Medtronic

Reveal LINQ

INSERTABLE CARDIAC MONITOR

2 pirkimo dalis. Vaikiškas implantuojamas įvykių registratorius ("Loop recorder")

Produkto Specifikacija

Prietaiso Charakteristikos

2.Prietaiso svoris 2,5 g;
3.Korpuso tūris - 1,2 cm3;

Size and Mass	
Tūris	1.2 cm^3
Išmatavimai	44.8 mm x 7.2 mm x 4.0 mm
Masė	2.5 g ± 0.5
Distancija tarp elektrodų	37.7 mm

Suderinamumas ir identifikacija	
MRI Suderinamumas	MR Tinkamas
Rentgeno ID dalyje	"M" formos ženklas viršutinėje

Baterija	
Chemija	Ličio anglies monofluoridas
Projektinė Tarnavimo trukmė	3 metai

1.Prietaiso tarnavimo trukmė 36 mėnesiai

Jautrumas	
Atrankos Dažnis	256 Hz
Atrankos Rezoliucija	16 dūžiai/pavyzdžiui
Pralaidumas	0.5 - 95 Hz

Programuojami Parametrai

R-wave sensing	
Parametrai	Programuojami dydžiai
Jautrumas	0.025; 0.035 ◈; 0.05; 0.075; 0.1 … 0.2 mV ± 20% programuoto dydžio + 0.005 mV)
Jautrumo Slenksčio Mažėjimo Atidėjimas	130; 150 ◈; 200; 300; 400; 500 ms (±10 ms)
Aklumas po Jautrumo	130; 150 ◈; 170; 200; 250; 300; 400 ms (±10 ms)

Pauzių detekcija	
Parametrai	Programuojami dydžiai
Pauzė (Asistolija) detekcija	Įjung◈ ; Išjg.
Pauzė (Asistolija) Trukmė	1.5; 3.0 ◈; 4.5 s (± 10 ms)

8.Automatinė EKG įrašo aktyvacija, esant asistolijai (programuojama pauzės trukmė)

Actual Size

10.Prieširdžių virpėjimo/prieširdinių tachiartimujų automatinio atpažinimo ir kiekybinio įvertinimo galimybė

AT/AF detekcija	
Parametrai	Programuojami dydžiai
AT/AF Detekcija	Įjung. - AT/AF; Įjung. - tik AF ◈ ; Išjg.
AF detekcijos Jautrumas	Mažiausiai Jautrus; Mažiau Jautrus; Labiau Jautrus; Subalansuotas jautrumas
Ektopijod Atmetimas	Išjg.; Nominalus, Agresivus
AT/AF Įrašymo Slekstis	Visi epizodai; ≥ 6 min; ≥ 10 min; ≥ 20 min; ≥ 30 min; ≥ 60 min; Tik ilgiausi epizodai
Detektuoti labai reguliarius AT ritmus	Išjg ◈ ; Įjung. -Dažniai ≥ 67 min^{-1} ; Įjung. -Dažniai ≥ 100 min^{-1}; Įjung. – Visi Dažniai

4.Įrašomos EKG trukmė - ne mažiau 40 minučių

6.Automatinė EKG įrašo aktyvacija, esant bradikardijai (programuojamas širdies susitraukimų dažnis)

Bradikardijos detekcija	
Parametrai	Programuojami dydžiai
Bradikardijos Detekcija	Įjung.;Išjng.
Bradikardijos Intervalas(Dažnis)	1,000; 1,200; 1,500; 2,000 ◈ ms (± 10 ms) 60; 50; 40; 30 ◈ min
Bradikardijos Trukmė	4 ◈; 8; 12; 32; 48 dūžiai

7.Automatinė EKG įrašo aktyvacija, esant tachikardijai (programuojamas širdies susitraukimų dažnis)

Tachikardijos detekcija	
Parametrai	Programuojami dydžiai
Tachikardijos Detekcija	Įjung.;Išjng.
Tachikardijos Detekcijos Intervalas (Dažnis)	270; 280 … 340 ◈ … 520 ms (± 10 ms) 222; 214; 176◈ … 115 min^{-1}
Tachikardijos trukmė	5; 12; 16 ◈; 24; dūžiai

Symptomatinių Epizodų trukmė	
Parametrai	Programuojami dydžiai
Simptomatinio epizodo trukmė	Keturi 7.5 min epizodai◈ ; trys 10 min epizodai; du 15 min epizodai

Prietaiso duomenų rinkimas	
Parametrai	Programuojami dydžiai
Monitoravimo priežastis	Syncope; smarkus plakimas; smūgiai; Skilvelių Tachikardija; Įtariamas AF; AF Abliacija; AF Gydymas; Insultas; Kita.
Prietaiso Data/Laikas …[b]	Įvesti esamą data ir laiką ◈
Belaidžio perd.laikas	00:00 ; 01:00; 02:00 … 11:00; 12:00; 13:00 … 23:00
Belaidžių Duomenų Prioritetas	Brady, Tachy, Pause; Brady, Pause, Tachy; Tachy, Brady, Pause; Tachy, Pause, Brady; Pause, Tachy, Brady; Pause, Brady, Tachy;
Prietaiso duomenų rinkimas	On

Medtronic

Reveal LINQ™
INSERTABLE CARDIAC MONITORING SYSTEM

MyCareLink™
PATIENT MONITOR

Reveal LINQ Insertable Cardiac Monitoring System Product Specifications

Device Characteristics

Size and Mass	
Volume	1.2 cm^3
Dimensions	44.8 mm x 7.2 mm x 4.0 mm
Mass	2.5 g ± 0.5
Distance between electrodes	37.7 mm

Compatibility and identification	
MRI Compatibility	MR Conditional[a]
Radiopaque ID	"M" shape identifier on the header

[a] The Reveal LINQ Insertable Cardiac Monitor (ICM) has been demonstrated to pose no known hazards in a specified MR environment with the conditions of use specified in the Reveal LINQ ICM Clinical Manual. Please see the Reveal LINQ ICM Clinical Manual for additional details.

Battery	
Chemistry	Lithium carbon monofluoride
Projected Longevity[a]	3 Years

[a] Under the following usage scenarios:
- Average of 1 auto-detected episode per day
- Average of 1 patient-activated episode per month
- Less than or equal to 6 months shelf life (between device manufacture and insertion).

Note: Under maximum shelf storage time (12 months), longevity is reduced by approximately 3 months.

Sensing	
Sampling Rate	256 Hz
Sampling Resolution	16 bits/sample
Bandwidth	0.5 - 95 Hz

Programmable Parameters

R-wave sensing

Parameter	Programmable values
Sensitivity	0.025; 0.035 ◆; 0.05; 0.075; 0.1 … 0.2 mV ± 20% of the programmed value + 0.005 mV)
Sensing Threshold Decay Delay	130; 150 ◆; 200; 300; 400; 500 ms (±10 ms)
Blank after Sense	130; 150 ◆; 170; 200; 250; 300; 400 ms (±10 ms)

Pause detection

Parameter	Programmable values
Pause (Asystole) Detection	On ◆; Off
Pause (Asystole) Duration	1.5; 3.0 ◆; 4.5 s (± 10 ms)

Actual Size

AT/AF detection

Parameter	Programmable values
AT/AF Detection	On - AT/AF; On - AF only ◆; Off
AF Detection Sensitivity[a]	Least Sensitive; Less Sensitive; Balanced Sensitivity; More Sensitive
Ectopy Rejection[a]	Off; Nominal; Agressive
AT/AF Recording Threshold[a]	All episodes; ≥ 6 min; ≥ 10 min; ≥ 20 min; ≥ 30 min; ≥ 60 min; Only longest episode
Detect Very Regular AT Rhythms	Off ◆; On -Rates ≥ 67 min^{-1}; On - Rates ≥ 100 min^{-1}; On -All Rates

Brady detection

Parameter	Programmable values
Brady Detection	On; Off
Brady Interval (Rate)	1,000; 1,200; 1,500; 2,000 ◆ ms (± 10 ms) 60; 50; 40; 30 ◆ min^{-1}
Brady Duration	4 ◆; 8; 12 beats

Tachy detection

Parameter	Programmable values
Tachy Detection[e]	On; Off
Tachy Detection Interval (Rate)	270; 280 … 340 ◆ … 520 ms (± 10 ms) 222; 214; 176 ◆ … 115 min^{-1}
Tachy Duration	5; 12; 16 ◆; 24; 32; 48 beats

Symptomatic Episode Duration

Parameter	Programmable values
Symptomatic Episode Duration	Four 7.5 min episodes ◆; three 10 min episodes; two 15 min episodes

Device data collection

Parameter	Programmable values
Reason for Monitoring[a]	Syncope; Palpitations; Seizures; Ventricular Tachycardia; Suspected AF; AF Ablation; AF Management; Stroke; Other
Device Date/Time …[b]	Enter current date and time
Wireless Transmission Time …[c]	00:00 ◆; 01:00; 02:00 … 11:00; 12:00; 13:00 … 23:00
Wireless Data Priority	Brady, Tachy, Pause; Brady Pause, Tachy; Tachy, Brady Pause; Tachy, Pause, Brady; Pause, Tachy, Brady; Pause Brady, Tachy
Device Data Collection[d]	On

[a] Reason for Monitoring is used to set arrhythmia detection parameters to pending automatically.
[b] The times and dates stored in episode records and other data are determined by the Device Date/Time clock.
[c] Wireless Transmission Time programming is based on the Device Date/Time clock.
[d] Turning on Device Data Collection enables sensing and data collection (all episode types). After being turned on, Device Data Collection cannot be turned off.
[e] Tachy Detection based on 230 – Date of Birth

Patient Assistant Model 9538

Telemetry Status Light:
A solid status light and long beep indicates the device has successfully responded.

Record button:
Patient presses button to record ECG with symptoms.

Response Indicator:
Indicator illuminates after successfully recording an event.

Battery:
Indicator illuminates when Patient Assistant battery is low.

Battery type: Size N

ECG Data Storage

Up to 30 minutes of patient-activated episodes

- Four episodes at 7.5 minutes each ..... 6.5 min + 1 min (Patient activation)
- Three episodes at 10 minutes each ..... 9 min + 1 min (Patient activation)
- Two episodes at 15 minutes each ..... 14 min + 1 min (Patient activation)

27 minutes of automatically detected episodes

Episode types: Pause, Brady, Tachy

End of episode
30 sec + 27 sec
Automatic detection

Atrial episodes: AT/AF

- Two minutes (included in the 27 minutes of automatically detected episodes) of ECG data recorded before detection

2 min
Automatic detection

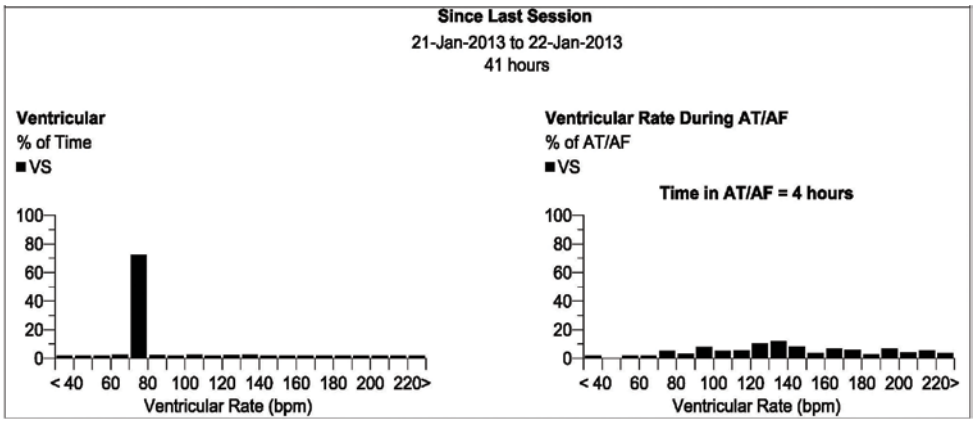
Two minutes of longest AF episode stored since last interrogation *in addition* to the 27 minutes of automatically detected episodes.

Rate Histogram

The Rate Histogram report is based on a continuous recording of ventricular rates since the last patient session. The Rate Histograms report presents heart rate data in 2 types of histograms:

- ventricular rate
- ventricular rate during AT/AF

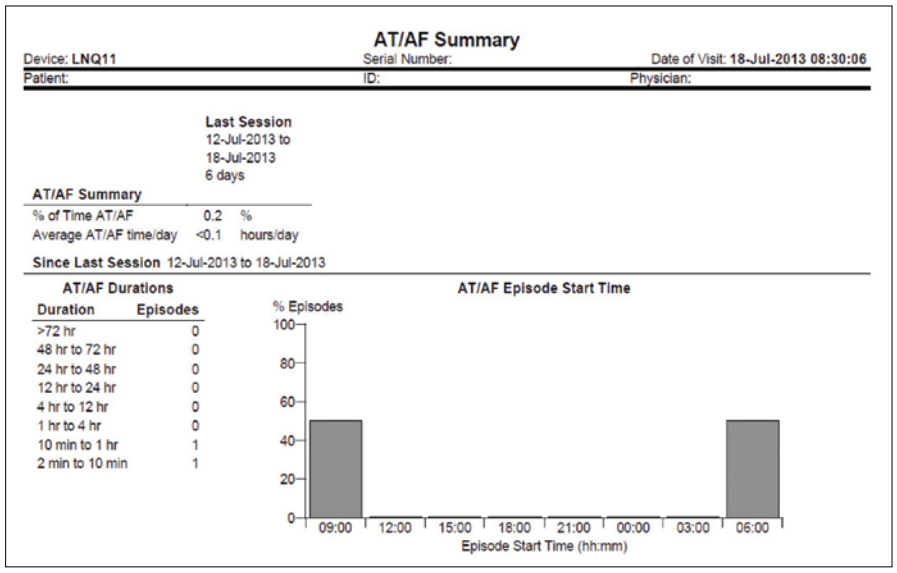
The report includes data from the current (since last session) collection period.



Širdies susitraukimų dažnio histogramos sudarymo galimybė.

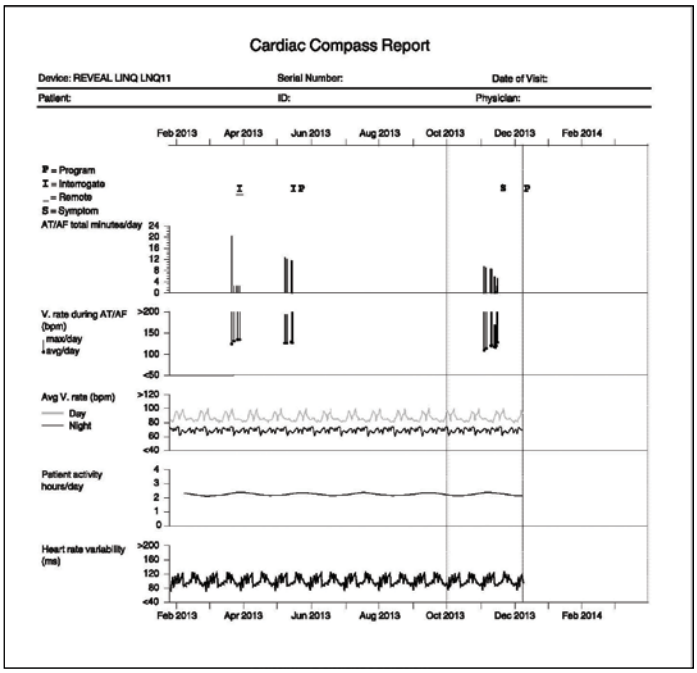
AT/AF Summary

AT/AF Summary report provides an overview of all atrial arrhythmias detected, including percentage of time in AT/AF, average time in AT/AF per day, and number of episodes at a given duration.



Cardiac Compass® Trends

Cardiac Compass Report provides trending data, which includes daily AT/AF burden, V. rate during AT/AF, average day and night V. rate, daily activity, and heart rate variability.



All patient and clinical data are fictitious and for demonstration purposes only.

MyCareLink™

Model 24950 Patient Monitor Specifications

Monitor Specifications

Open Source Software

This product contains certain third party software that is subject to specific license terms. You may go to: www.Medtronic.com/monitorsource to obtain the terms and warranty limitations applicable to the software and, in some cases, a free copy of the software (subject to nominal distribution charges).

Standards (The monitor complies with the following:)

EMC: CFR 47 Part 15
Patient Safety: IP22 (monitor base); IP21 (reader); IEC 60601-1, ETL, Type BF applied part (reader), ordinary, continuous operation, Class II, not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.

Recommended Environmental Conditions During Storage and Transport

Temperature: -40 °C to 70 °C (-40 °F to 158 °F)
Relative Humidity: 5% to 95%
Safe when stored or transported in temperatures from -40 °C without relative humidity control to 70 °C at a relative humidity of 5% to 95%, including condensation.

Recommended Operating Conditions

Temperature: 5°C to 40°C (41°F to 104° F)
Safe when operated at temperatures from 5°C to 40°C (41°F to 104°F) in relative humidity from 15% to 93%, non-condensing.

Power Supply

To assure compliance to the specified standards, use only the power supply that came with your monitor: MENB1020A0502-XXX.
Rated Voltage AC 100 - 240V
Rated Line Frequency 50 - 60Hz
Current 0.5A Max. at 100 VAC input
The power supply is to be used for mains disconnection.

Expected Service Life

The expected service life of a monitor is 5 years.

Disposal

Follow local regulations for proper disposal of this product. Do not dispose of this product in the unsorted municipal waste stream. This product contains materials that can harm the environment.
See http://recycling.medtronic.com for instructions on proper disposal of this product.

Testing

Electromagnetic Compliance (EMC) testing shows that the monitor provides reasonable protection against harmful interference in a typical medical installation. However, there is no guarantee that interference will not occur in a particular installation.

Length: 8.15" (20.7 cm) Width: 6.03" (15.3 cm)
Height: 2.60" (6.6 cm)
NOTE: All dimensions are approximate.

Testing (continued)

If the monitor does cause harmful interference to other devices or is negatively impacted by other devices, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the devices.
- Increase the separation between the devices.
- Consult Medtronic for help.

If you experience performance issues with your Model 24950 MyCareLink Monitor, try using it at least two meters (6 feet) away from all wireless communication devices such as cellular phones, television monitors, or computer screens.

Safety and Technical Inspection

An annual safety and technical inspection of the monitor is not required.

Consumer Information and Requirements

Declaration of Conformity

Medtronic declares that this product is in conformity with the essential requirements of Directive 1999/5/EC on Radio and Telecommunications Terminal Equipment and Directive 90/385/EEC on Active Implantable Medical Devices.

FCC Requirements

The monitor has been tested for compliance to FCC regulations. Changes or modifications of any kind not expressly approved by Medtronic could void the user's authority to operate the monitor.

FCC ID LF524950

FCC ID LF524955 (contains FCC ID T7V1315)

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this Device must accept any interference received, including interference that may cause Undesired operation. The monitor has been tested for compliance to FCC regulations.

Changes or modifications of any kind not expressly approved by Medtronic could void the user's authority to operate the monitor.

This transmitter is authorized by rule under the Medical Device Radiocommunication Service (in part 95 of the FCC Rules) and may not interfere with stations operating in the 400.15-406 mhz band in the meteorological aids, meteorological satellite, and earth exploration satellite services (i.e. transmitter and receivers used to communicate weather data) and must accept any interference received, including interference that may cause undesired operation. This transmitter shall be used only in accordance with FCC Rules governing the Medical Device Radiocommunication Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communication Commission there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.

Industry Canada Requirements

IC: 3408D-24950

IC: 3408D-24955 (contains IC: 216Q-1315)

Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device. "This device may not interfere with stations operating in the 400.150-406.000 MHz band in the meteorological aids, meteorological-satellite, and earth exploration-satellite services and must accept any interference received, including interference that may cause undesired operation."

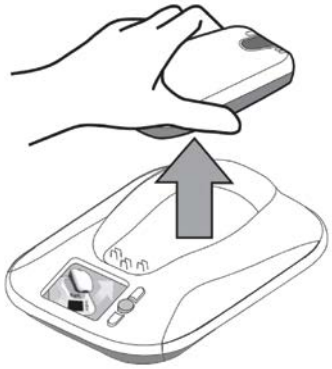
The Medtronic model 24950 MyCarelink Patient Monitor is used for wireless gathering of patient data from a Medtronic implanted cardiac device. This data is then transmitted to the clinic or to a medical database for diagnostic and follow up use by qualified medical professionals. Wireless data gathering of this device is done by means of low power wireless radio transmissions with the following specifications.

Standard/Protocol	MICS (Medical Implant Communication Service)
Operating frequency	402-405 MHz
Number of RF Channels	at least 9
Transmitter RF output	less than 25 microWatts E.I.R.P.
Modulation	FSK
Duty Cycle	less than 10%
Antenna	integral antenna, no external antenna connector
Modulation Bandwidth	less than 300 kHz
Certifications	ETSI EN 301 839 (Radio) ETSI EN 301 489 (EMC)

Standard/Protocol	Inductive wireless telemetry in 9 -315 kHz band
Operating frequency	150 - 200 kHz
Number of RF Channels	1, Single channel operation
Transmitter RF output	Maximum H field strength of 6 dBuA/m at 10 meters
Modulation	FSK or OOK depending on the data rate
Duty Cycle	less than 10%
Antenna	integral loop antenna, no external antenna connector
Modulation Bandwidth	less than 50 kHz
Certifications	ETSI EN 302 195 (Radio) ETSI EN 301 489 (EMC)

Standard/Protocol	MEDS (Medical Data service)
Operating frequency	401-402 MHz
Number of RF Channels	10 channels
Transmitter RF output	Not applicable, receive mode operation only
Antenna	integral antenna, no external antenna connector
Certifications	ETSI EN 302 537 (Radio) ETSI EN 301 489 -29 (EMC)

Standard/Protocol	Bluetooth
Operating frequency	2,400-2483.5 MHz
Number of RF Channels	79
Transmitter RF output	12 dBm (typical EIRP)
Modulation	FHSS
Antenna	integral antenna, no external antenna connector
Certifications	ETSI EN 300 328 (Radio) ETSI EN 301 489 (EMC)



24950 MyCarelink Patient Monitor

Brief Statement
See the device manual for detailed information regarding the implant procedure, indications, contraindications,warnings, precautions, and potential adverse events.

The Medtronic MyCareLink Patient Monitor and the Medtronic CareLink® Network are indicated for use in the transfer of patient data from Medtronic implantable cardiac devices. These products are not a substitute for appropriate medical attention in the event of an emergency. Data availability and alert notifications are subject to Internet connectivity and access, and service availability. The MyCareLink Patient Monitor must be on and in range of the device. Alert notifications are not intended to be used as the sole basis for making decisions about patient medical care.

Medtronic CareLink Programmer
The Medtronic CareLink programmer is a portable, microprocessor-based instrument used to program Medtronic implantable devices.

www.medtronic.com/manuals

Consult instructions for use at this website. Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

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