

Cardiac Rhythm Therapy

Patient's Manual

Things to Know About Your Congestive Heart Failure Therapy System



BIOTRONIK
excellence for life

Things to Know About Your Congestive Heart Failure Therapy System



www.biotronik.com

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Introduction

Using electrotherapy to treat congestive heart failure

This brochure contains valuable information about BIOTRONIK's new congestive heart failure (CHF) therapy system.

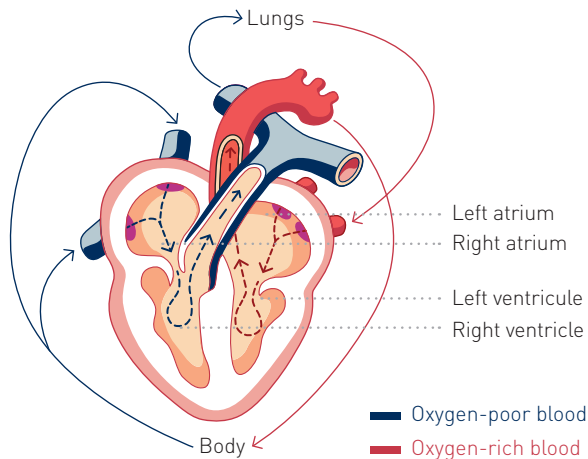
If you have further questions, please consult your primary care physician or cardiologist.

How the Heart Works

The heart is a fist-sized hollow muscle consisting of four chambers. The two atrial chambers (atria) make up the top half of the heart, the two main chambers (ventricles) the bottom half.

The heart muscle (called the myocardium) regularly contracts and relaxes in sequence. This motion pumps blood through the body. Blood from the body that is low in oxygen first passes through the right half of the heart and into the lungs, where the blood is then replenished with oxygen. The blood then flows from the lungs to the left half of your heart. From here, the blood is returned to the body, supplying the tissues and organs with oxygen and nutrients.

For the myocardium to be able to contract and relax, the heart creates little electrical pulses that are conducted from the top half of the heart to the bottom half. These pulses control the muscles.



❖ Healthy heart at the center of the circulatory system

In a healthy heart, the four chambers work together in harmony.

The pumping, which occurs when the myocardium contracts, is coordinated. Only in this way can there be effective circulation of blood through the body.

Symptoms of Congestive Heart Failure

Congestive heart failure is a summarizing technical term for a weakened heart. This condition is one of the most increasingly common cardiac diseases. However, the cause is not always known.

CHF develops when the heart muscle is not strong enough to pump enough blood into the body. The body is not sufficiently supplied with oxygen and nutrients. Affected people usually notice the body's insufficient oxygen supply due to a deterioration in their ability to cope with physical stress. Fatigue and dizzy spells are common.

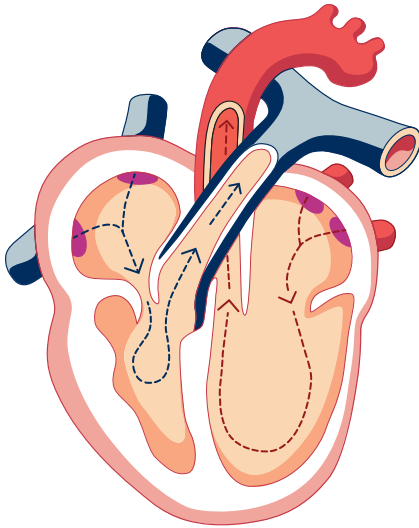
A backlog of blood is particularly prominent: In many patients, fluid collects in the tissues (edemas), for example at the ankles. Often the legs swell up.

If water collects in the lungs, patients experience shortness of breath and have coughing attacks, especially when lying down.

Asynchronous contraction of the right and left heart chambers reduces the pumping function of the heart in many patients.

Heart rhythm disturbances (arrhythmias) may also arise. In this case, the heart beats irregularly because the development or conduction of the heart's own electrical pulses is impaired.


The heart no longer beats in a coordinated fashion, so the pumping function becomes even more reduced, which results in the body not being supplied with enough oxygen-rich blood.



❖ Pathologically enlarged heart with CHF (cf. fig. p. 7)



◆◆ Monika S., born in 1950, early retiree from Hamburg



"In recent years my health got worse and worse. In the end, I had to take a breather after every ten steps on the way upstairs to my second-floor apartment. And my legs swelled up more and more. Finally I got a full check-up at a nearby clinic, and I got a modern device implanted with three leads. Now, over four months later, I feel like I've been born again: I enjoy going down to the bakery in the morning for fresh bread rolls, and playing with my grandchildren. And thanks to the treatment, my legs aren't swollen any more. I'm glad my physicians told me about this new treatment, and I look forward to every new day."

Medication and Further Therapeutic Measures

Using the following four most commonly pre-scribed classes of medication, drug therapy aims to relieve the strain on the heart and strengthen the heart muscle.

❖ Diuretics

Dehydrate the body, which reduces the amount of fluids in the tissues. This medication reduces the amount of blood, thus relieving strain on the heart.

❖ Glycosides or Digitalis

Improve the strength of the contraction and thus the heart's ability to pump.

❖ Vasodilators and ACE inhibitors

Expand blood vessels, improving the blood flow.

❖ Beta blockers

Reduce the heart's activity, and therefore the overall workload of the heart.

There is no one "right" medication for all CHF patients. For this reason, it may be necessary to combine different drug classes.

The medication your physician prescribes will depend on the severity and type of your illness.

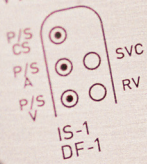
As a patient, you can contribute a lot to your own well-being by keeping a proper diet with lots of fruit and vegetables, little salt and no more than 1.5 liters of liquid per day. Do not consume alcohol or tobacco. Having a regular daily routine with an adequate amount of resting phases in-between can help to stabilize your condition. Following consultation with your physician, regular physical activity such as hiking, swimming or floor exercises, may be advisable.

Until now, a heart transplant was the only solution for patients whose symptoms were so serious that no medication or other forms of therapy were effective.

Lumax 540 HF-T

Home Monitoring

VVE-DDDRV



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BIOTRONIK
Made in Germany

A New Approach to Treating Congestive Heart Failure

BIOTRONIK® offers two different congestive heart failure therapy systems for cardiac resynchronization, which relieve strain on the weakened heart muscle.

CHF pacemakers

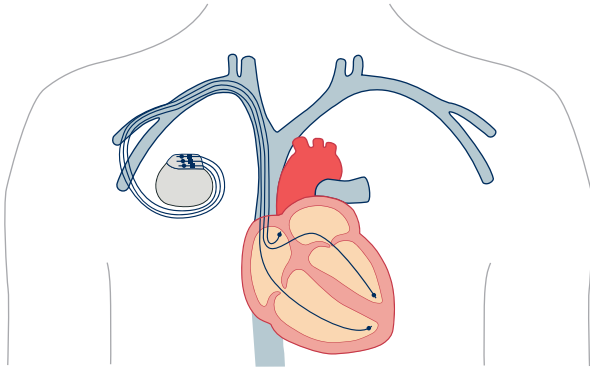
By delivering electrical pulses, this system causes the heart muscle to contract, optimizing the natural functioning of the heart.

With this kind of therapy, there is a lead in the right and left ventricle as well as in the right atrium.

With the system delivering pulses in the three chambers of the heart, the interaction and synchronization of the chambers of the heart can be restored to a great extent, improving the heart's ability to pump blood.

The CHF pacemaker primarily consists of an electronic circuit and a battery. The device is usually implanted beneath the skin, under the left collarbone. This is similar to a standard pacemaker implantation.

Three thin insulated wires, the leads, are also part of the pacemaker system. These wires connect the CHF pacemaker to the heart.



- ❖ The congestive heart failure therapy system is connected to the heart via three leads

The leads conduct the electrical pulses to the heart, and also transmit information about the heart's activity back to the CHF pacemaker, allowing it to react appropriately to every situation.





Congestive heart failure ICD

The congestive heart failure ICD, an implantable defibrillator, can also deliver shock therapy.

The electrical shock is intended to end episodes of tachycardia – heart rates that are so fast that blood can no longer circulate properly.

Causes for tachycardia could be a narrowing of the coronary arteries, a heart attack, or other heart problems that often accompany congestive heart failure.

The ICD also has a battery and an electronic circuit, as does a pacemaker, but it also has a capacitor for storing the energy needed to deliver the shock.

Three leads connect the ICD to the heart. They transmit information about the heart's intrinsic activity to the ICD and deliver stimulation pulses or an electric shock.

Living with a Congestive Heart Failure Therapy System

You can gradually return to your daily routine after the surgery according to your physician's instructions.

Please note the following:

- ❖ Should you need medication in addition to having a CHF therapy system, please take it as prescribed by the physician.
- ❖ Always go to the follow-up examinations.
- ❖ Always carry your CHF therapy system ID card with you – whether you are traveling or not.
- ❖ Contact your physician if you notice anything strange in connection with your CHF therapy system.

Better Quality of Life Thanks to a CHF Therapy System

With the help of the CHF therapy system (pace-maker or ICD), the heart can once again work efficiently and pump a sufficient amount of blood through your body.

The improvement in circulation reduces congestive heart failure and the symptoms associated with it.

Patients using a CHF therapy system benefit from a better quality of life and improved physical endurance.

Electrical Appliances

BIOTRONIK CHF therapy systems are protected against the impact of electrical appliances and their radiation as much as possible. Should you experience symptoms such as an increased heart-beat, irregular pulse, or dizziness in the vicinity of electrical devices, please move away from the device and/or turn it off immediately. If in doubt, inform your physician about this incident.

You can use the following devices without hesitation:

- ❖ Television sets, radios, stereos, wireless headphones, or similar audiovisual equipment
- ❖ Cordless phones
- ❖ Hair dryers, electric shavers, or other electric devices in the bathroom
- ❖ Washing machines, vacuum cleaners, microwaves, dishwashers, and similar household appliances

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- ❖ Computers, WLAN, fax machines, copiers, printers, etc.
 - ❖ All kitchen devices
 - ❖ Pulse measurement devices

Please note that some devices, such as headphones, are equipped with magnets, which may cause interference at short distance to the implant. Therefore, please maintain a distance of 3 centimeters between the headphones and the CHF therapy system.

You can use the phone without hesitation. If you want to use a cellular phone, you should talk to your physician. To prevent possible interference, you should always hold the cell phone on the opposite side from the implanted CHF therapy system. Even when not in use, you should not keep it close to the implant.

Note: Always ensure that your devices are working properly and only have them maintained by a trained professional. If possible, do not place portable devices directly above the CHF therapy system.

Regarding the use of the following devices/equipment, please consult your physician first and pay attention to manufacturer's notes that may restrict the use for pacemaker or defibrillator patients:

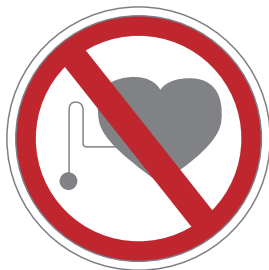
- ❖ Machines that generate strong vibrations (electric drills etc.)
- ❖ Firearms
- ❖ Electrical devices with strong electromagnetic fields, high-voltage cables, transmission facilities for radio, television and radar, electric, unshielded ignition systems

- ❖ Electric welders
- ❖ Induction stoves
- ❖ Body fat scales

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This symbol is shown on devices /
equipment which are prohibited for
pacemaker and defibrillator patients:


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- ❖ Prohibited for pacemaker and defibrillator patients



❖ Rainer B., born in 1944, financial director from Frankfurt

A thick, light blue vertical bar is positioned on the left side of the page, extending from the top margin to the bottom margin.

"As the result of a serious viral infection, my physician diagnosed severe chronic heart failure as the cause of my poor medical condition. It was considered that my name should be put on the transplant patient list. Then, however, I was given a resynchronization implant. Week by week, my condition improved. I'm back at work full-time and live a fulfilled life."

Traveling

In general, trips – whether by plane, ship, train, or car – are no problem for CHF therapy patients.

If you need addresses of follow-up clinics or physicians either domestically or abroad, e.g. for your vacation, please contact BIOTRONIK, Tel. +49 (0) 30 68905-0 directly or by e-mail (patients@biotronik.com).

If you are traveling by plane, inform the security and ground personnel at the airport and show your implant ID card if required. You will be informed in detail about what to do during the security check.

Please consult your physician as to whether you may drive a car or ride a motorcycle. It is possible that, depending on your type of heart condition, an observation period may be necessary in order to assess your fitness to drive.

The Doctor's Visit

Before any examination, please inform your physician, dentist, or the office or hospital personnel that you have a CHF therapy system.

The following examination methods are harmless for you:

- ❖ X-ray examinations
- ❖ The usual dental treatment – such as drilling and ultrasonic tooth cleaning

Attention: Specific examinations or therapies such as lithotripsy, transcutaneous electric nerve stimulation, magnetic resonance imaging, radiotherapy, or electrocautery, should be preceded by a risk-benefit assessment. If they are absolutely essential, the hospital staff must take the necessary precautions.

Some congestive heart failure therapy systems are designed to undergo MR scans under specific conditions. Your patient ID card will indicate if this is the case with your system. Please inform your physician of the possibility of undergoing an MR scan.

Frequently Asked Questions

Can I go through airport security systems or anti-theft detectors with my CHF therapy system?

Yes. BIOTRONIK CHF therapy systems are shielded against external influences. Do not stop within such facilities, however, but pass through them quickly. You might want to point out that you have a CHF therapy system because the metal housing of the system could set off an alarm.

Will I notice the activity of my CHF therapy system?

The CHF therapy system generates a small electric current, which affects only the heart. However, should you note anything abnormal (e. g. persistent hiccups), please inform your physician.

If you have a congestive heart failure ICD, you might receive a shock pulse to end an arrhythmia. Your physician will tell you what to do in such a situation.

How long does the CHF therapy system battery last?

The service lifetime of the battery depends on your medical condition and on the pacing frequency of the system. In general, CHF therapy systems work for several years. Your physician will provide you with details.

Will the CHF therapy system still treat me sufficiently when the battery gets weaker?

Yes. Also, the physician checks the state of the battery during each of the regular follow-ups. If it should get weaker, your CHF therapy system will be replaced with a new one.

What happens when my CHF therapy system is replaced?

The CHF therapy system is replaced in a minor surgical procedure. Functioning leads are left in the heart and a new CHF therapy system is connected. Normally, only a short hospital stay is necessary.

Does the CHF therapy system need to be reprogrammed after the implantation?

Possibly. This depends on your medical condition and/or your individual needs. Corrections can also be made at a later time.

Can the CHF therapy system artificially sustain the life of a person?

A heart can only function when it is supplied with enough blood and energy. In the event of death, the small electrical pulses from the CHF therapy system will have no effect on the heart. Therefore, an artificial extension of life is not possible.

Can I use a cellular phone?

Yes. You can use a cellular phone, but please take the following precautions: Discuss your individual situation with your physician. Do not carry your cellular phone close to your CHF therapy system, such as in a shirt pocket. Use the phone on the side opposite from the CHF therapy system.

Can I still use electric devices, such as micro-waves, hair dryers, electric blankets, and massage devices?

Properly working household appliances can be used without hesitation. Your CHF therapy system is not affected by them. Necessary repairs should always be carried out by a professional to ensure proper functioning.

Can the CHF therapy system trigger allergic reactions?

Normally it does not. BIOTRONIK only uses materials that are well tolerated by the human body. These include titanium and other medically compatible and tested materials.

How will I notice the different therapies delivered by the congestive heart failure ICD?

The ICD delivers impulses of varying intensity, depending on the circumstances. Most tachycardia episodes can be terminated by weak stimulation, which will pass by unnoticed. A strong shock impulse is rarely required. In the case of severe arrhythmia, most people have already lost consciousness and are not aware of the strong impulse being delivered. Should you be conscious as the ICD delivers the shock impulse, you will feel a sharp blow in your chest with an intense but brief pain.

Can the shock delivered by the congestive heart failure ICD be dangerous to another person?

Anybody who is in physical contact with your chest or back when you receive a strong pulse may feel a minor electrical tingling sensation. This is entirely painless and harmless. People who are informed about your situation should not be afraid by this.

Does the implant impair my sex life?

There is no need to restrict your sexual activity. Some patients are concerned because of an increased heart rate. The ICD is programmed to distinguish between a fast heartbeat and a tachycardia.

For additional information on congestive heart failure, please contact your attending physician.



The BIOTRONIK Group

The history of BIOTRONIK can be traced back to the research activities of the physicist Max Schaldach at the Physical Institute of the Technical University of Berlin. There, the future company founder developed the first German pacemaker.

In 1963, Professor Dr. Schaldach launched the enterprise. Since then, BIOTRONIK has developed into a medical technology company of international significance with research and production facilities all over the world.

Roughly 4,500 highly motivated employees develop and produce systems for bradycardia and tachyarrhythmia therapy, interventional cardiology, and electrophysiology. The long-time experience of the employees, the reliability and efficiency of the products, e.g. pacemakers and implantable defibrillators, have made BIOTRONIK a respected partner for physicians and patients.

Medical Terms

Arrhythmia: Abnormal or irregular rhythm of the heartbeat.

Asystole: Cardiac arrest, absence of heartbeat.

Atrium: Atrial chamber of the heart, i.e. the two upper chambers of the heart. One distinguishes between a left and a right atrium.

AV node: Atrioventricular node; tissue which transmits the electrical signals from the atria to the ventricles.

Block or heart block: Permanent or temporary disturbance of the electric conduction of pulses in the heart.

Bradycardia: A heart rhythm that is too slow, usually below 60 beats per minute.

Coronary arteries: Arteries that supply the heart with blood.

Dual-chamber pacemaker: A pacemaker with one lead in the atrium and one in the ventricle. Such pacemakers allow coordination of the atrial and ventricular pulses similar to a healthy heart.

Electrocardiogram (ECG): Graphic display of the electric actions of the heart during a heartbeat.

Endocardial lead: A lead that is placed at the internal skin of the heart muscle (endocardium).

Epicardial lead: A lead that is placed at the external surface of the heart muscle (epicardium).

Fibrillation: Fast, uncoordinated contraction of the heart muscle.

ICD: Implantable cardioverter-defibrillator; implant used to detect and treat ventricular tachyarrhythmia.

Lead: Insulated cable with electrodes that connects the pacemaker to the heart and conducts electric pulses to the heart.

Programmer: A small computer for external communication with the pacemaker. It is used to check the activity of the pacemaker, adjust the pacemaker program to individual needs, and record the ECG without additional devices.

Pulse: The rhythmic extension of the artery due to the pumping action of the heart.

Rate-adaptive pacemaker: Pacemaker that can adapt the pacing rate to the level of physical activity.

Resynchronization therapy: Implantation of a pacemaker or ICD to coordinate the activity of the ventricles.

Sinus node: Natural timer of the heart. It is located at the junction of the superior vena cava with the right atrium and produces the intrinsic electric signals that travel through the heart and make it beat regularly.

Systole: The contraction of the heart chambers. The blood is pumped from the left ventricle into the body's circulation system and from the right ventricle into the lungs.

Tachycardia: Heart rhythm that is too fast, usually above 100 beats per minute.

Ventricle: The lower heart chambers. When they contract or beat, the blood is pumped into the body and into the individual organs.

Notes

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