

12-Lead Chest Lead Set Instructions for Use

Комплект гръдни отвеждания за ЕКГ с използване на 12 отвеждания Указания за употреба

Sada hrudních svodů pro 12svodové EKG Návod k obsluze

Brystafledningssæt til 12-aflednings-EKG Brugerhåndbog

12-Kanal-Brustwandkabel-Set Gebrauchsanweisung

Σετ απαγωγών θώρακα για ΗΚΓ 12 απαγωγών Οδηγίες χρήσης

Juego de latiguillos precordiales de 12 derivaciones Instrucciones de uso

12-lülituselise EKG rindkere lülituskomplekt kasutusjuhend

Rintakytöntäsarja, 12-kytk. EKG Käyttöopas

Jeu de fils d'électrodes précordiales à 12 dérivations Instructions d'utilisation

Mellkasi elvezetékészlet, 12 elvezetéses EKG-hoz Használati útmutató

Set Plumbum Dada 12 Titik Petunjuk Penggunaan

Set di derivazioni toraciche per 12 derivazioni Istruzioni d'uso

12-리드 흉부 리드 세트 설명서

Set Plumbum Dada 12 Plumbum Arahan Penggunaan

12-afleidingen, afleidingenset borst Gebruiksaanwijzing

Ledningssett, bryst, for 12-avlednings EKG Brukerhåndbok

Zestaw odprowadzeń przedsercowych do EKG 12-odprowadzeniowego Instrukcja obsługi

Conjunto de derivações de tórax de 12 derivações Instruções de uso

Комплект грудных отведений для получения ЭКГ в 12 отведениях Инструкция по эксплуатации системы

Návod na použitie s Súprava hrudných zvodov na 12-zvodové EKG

Bröstelektrodkabel för 12-avlednings-EKG Bruksanvisning

12 Derivasyonlu EKG İçin Göğüs Derivasyon Seti Kullanım Talimatları

Bộ chuyển đạo ngực 12 chuyển đạo Hướng dẫn sử dụng

胸部导联组使用说明

12 導程胸導程組使用說明

Uputstvo za upotrebu za komplet vodova za grudi sa 12 vodova

English	1
Български	3
Česky	5
Dansk	8
Deutsch	10
Ελληνικά	13
Español	15
Eesti	18
Suomi	20
Français	22
Magyar	25
Bahasa Indonesia	27
Italiano	29
Melayu	32
Nederlands	34
Norsk	37
Polski	39
Português	42
Русский	44
Slovenčina	47
Srpski	49
Svenska	51
Türkçe	53
Tiếng Việt	56
한국어	58
简体中文	61
繁體中文	63

DEVICES

The information in this *Instructions for Use* applies to the following devices:

PN	Device
989803151671	12-Lead Chest Lead Set (AAMI/IEC), standard length
989803151691	12-Lead Chest Lead Set (AAMI/IEC), long

DESCRIPTION

The 12-Lead Chest Lead Set transmits electrical signals from electrodes on the patient's body to the ECG machine.

INTENDED USE/INTENDED PURPOSE/INDICATIONS FOR USE

Philips reusable ECG lead sets are limited by the indications for use of the connected diagnostic equipment, and are for use only by healthcare professionals. They are designed for multiple patient use, and indicated for monitoring cardiac signals for diagnostic purposes for the same patient populations as the host device.

PRINCIPLE OF OPERATION

The lead set transmits electrical signals acquired by electrodes to an ECG device.

INTENDED USERS/USER PROFILE

Clinicians.

INTENDED PATIENT POPULATION/PATIENT SELECTION CRITERIA

Patients include adult and pediatric patients, with or without symptoms.

MEDICAL CONDITIONS

The lead set should be used in conjunction with the host device for resting ECG diagnosis.

ENVIRONMENT FOR USE

The lead set is intended for use in hospitals and physicians' office environments.

BODY PART

The lead set should be used only on intact skin.

CONTRAINDICATIONS

There are no contraindications for the use of the complete lead set.

NOTICE

- Any serious incident that has occurred in relation to this device should be reported to Philips and the competent authority of the European Economic Area (EEA) countries, including Switzerland and Turkey, in which the user and/or patient is established.

CAUTIONS

- The lead set is an integral part of the cardiograph safety features. Use of any non-approved accessory may lead to the distortion or corruption of patient ECG data, may compromise defibrillation protection and degrade cardiograph performance, and overall cardiograph safety may be seriously degraded.
- Use of non-Philips approved cables and accessories can result in increased emissions or decreased immunity of the medical equipment.
- Always clean the patient cable using the recommended method and chemicals after each use, if the patient cable comes into direct contact with the patient's skin. Disinfect the patient cable using the recommended method and chemicals if the patient cable becomes contaminated with blood-borne pathogens. Failure to properly clean and disinfect the patient cable may cause infectious materials to be transferred between patients. Otherwise, clean the patient cable on a weekly basis.
- Do not connect the plugs for connection of lead sets to Mains socket or other outlets of the cardiograph.
- Do not touch any loose or exposed leads during defibrillation. Death or injury may occur from the electrical shock delivered by the defibrillator.
- Ensure that the electrodes or patient cable do not come in contact with any other conductive materials (including earth-grounded materials) especially when connecting or disconnecting electrodes to or from a patient.
- Always ensure that the leads connected to the patient cable are the same leads that are displayed on the cardiograph screen.
- Ensure that the lead set is securely connected to the connector on the PIM.
- Keep the lead set away from power cords and any other electrical equipment. Failure to do so can result in AC power line frequency interference on the ECG trace.
- Do not modify the lead set. If a lead set is modified by anyone other than an authorized Philips technician, the lead set is no longer covered under warranty.
- To maximize clinical efficiency and minimize patient risk, select the most appropriate lead set length for the patient's torso.

COMPATIBLE DEVICES

The 12-Lead Chest Lead Set is suitable for use with the following devices:

PN	Device	PN	Device
860306	TC30	860353	TC70 w/o trolley TAA*
860310	TC50	860439	CW** 5000 12L PIM
860315	TC70	860440	CW** 5000 18L PIM
860354	TC30 w/trolley TAA*	860441	CW** 7000 12L PIM
860355	TC30 w/o trolley TAA*	860442	CW** 7000 18L PIM
860429	TC50 TAA*	860450	CW** 5000 TAA*
860352	TC70 w/trolley TAA*	860451	CW** 7000 TAA*

* Government bundles, available only in the U.S.

** Cardiac Workstation

TECHNICAL SPECIFICATIONS

Standard 12-Lead Chest Lead Set contains:

- Chest leadwire set (1): 698 mm
- Color rings (18), AAMI or IEC
- Banana clips (3), IEC only
- Yoke labels (4)

Long 12-Lead Chest Lead Set contains:

- Chest leadwire set (1): 1066 mm
- Color rings (18), AAMI or IEC
- Banana clips (3), IEC only
- Yoke labels (4)

Note: Leadwire set can be used for V1-V3/C1-C3 or V4-V6/C4-C6.

TRANSPORTATION AND STORAGE CONDITIONS

- Temperature: -20° to 50 °C (-4° to 122°F);
- Humidity: 10% to 90% (non-condensing);
- Atmospheric pressure: 1014 to 572 hpa.

OPERATING CONDITIONS

- Temperature: 10° to 40°C (50° to 104°F);
- Humidity: 10% to 90% (non-condensing);
- Atmospheric pressure: 1014 to 572 hpa.

This set of leadwires meets the requirements of the standard, ECG TRUNK CABLES and PATIENT LEADWIRES (ANSI/AAMI EC53). This set of leadwires is intended for MULTI-PATIENT USE.

LIFETIME

The 12-Lead Chest Lead Set is designed to be used for up to 40,000 ECG cycles, based on appropriate use and handling, and required maintenance described in this *Instructions for Use*. Bending or flexing the lead set acutely can greatly reduce its life expectancy, and should be avoided.

Prior to each use, inspect the entire lead set for signs of deterioration, such as cracks in the insulation or at the base of connector pins, pitting, discoloration, kinks, or corrosion on plastic or metal. If the lead set shows any sign of deterioration, do not use it. Replace any damaged lead set.

Before conducting a study, you should verify signal quality and lead integrity. Refer to "Checking Signal Quality" in the *Instructions for Use* provided with the cardiograph. You should also periodically perform the lead wire performance test described in the *Instructions for Use* provided with the cardiograph.

ASSEMBLING THE LEAD SET

Assemble the lead set as shown:



AAMI



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The following products comply with
Regulation (EU) 2017/745 on medical
devices (MDR) and carry the CE marking
accordingly: 989803151671,
989803151691

PN 453564097241
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Revision D
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<https://www.patientcare.shop.philips.com/>



In the U.S., Federal law restricts this device to sale by or on the order of a
Physician.



www.Philips.com/IFU

