

1.1. Kardiotokografo bevielių
daviklių stotelė



Avalon Cableless Monitoring

Avalon CL Base Station 866074

Avalon CL Toco⁺ MP Transducer 866075

Avalon CL Ultrasound Transducer 866076

Avalon CL ECG/IUP Transducer 866077

Technical Data Sheet

The Avalon CL Transducer System offers the choice of freedom, eliminating cables for all possible fetal and maternal measurements. With the Avalon CL Transducer System, you have the full performance and features available as with the wired Smart Transducers: same ultrasound performance, monitoring twins and triplets, Smart Pulse, and Transducer Finder LED. Maternal measurements can be also monitored wireless using the IntelliVue CL Pods.

The Avalon CL Transducer System combines convenience and versatility with ease of use; freeing the mother from cables during all stages of care, especially in labor and delivery.

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Features

It offers: Belaidžiai, atsparūs vandeniui ir lengvi davikliai (US ir TOCO)

- 1.1.3. • **Cableless, waterproof, light-weight transducers**
- Constant strong performance of the CL US transducers throughout the operating time
- Higher clinical confidence, by allowing expectant mothers continuously be monitored, including during a bath or shower, or while ambulating
- On demand audible patient call from the fetal monitor
- Cableless monitoring for twins and triplets
- 1.1.2. • **Reliable fetal parameter signal quality with a line-of-sight operating range of up to 100 m/ 300 ft¹**
Teikia patikimus nuolatinius vaisiaus ir motinos parametrų matavimus 100 m atstumu nuo stacionarių kardiografų (vaisiaus monitorių)
- Automatic out-of-range notification for the patient
- User-friendly intuitive controls at the display of the connected fetal monitor
Didelės talpos, įkraunama ličio jonų baterija, veikia ilgiau nei 8 valandas vienu įkrovimu
- 1.1.5. • **High capacity, rechargeable Lithium-Ion batteries, combining an operating time of more than 8 hours** per charge cycle with a short recharge time of less than 3 hours
- Easy and quick assignment of transducers and CL Pods by simply docking them at the base station
Stotelė prisijungia prie bet kurio Philips Avalon FM30 daviklio
- 1.1.1. • **The base station connects to any fetal sensor socket on the Philips Avalon FM20, FM30, FM40 and FM50 fetal monitors, or to the rear telemetry connectors of the FM40 and FM50**
- The Avalon CL base station is powered by the fetal monitor with an interface cable, and so eliminating the need for an extra connection to the AC power source

Description

The Avalon CL Transducer System consists of a base station and the following optional transducers: Belaidis UG daviklis

- 1.1.3. • **A cableless US transducer** measuring fetal heart rate and fetal movement profile
Belaidis Toco+MP daviklis matuojantis motinos pulsą ir tiesioginę EKG
- 1.1.6. • **A cableless Toco+MP transducer measuring** uterine activity externally, **maternal pulse**, and either **DECG**, **MECG**, or **IUP**
- 1.1.8. • A cableless ECG/IUP transducer measuring either **DECG**, **MECG**, or **IUP**
- In addition the base station provides an interface to the IntelliVue CL SpO₂ Pod and IntelliVue CL NBP Pod, refer to the Technical Data Sheet of the IntelliVue Cableless Measurements

Operation

The Avalon CL base station is configured and operated with the touch screen of the connected fetal monitor.

Assignment and Charging Slots

There are three CL transducer slots and one slot for the CL Pods. You can assign up to four CL transducers and two CL Pods. Whenever the Avalon CL base station is connected to a fetal monitor, the docked CL transducers and CL Pods are automatically assigned and recharged.

Transducers

Kiekvienas belaidis daviklis turi šviesos diodą, kuris šviečia keliomis spalvomis ir rodo, pavyzdžiui, daviklio akumuliatoriaus įkrovos būseną arba daviklio ryšio su stotele būseną.

Each cableless transducer has an LED that lights up in multiple colors to indicate, for example, the battery charge status of the transducer, or the transducer's connectivity status to the base station.

1.1.4.

For monitoring twins and triplets, additional transducers can be easily assigned by briefly docking them on the Avalon CL base station.

Radio Frequency Transmission

The CL transducers transmit measurement data with radio to the Avalon CL base station which transfers the data to the connected fetal monitor.

The transducers can be configured to available local radio frequency channels operating within the country specific frequency range. Be sure to comply with any local regulations regarding approved frequencies, and contact Philips for assistance with your specific requirements.

Frequency Ranges

Country/Country Group	Hardware RF Tuning Range (MHz)
Japan	920.6 – 923.4
Most European Countries (covers Industrial, Scientific, and Medical [ISM] band)	433.05 – 434.79
USA, Canada, Australia (covers Wireless Medical Telemetry Service [WMTS] band)	608 – 614

Alarms

Alarms are available for the loss of the radio connection, low/empty battery, and malfunctioning of the cableless transducers.

Safety Features

- Optical alarm before the battery is empty
- Optical and acoustic alert if the patient moves out of the range of monitoring
- Automatic resume after power failure

¹ The effective operating range can vary depending on the geographical and constructional characteristics of the building where the system is installed, and whether underwater monitoring is performed.

Interface Capabilities

Avalon FM20/FM30/FM40/FM50 Fetal Monitors

The Avalon CL base station interfaces to the Avalon family of fetal monitors² with a cable. The cable connects to any of the four red fetal sensor sockets on the fetal monitor with the red connector. Alternatively, for the FM40/FM50, a cable with a black connector connects to the black telemetry sockets at the rear of the fetal monitor. Whether the Avalon CL base station is delivered with a red or black connector, is an ordering option (K30/K40).

Related Products

For monitoring the maternal parameters, you can use the IntelliVue CL SpO₂ Pod and the IntelliVue CL NBP Pod with the Avalon CL base station. Refer to the Technical Data Sheet for the IntelliVue Cableless Measurements for details on their features.



The Avalon CL base station communicates with a built-in short range radio and integrated antenna with the IntelliVue CL Pods (in-room operating range). The option to monitor with the IntelliVue CL Pods is not available for the FM20/30 #E25 Battery Option.

Standards Compliance

Federal Law in the USA restricts this device to use by or on the order of a physician.

The Avalon CL Transducer System complies with the requirements of the Medical Devices Directive (93/42/EEC) and the Radio and Telecommunications Terminal Equipment Directive (1999/5/EC), and with the following standards:

Safety, Performance

- IEC 60601-1:2005+A1:2012 / EN 60601-1:2006+AC:2010
- IEC 60601-1-6:2010 / EN 60601-1-6:2010
- IEC 60601-1-8:2006 / EN 60601-1-8:2007+AC:2010
- IEC 60601-2-27:2011+AC:2012 / EN 60601-2-27:2006+AC:2006 except clauses 201.6.2, 201.8.5.5, 201.12.1.101, 202.6.2.101)
- IEC 60601-2-37:2007 / EN 60601-2-37:2008

- IEC 60601-2-49:2011 / EN 60601-2-49:2001
- ANSI/AAMI ES60601-1+C1:2009+A2:2010
- CAN/CSA C22.2#60601-1-08+TC2:2011
- JIS T 1303 2005
- AS/NZS 3200.1.0-1998

The possibility of hazards arising from hardware and software errors was minimized in compliance with ISO 14971:2012.

Electromagnetic Compatibility

- IEC 60601-1-2:2007 / EN 60601-1-2:2007+AC:2010
 - ICES-003:2012
- 866074 is classified as electromagnetic emissions Class A.

Radio

- ETSI EN 300 220-1:2012
- ETSI EN 300 220-2:2012
- ETSI EN 301 489-1:2011
- ETSI EN 301 489-3:2003
- FCC 47 CFR Part 95
- IC RSS-210 Issue 8
- ARIB STD-T108
- ETSI EN 300 328:2006
- ETSI EN 301 489-17:2009
- FCC 47 CFR Part 2 & 15
- AS/NSZ 4268
- AS/NSZ 4771:2000+A1:2003
- ARIB STD-T66

Environmental Specifications

The Avalon CL base station and the CL transducers may not meet the given performance specifications if stored and used outside the specified temperature and humidity ranges.


Transducers and Base Station		
Temperature Range	Operating	
Base Station		0 – 45°C (32 – 113°F)
Transducers	Operating	0 – 40°C (32 – 113°F)
	Storage	-20 – +60°C (-4 – 140°F)
Humidity Range	Operating	< 95% relative humidity @ 45°C (113°F)
	Storage	< 95% relative humidity @ 60°C (140°F)

² Requires monitor software revision J.3 or higher.

Physical Specifications

Base Station Specifications		
Power	Powered by connected fetal monitor	
Dimensions and Weight	Width x depth	349 x 183 x 74 mm
	x height	(13.7 x 7.2 x 2.9 in)
	Weight	0.985 kg (2.2 lbs) without transducers
Type of Protection Against Electrical Shock	Class II equipment	
Water Ingress Protection Code	IP 31	

Transducer Specifications		
Toco ⁺ MP	Diameter	75.5 mm (2.9 in)
Transducer	Height	36.6 mm (1.4 in)
866075	Weight	123 g ± 10% (4.3 oz ± 10%)
US	Diameter	75.5 mm (2.9 in)
Transducer	Height	36.6 mm (1.4 in)
866076	Weight	131 g ± 10% (4.6 oz ± 10%)
ECG/IUP	Diameter	75.5 mm (2.9 in)
Transducer	Height	36.6 mm (1.4 in)
866077	Weight	121 g ± 10% (4.2 oz ± 10%)
Battery	Type	Integrated rechargeable Li-ion battery with a battery gauge and a cycle counter
	Runtime (fully charged battery)	min. 8 hours
	Life	> 500 charge/discharge cycles or longer than 4 years
	Transducer Storage Time	≥ 1 year at 25°C (77°F) (battery should be charged to 40 – 50% every 6 months)
	Recharging Time	100% charged ≤ 3.0 h
	Recharging Time with an FM20/30 #E25	100% charged > 6.0 h
Operating Range	Receiving Range (line of sight)	approximately 100 m (300 ft. ¹)

Transducer Specifications		
Degree of Protection Against Electrical Shock	For US, ECG/IUP (DECG/MECG), and Toco ⁺ MP parameters, CL transducers are battery operated	Type CF 
Water Ingress Protection Code	IP 68 (1.0 m immersion for 5 hours)	
	1.1.3.	Apsauga nuo vandens: IP 68
Usability Underwater	≤ 1.0 m	
Shock Resistance	Withstands a 1.5 m drop to a concrete surface with possible cosmetic damage	
Nominal RF Output Power	< 1 mW (ERP)	

¹ The effective operating range can vary depending on the geographical and constructional characteristics of the building where the system is installed, and whether underwater monitoring is performed.

Performance Specifications

CL US		
US Intensity	Average output power	$P = (12.4 \pm 0.4) \text{ mW}$
	Peak-negative acoustic pressure	$p_- = (49.1 \pm 5.2) \text{ kPa}$
	Output beam intensity (I_{ob}) (= spatial average - temporal average intensity)	$I_{sata} = (2.77 \pm 0.56) \text{ mW/cm}^2$
	Spatial-peak temporal average intensity	$I_{spta} = (21.1 \pm 5.1) \text{ mW/cm}^2$
	Effective radiating area @ -12 dB	A-12 dB = $(4.47 \pm 0.89) \text{ cm}^2$
	Thermal index (TI) and mechanical index (MI) are always below 1.0	
	Beat-to-Beat change (max.) for Ultrasound	28 bpm
US Frequency	1 MHz ± 100 Hz	
US Signal range	3.5 μVpp – 350 μVpp @ 200 Hz	
US Burst	Repetition Rate	3.0 kHz
	Duration	≤ 100 μs
FMP Signal Range @ 33 Hz	200 μVpp – 40 μVpp	

Toco	
Measurement Method	Strain Gauge Sensor Element
Sensitivity	1 unit = 2.5 g
Measurement Range	400 units
Signal Range	0 – 127 units
Maximum Offset Range	-300 units
Baseline Setting	20 units
Auto Offset	3 seconds after activating the transducer, the
Correction	Toco value is set to 20 units
Auto Zero	The Toco value is set to zero following a negative
Adjust	measurement value for 5 seconds

Motinos pulsas matuojamas TOCO davikliu. Diapazonas: nuo 40 iki 240 k/min.

Maternal Pulse from Toco	
Emitted Light Energy	≤ 15 mWV
Wavelength Range	780 – 1.100 nm
Range	1.1.7. 40 – 240 bpm
Accuracy	± 2% or 1 bpm, whichever is greater
Update Rate	Every 4 seconds

IUP	
Measurement Method	Passive Resistive Strain Gauge Elements
Measurement Range	-100 – +300 mmHg
Signal Range	-99 – 127 mmHg or -13.2 – 16.9 kPa
Sensitivity	5 µV/V/mmHg
Offset Compensation	+100 – -200 mmHg
Accuracy (not including sensor accuracy)	± 0.5% per 100 mmHg
Auto Offset	3 seconds after activating the measurement, the
Correction	IUP value is set to 0 mmHg

ECG		
Performance Specifications Type	DECG	(Single Lead) ECG (derived from Fetal Scalp Electrode)
	MECG	Single Lead ECG (derived from RA and LA electrodes)
Measurement Range	30 – 240 bpm	
Wave Speed (Global Speed)	6.25 mm/sec, 12.5 mm/sec, 25 mm/sec, 50 mm/sec	
Accuracy	± 1 bpm or 1%, whichever is greater (non-averaging)	
Beat-to-Beat change (max.)	MECG: 28 bpm DECG: 28 bpm (with Artifact Suppression On)	
Differential Input Impedance	> 15 MΩ	

ECG		
Electrode Offset Potential Tolerance	± 400 mV	
INOP Auxiliary Current (Leads Off Detection)	< 100 µA	
Input Signal Range	DECG	20 µVpp – 6 mVpp
	MECG	150 µVpp – 6 mVpp
Dielectric Strength	1500 Vrms	
Defibrillator Protection	None	
ESU Protection	None	
Paced Pulse Detection	None	

Complies with IEC 60601-2-27:2011+AC:2012 /

EN 60601-2-27:2006+AC:2006 except clauses listed below:

- 201.6.2, 201.8.5.5
- 201.12.1.101
- 202.6.2.101

Sub clause 201.12.1.101.15 on heart rate range and accuracy is passed.

Ordering Guide and Accessory Options

You can order the Avalon CL Fetal Transducer System under the product number 866074. To order, precede the required option number with 866074 (for example, you would order an Avalon CL base station together with one CL Toco⁺MP and one CL US transducer using 866074 #A02). “K” options let you modify your order. The following tables provide an overview of the various options. Order upgrade options by using the prefix **866074 AU**.

System Hardware Components	Product Number
Base Station	866074
Cableless Toco ⁺ MP Transducer	866075
Cableless Ultrasound Transducer	866076
Cableless ECG Transducer	866077
Mounting brackets	order directly from GCX

866074 Modification Options	
Option No.	Description
K30	Avalon CL base station (red connector), for connection to fetal sensor sockets of the Avalon FM20/FM30/FM40/FM50 fetal monitors (the monitor requires the software revision J.3 or higher)

866074 Modification Options	
Option No.	Description
K40	Avalon CL base station (black connector), for connection to the telemetry sockets of the Avalon FM40/FM50 fetal monitors only (the monitor requires software revision J.3 or higher)
K60	External Power Supply for the Avalon CL base station (only required if the base station is used as a charging station; not yet available)

Transducer Options

Option No.	Description
K01	1 Avalon CL Ultrasound Transducer
K02	2 Avalon CL Ultrasound Transducers
K03	3 Avalon CL Ultrasound Transducers
K11	1 Avalon CL Toco ⁺ MP Transducer
K21	1 Avalon CL ECG/IUP Transducer
K22	2 Avalon CL ECG/IUP Transducers

System Accessories and Supplies

Accessory		Order Number
Waterproof belts		M1562B
Disposable abdominal belts (case of 100)		M2208A
Avalon CL Belt Clips		989803184851
Avalon CL Connector Caps		989803184841
Ultrasound gel	12 Bottles	40483A
	5 liter refill (with dispenser) for 40483A	40483B
	Shelf life: at least 6 months	

Accessory		Order Number
DECG accessories	DECG reusable leg plate adapter cable (with flushing port)	989803137651
	DECG leg attachment electrode for the DECG leg plate adapter cable	989803139771
	DECG fetal scalp electrode: single spiral, worldwide availability	989803137631
	DECG fetal scalp electrode: double spiral, Europe only, not for the USA	989803137641
MECG adapter cable		M1363A
MECG electrodes		40493E
Avalon CL Battery Replacement Kit		989803184861

Mounting Options

Product	Option No.	Description
M2740A	C02	Avalon FM Cart
	U01	Mounting Kit for the Avalon FM Cart

Mounting Solutions

There are several ways to mount the Avalon CL base station:

- On a dedicated mounting shelf, available for the Avalon FM Cart
- On top of the Avalon FM40/FM50 fetal monitors using mounting brackets
- On top of carts or desks



Avalon FM Cart with an Avalon CL mounting kit



Avalon FM Cart with an Avalon CL mounting kit

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The 866074 Avalon CL Fetal Transducer System complies with the requirements of the Council Directives 1993/42/EEC (Medical Device Directive) and 1999/5/EC (Radio and Telecommunications Terminal Equipment Directive).

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