d.

Gamintojo įgaliojimas

Tam kam tai aktualu,

Mes, Shenzhen Mindray Bio-Medical electronics Co., Ltd. („Mindray“) pacientų monitorių: BeneVision N/ePM/uMEC/VS serijos, Elektrokardiografų: R serijos, Defibriliatorių: BeneHeart D3/6, Anestezijos mašinų: A/Wato serijos, Ventilatorių: SV serijos („Produktų“) gamintojas, šiuo dokumentu patvirtiname, kad įgaliojame: UAB „Graina“, įsikūrusią Durpyno g. 22, LT-36237 Panevėžys, Lietuvoje („Jūs“) kaip platintoją parduoti bei teikti techninę priežiūrą aukščiau paminėtiems produktams Lietuvoje („Teritorijoje“).

Kaip gamintojas, Mindray suteikia garantiją dėl produktų gamybai panaudotų medžiagų bei pagaminimo defektų, ir suteikia garantinį aptarnavimą pagal Mindray garantijų politikos sąlygas ir taisykles.

Šis distribucijos teisių įgaliojimas galioja nuo jo išdavimo datos iki 2022 metų gruodžio 31 dienos. Mindray pasilieka teisę nutraukti šio įgaliojimo galiojimą be jokios kompensacijos Jums apie tai raštu pranešęs prieš 15 dienų.

Nei šis įgaliojimas, nei bet kuris jo pratęsimas nėra joks įsipareigojimas, ir nesuteikia jokių teisių toliau vykdyti Produkto platinimą, taip pat nesuteikia teisės nei vienai iš šalių reikalauti kompensacijos už gerovę, sukurtą šio įgaliojimo, ar bet kurio jo pratęsimo galiojimo laikotarpiu.

Nuoširdūs linkėjimai,

/parašas//antspaudas/

Tu Haitao

Šiaurės Rytų Europos pardavimo ir rinkodaros skyriaus generalinis direktorius

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

Vertimą tvirtino UAB "Graina" direktorius





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 044751 0167 Rev. 02

Manufacturer: **Shenzhen Mindray Bio-Medical
Electronics Co., Ltd.**

Mindray Building
Keji 12th Road South
High-Tech Industrial Park
Nanshan
518057 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Patient Monitoring Devices,
Vital Signs Monitor,
Center Monitoring System,
Telemetry Monitoring System,
Ambulatory Blood Pressure Monitor,
Pulse Oximeter, Temperature Probe,
SPO2 Sensors, Electrocardiograph,
Ventilator, Anesthetic Vaporizer,
Air compressor,
Ultrasonic Diagnostic Equipment,
Ultrasonic Transducer,
Digital Radiography System,
Radiography System

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.: SH1905503

Valid from: 2019-11-13

Valid until: 2024-05-26

Date, 2019-11-13

Christoph Dicks
Head of Certification/Notified Body

Page 1 of 2
TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany



TÜV SÜD
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT



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 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 044751 0167 Rev. 02

Facility(ies):

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
 Mindray Building, Keji 12th Road South, High-Tech Industrial Park,
 Nanshan, 518057 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
 1203 Nanhuan Avenue, Guangming District, 518106 Shenzhen,
 PEOPLE'S REPUBLIC OF CHINA

TÜV SÜD
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認 證 證 書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Vertimas iš anglų kalbos į lietuvių kalbą

EC sertifikatas

Kokybės užtikrinimo sistema

Medicininį įrenginių direktyvos 93/42/EEC Priedas II išskyrus (4)

(IIa, IIb ar III klasės įrenginiai)

Nr. G1 044751 0167 Rev. 02

Gamintojas: Shenzhen Mindray Bio-Medial Electronics Co., Ld.
Mindray Building,
Keji 12th Road South
Hi-tech Industrial Park
Nanshan
518057 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Produktų kategorija: Pacientų monitoravimo įranga, gyvybinių funkcijų monitoriai, centrinė monitoravimo sistema, telemetrijos monitoravimo sistema, ambulatorinio kraujo spaudimo monitoriai, pulsoksimetrai, temperatūros davikliai, SpO2 sensoriai, elektrokardiografai, ventiliatoriai, anestetinis garintuvas, oro kompresoriai, ultragarsinė diagnostinė įranga, ultragarsiniai davikliai, skaitmeninė radiografijos sistema, radiografijos sistema

Sertifikavimo įstaiga TÜV SÜD Product Service GmbH skelbia, kad minėtas gamintojas įdiegė kokybės užtikrinimo sistemą atitinkamų produktų / produktų kategorijų kūrimui, gamybai ir galutiniam tikrinimui pagal Medicininį įrenginių direktyvos MDD Priedą II. Ši kokybės užtikrinimo sistema atitinka atitinka Direktyvos reikalavimus ir yra periodinio tikrinimo objektas. III klasės produktų pardavimui yra privalomas papildomas Priedo II(4) sertifikatas. Žiūrėti pastabas kitoje lapo pusėje.

Ataskaitos Nr. SH1905503
Galioja nuo: 2019-11-13
Galioja iki: 2024-05-26

Data, 2019-11-13

/parašas/
Christoph Dicks
Sertifikavimo vadovas/įgaliotas asmuo

Puslapis 1 iš 2

TÜV SÜD Product Service GmbH yra įgaliota įstaiga ir jos identifikavimo Nr. 0123

TÜV SÜD Product Service GmbH yra sertifikavimo įstaiga, Ridlerstrabe 65, 80339 Munich, Germany

EC sertifikatas

Kokybės užtikrinimo sistema

Mediciniųjų įrenginių direktyvos 93/42/EEC Priedas II išskyrus (4)

(IIa, IIb ar III klasės įrenginiai)

Nr. G1 044751 0167 Rev. 02

Veiklos vieta:

Shenzhen Mindray Bio-Medial Electronics Co., Ltd.
Mindray Building, Keji 12th Road South,
Hi-tech Industrial Park, Nanshan, 518057
Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Shenzhen Mindray Bio-Medial Electronics Co., Ltd.
1203 Nanhuan Avenue, Guangming District, 518106 Shenzhen,
PEOPLE'S REPUBLIC OF CHINA

Puslapis 2 iš 2

TÜV SÜD Product Service GmbH yra įgaliota įstaiga ir jos identifikavimo Nr. 0123

TÜV SÜD Product Service GmbH yra sertifikavimo įstaiga, Ridlerstrabe 65, 80339 Munich, Germany

Vertimą tvirtino UAB „Graina“ direktorius val

