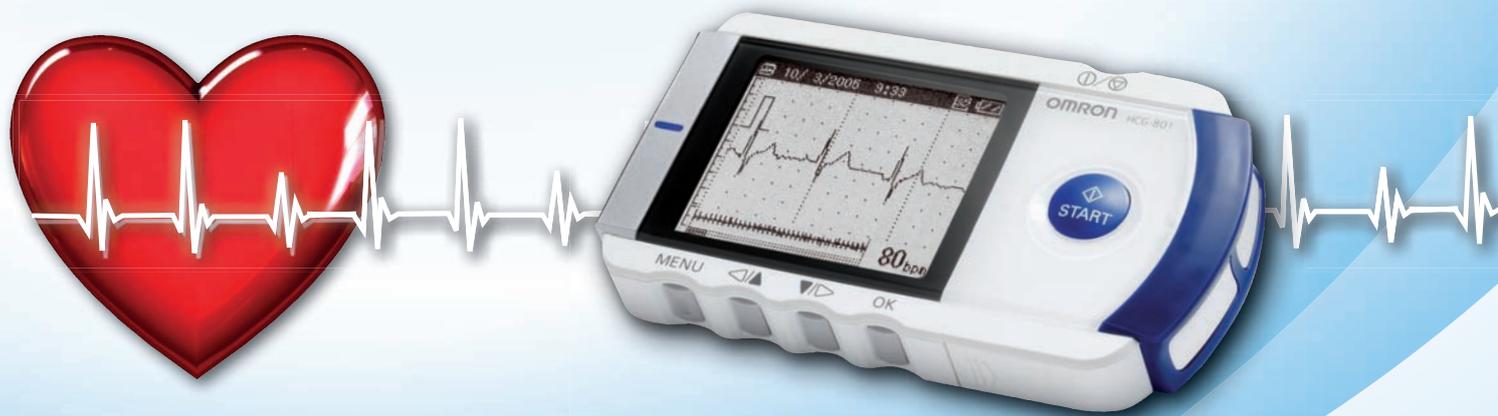


Heart Scan

OMRON

Screening & Self-Monitoring
of cardiac events



Portable, cordless,
single-channel
ECG Monitor (HCG-801-E)

Compact - Cordless -
Simple operation -
Fast - Discrete



A Good Sense of Health

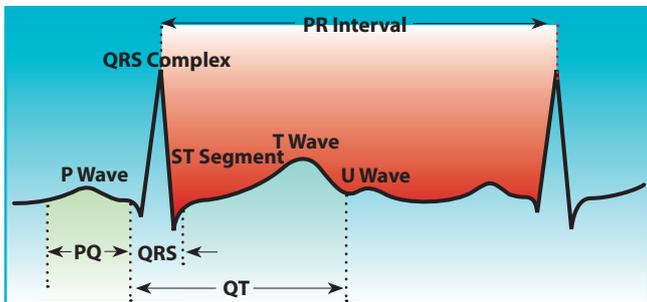
www.omron-healthcare.com

Taking a closer look at Cardiovascular Risk Monitoring

In Europe the main cause of mortality is cardiovascular disease or CVD (e.g. stroke, heart attack, heart failure) ¹. A major risk factor for CVD is high blood pressure ². OMRON has an established reputation for blood pressure monitoring in home as well as hospital settings. Now OMRON has applied their traditional expertise in sensor technology to take the next step in CVD monitoring in the homecare situation.

According to the company philosophy, OMRON has developed a new home monitoring device. The new HeartScan ECG Monitor senses the heart waveform and indicates potential ECG abnormalities.

The ECG waveform from the heart shows when the heart contracts and relaxes and gives the heart rhythm of consecutive heartbeats. In a healthy heart the waveform pattern shows a regular shape and rhythm. In case of heart disease, abnormalities can be detected. Symptoms such as heart pain, palpitations, and shortness of breath may be signs of heart diseases such as angina or cardiac infarction.



With the OMRON Portable HeartScan ECG Monitor, a recording of about 30 seconds can be made when symptoms occur whether at home or away. These recording details can then be shown for information to the doctor, who can examine it and use it for correct diagnosis. From an analysis of the waveform some information can

be obtained on the presence of arrhythmia or ST-level deviations related to ischaemic heart disease.

Taking the condition of the user into consideration, the user-friendly and ergonomic design allows the user to take a reading instantly and discretely. The design of the pick-up sensor system provides a sufficiently clear signal for further evaluation in the ECG device.

By comparing your electrocardiogram rhythm and shape with normal waves, various heart diseases can be diagnosed.

Arrhythmia

For example, problems between RR's indicate a problem with your heartbeat rhythm.

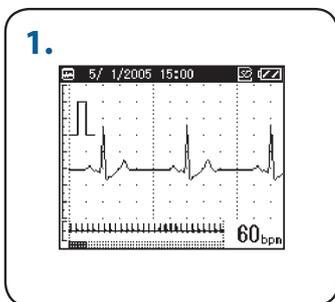
Problems with Heart Shape & Functions

For example, increases or decreases in the ST portion are shown if there is a cardiac infarction or angina. This ST portion is also used to determine ischemic heart disease.

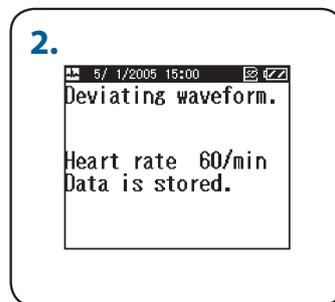
¹ European cardiovascular disease statistics. BritishHeart Foundation / European Heart Network February, 2005 edition.

² European guidelines on cardiovascular disease prevention in clinical practice European Society European guidelines on cardiovascular disease prevention in clinical practice European Society of Cardiology European Heart Journal (2003) 24.

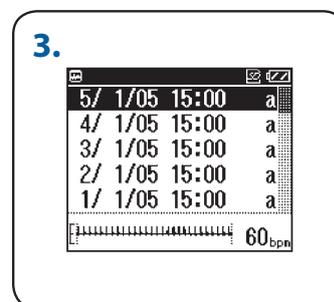
Basic Functioning Principle OMRON HeartScan



1.
Actual Heart rate
Detail ECG
30 second ECG recording with window indication.



2.
ECG analysis result on:
• Heart rate
• Heart rhythm
• Heart waveform
30 seconds average heart rate
3-stage deviation level indication
• Store data Yes/No?
(None or slight deviations from normal)
• Data is stored.
(Moderate deviations from normal)
• Data is stored. Please show to your doctor.
(Significant deviations from normal)



3.
Date and time of measurement
ECG analysis result indicator
30 seconds wave form
30 seconds average heart rate

Result indicator

- a Stable waveform
- b Fast heart rate
- c Fast and irregular heart rate
- d Fast heart rate and deviating waveform
- e Fast and irregular heart rate, deviating waveform
- f Slow heart rate
- g Slow and irregular heart rate
- h Slow heart rate and deviating waveform
- i Slow and irregular heart rate, deviating waveform
- j Irregular heart rate
- k Irregular heart rate and deviating waveform
- l Deviating waveform
- m Analysis impossible. Please measure again.

Where can HeartScan be used?

The unique features of the HeartScan ECG Monitor make this a versatile multi-purpose tool for medical professionals. The cordless operation and direct on-screen display allows a quick-scan of the heart condition. Due to the compact design the device fits in a white-coat pocket or doctor's bag.

Primary Care

Office



In primary care the HeartScan ECG Monitor offers a fast way to pre-screen patients in the office on possibly CVD related complaints.

Instead of palpitation, the device can give a clear picture of the heart rhythm in only 30 seconds. The device can show events such as extra systoles, premature ventricular contractions, supra-ventricular premature contractions and ST-level deviations.

Outpatient visit

The portability of the device makes it very suitable to use in the outpatient visits. The direct on-screen display makes it possible to evaluate the ECG without first printing or downloading the reading.



Home-care situation

Worried patients without obvious CVD risk factors in daily practice can be lent the device for home monitoring. By having these patients monitoring themselves the complaints can be confirmed to be related to a cardiac condition.

The device can help assess the necessity to refer the patient to secondary care.



Secondary Care

Clinic

When after 12-lead ECG, exercise and Holter/event monitoring, the complaints cannot be explained due to the transient character, the HeartScan ECG Monitor can be a valuable addition. Instead of discharging these patients the device can be lent out for a longer period of time to use when symptoms occur. Alternatively the patient can be instructed to measure at regular intervals to assess circadian influences. In situations where patients refuse implantation of an event recorder, this device can be a substitute. The decision to suggest the implanted recorder could be preceded by a period using the HeartScan ECG Monitor. After diagnosis is established and the patient is prescribed to take medication the HeartScan ECG Monitor can be used to check medication tolerance, efficacy and compliance. When the medication is properly dosed and the patient is complying with the medication regiment the use of the device can be stopped.

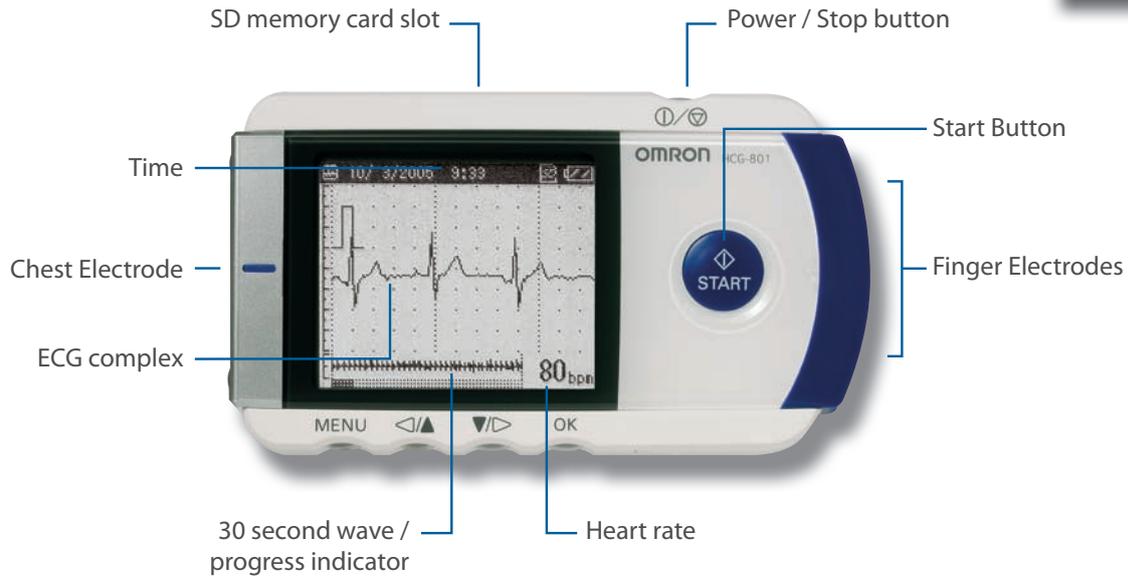


Wards

When hospitalized not all patients are under 24-hour surveillance for heart monitoring. There are several circumstances where the HeartScan ECG Monitor would be a valuable tool for a quick scan of heart function.

- Before and during dialysis
- Patients after an operation
- Patients in the emergency room





- Portable and compact
- Direct review of results on clearly readable, high resolution screen with backlight
- Cordless (no need to wear electrodes, no difficulties with cables)
- Very user-friendly
- Economically priced
- PC download through SD memory for 300, date & time stamped, measurements
- Low power consumption (works on rechargeable batteries - not included)
- Includes analysis software to show the results directly to the user with a clear recommendation on the results

Quick Start Guide for Correct Measurement

How to use the unit

Press the button to switch on the power, then place your finger **closely** on the two finger electrodes.

Do not press the START button until you are ready to take a measurement.

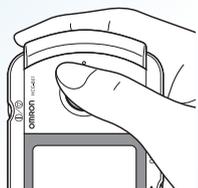
Appropriate Posture

Place the chest electrode on bare skin about 5 cm below your left nipple.

Press the chest electrode closely to your chest.

Taking a Measurement

Start Press the START button while maintaining the same posture.

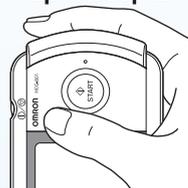


The unit beeps every second.

About 30 seconds

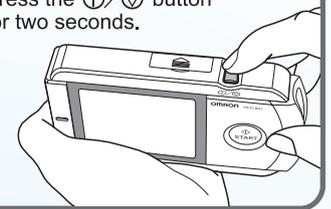
Keep still and do not move until the measurement is complete.

End The measurement ends automatically, indicated by 4 rapid beeps.



Power off

Press the button for two seconds.



HeartScan intended use



User-friendly screening and monitoring device, immediately available at any time to manually record transient cardiac events, suitable for patient and professional use.

Helpful in determining cardiacaetiology of symptomatic events. Monitoring of heart condition for ambulatory patients exposed to stroke, MI and sudden death risk. Monitoring of efficacy and tolerance to medication regimen. The HeartScan ECG Monitor should only be used by patients following consultation with a medical professional.

Patients with transient or paroxysmal events of	Patients with complaints of suspected cardiac origin	Patients on medication	Patients after medical cardiac intervention	Patients with high risk scores on CVD (e.g. ESC SCORE card)
Brady- and Tachycardia	Dizziness	Medication tolerance	Checking frequency of AF and Arrhythmia	Diabetes
Atrial Fibrillation (AF)	Palpitations	Medication efficacy	Checking severity of AF and Arrhythmia	Hypertension
Arrhythmia	Chest / arm pain	Medication compliance		Hypercholesterolemia
Syncope	Shortness of breath			Obesity
				Smoking, etc.



Monitoring on a regular basis...

Ischaemic heart disease or arrhythmia can be transient. ECG performed and read at a hospital clinic or doctor's surgery is part of the normal investigation to establish if cardiac conditions are present. Due to the transient symptoms, abnormalities are not always detected, although disease is actually a problem in daily life.

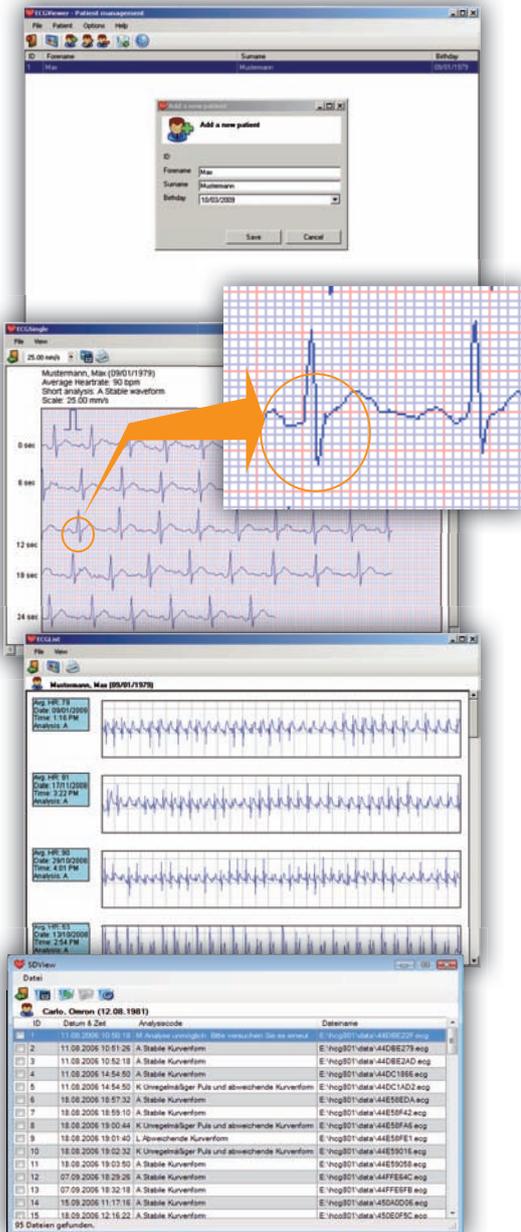
The Holter ECG is an alternative in these circumstances, but involves a minimum of 24 hours with the patient wearing the device and the attached electrodes and leads. It is also costly and time intensive for staff and still does not always record an event occurring. Sometimes the worsening of a heart condition (increasingly repetitive pattern of transient abnormalities) can alert and allows taking corrective treatments before a potential heart attack or stroke. The HeartScan ECG monitor can detect the waveform and provides relevant data to the doctor on the heart condition of the patient in daily life.

The prospective, multi-center validation by AFNET*, with more than 500 patients, confirms once more the diagnostic yield of the HeartScan compared with a standard 12-lead surface ECG. Analysis of the patient-activated ECG system detects over 90% of abnormalities in the 12-lead ECG, including ST-wave changes and bundle branch block.

* ESC 2008: Publication of the study poster

You can import ECG data into your computer and use it for diagnosis.

ECG Viewer is a software, which allows importing data from the HeartScan ECG Monitor into a computer so that it can be reviewed and printed. The software allows changing of the scale and range of the ECG to better observe specific events. This makes it very useful for doctors when making their diagnosis.



Simple patient management.

With the patient management you can manage the data of the patient such as name, first name and date of birth. Of course, you also have the possibility to add new patients and edit or delete existing patients.

The software allows changing the display scale freely in order to confirm details.

This feature can be used to display a detailed screen for close observation of a specific period.

Comparison between electrocardiograph complexes is possible.

Different measurements can be compared according to date or time using the electrocardiogram data list. Display of multiple detail screens to compare information is also possible.

Printing of ECG data.

It is possible to set printing details such as the scale of the ECG data. In addition, it is possible to select and print multiple ECG data, or print all ECG wave data in a folder.

Managing ECG data.

Recorded ECG data can be copied from the SD memory card to hard disk and redundant data may be deleted.

Hardware Requirements

Operating System	Windows 2000 Professional (Service Pack 4)
	Windows XP Professional (Service Pack 3)
	Windows Vista (Service Pack 1)
CPU	600 MHz or faster Intel Processor
Memory	256 MB or more
HDD Free Space *	150 MB or more
Other	Port for SD Memory Card Reader (for reading SD Memory Cards)

* This refers to your computer free space. Free space is necessary for saving electrocardiogram data separately.



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⚠ This medical equipment is meant only as a reference in assisting doctors make a diagnosis. It is not a diagnosis in itself.
 Self-diagnosis and treatment based on measurement results is very dangerous. Please ask your doctor to analyze the measurement results (electrocardiogram) and do not make a self-diagnosis based on displayed messages. Self-diagnosis based on measurement results can cause more serious symptoms.