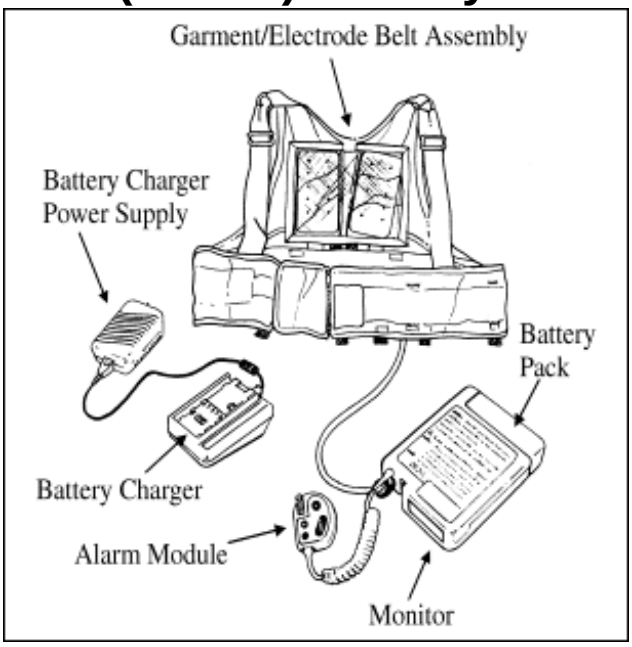
LIFECOR Wearable Cardioverter Defibrillator (WCD®) 2000 System-P010030



This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name:	LIFECOR Wearable Cardioverter Defibrillator (WCD®) 2000 System
Manufacturer:	Lifecor, Inc.
Address:	121 Freeport Road, Pittsburgh, PA 15238
Approval Date:	December 18, 2001
Approval Letter:	http://www.fda.gov/cdrh/pdf/p010030a.pdf

What is it? The wearable cardioverter defibrillator (WCD®) is used by adult patients 24 hours a day to monitor and treat dangerous, abnormally fast heart rhythms. These abnormal rhythms lead to a complete absence of heart beat (sudden cardiac arrest) and death (sudden cardiac death) if they are not treated. The WCD is a combination of two different devices. As a cardioverter, it uses low-energy electrical shocks to return an abnormally fast heart beat (ventricular tachycardia, or "VT") to a normal rhythm. As a defibrillator, it uses high-energy shocks to return a very fast, disordered heart beat (ventricular fibrillation, or "VF") to a normal rhythm. The Wearable Cardioverter Defibrillator (WCD) does the same job as an implantable cardioverter defibrillator (ICD). The difference is that the WCD is non-invasive, which means that it requires no surgery, implantation, or entry into the body. Instead, patients wear a vest-like garment that holds the WCD parts - a monitor, electrodes, and small "alarm module." The WCD is fully automatic and requires no patient action to deliver treatment - but the patient is able to prevent treatment if it is not needed.

How does it work? The WCD constantly and automatically checks the patient's heart rhythm with electrodes on the chest, in the same way a doctor or technician takes an electrocardiogram (ECG). If it detects an abnormal heart rhythm, it displays a message for the patient to press and hold two response buttons to prevent the treatment shock. Receiving a shock when conscious is painful. If the device

continues to detect the abnormal rhythm and the patient loses consciousness, the patient involuntarily releases the response buttons. Once the buttons are released, the WCD® device now "knows" that the patient is in danger, so it automatically delivers electrical shock therapy to restore the heart rhythm to normal.

When is it used? The WCD®device is worn if a patient has a risk of having a sudden failure of the heart to pump blood through the body (cardiac arrest) and an implantable defibrillator is not wanted or is not practical.

What will it accomplish? The WCD monitors the heart and protects the patient from death from sudden cardiac arrest - only if the patient is wearing it. A clinical study showed that the WCD device was 71% successful at treating sudden cardiac arrest. Patients who depended on a telephone call to 911 had only a 25% success rate.

When should it not be used? The WCD®device should not be used if the patient:

- Needs an implantable cardioverter defibrillator (ICD) or already has an ICD implanted and operating.
- Is under 18 years of age.
- Has a vision or hearing problem that may interfere with reading or hearing the WCD messages.
- Is taking medication that would interfere with pushing the response buttons on the WCD alarm module.
- Is unwilling or unable to wear the device continuously, except when bathing or showering.
- Is pregnant or breast-feeding.
- Is of childbearing age and not attempting to prevent pregnancy.
- Is exposed to excessive electromagnetic interference (EMI) from machinery such as powerful electric motors, radio transmitters, power lines, or electronic security scanners. EMI can prevent the WCD from detecting an abnormal heart rhythm.

Additional information: Summary of Safety and Effectiveness is available at:
http://www.fda.gov/cdrh/pdf/p010030.html

Other:

- American Heart Association:
  - Information on Cardioverters: http://216.185.112.5/presenter.jhtml?identifier=11227
  - Information on Healthy Lifestyle: http://216.185.112.5/presenter.jhtml?identifier=1200009
  - Information on How the Heart Works: http://216.185.112.5/presenter.jhtml?identifier=1557
  - Information on External Cardioverter: http://216.185.112.5/presenter.jhtml?identifier=1656

(Updated 02/15/02)