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Cardiac Rhythm Therapy

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Patient's Manual

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What You Need to Know about Your  
**Pacemaker**

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**BIOTRONIK**

excellence for life

# Pacemaker



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# Introduction

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You are now among the more than two million people in the world who have a pacemaker.

In the past, a pacemaker's only purpose was to save lives. Today, patients gain a new quality of life. Many of them are able to work in their profession again, to manage their household, to travel, and to engage in athletic exercises.

In other words: These people again live the life they were used to. This manual provides you with useful information about the heart and pacemakers. Your primary physician or cardiac specialist will be glad to answer any additional questions that you might have.

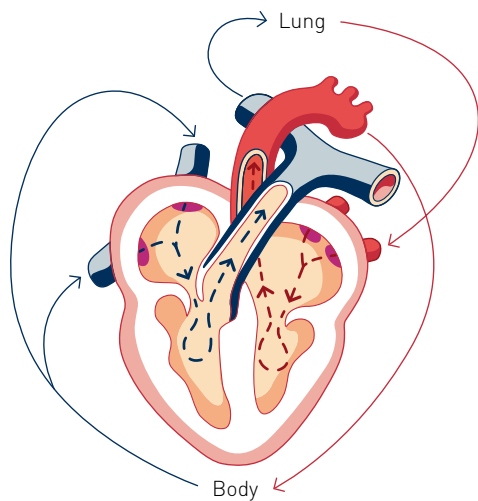
BIOTRONIK® – highest quality, technological progress, reliable pacemakers for more than 40 years.

# The Heart and Malfunctions of the Heart

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The heart is a fist-sized hollow muscle consisting of four chambers. The two atrial chambers (atria) form the upper half of the heart, the two main chambers (ventricles) the lower half. A wall (septum) divides the heart into a right and a left side. The heart muscle pumps blood through the body by contracting and expanding regularly. This ensures a sufficient supply of oxygen and nutrients to various tissues and organs of the body. To gather the blood and pump it into the circulation systems, the heart must be stimulated by small intrinsic electric pulses, which move from the upper to the lower chamber. In a healthy heart, the sinus node generates these pulses. Therefore it is also called the natural pacemaker of the heart. The sinus node causes the contraction of the heart chambers and thus supplies a regular, rhythmic heartbeat.

Each pulse of the sinus node triggers a contraction in the atria. From there, the blood is pumped into the ventricles.



■ Oxygen-enriched blood

■ Oxygen-depleted blood

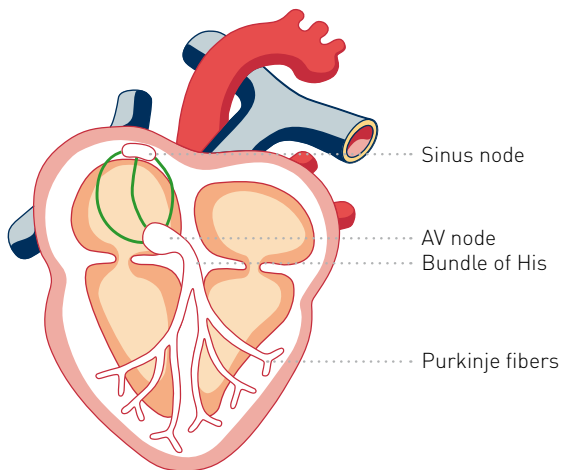
❖ A healthy heart in the center of the bloodstream

Via the cardiac conduction system, the electric pulse travels through cardiac tissue to cause the chambers to contract and pump the blood into the circulatory system.

A healthy heart beats between 60 and 80 times per minute, equivalent to about 100,000 heartbeats each day. During physical exercise or under emotional stress, the body needs more oxygen. To respond to these changed conditions, the heartbeat can increase to more than 100 beats per minute.

Malfunctions of the heart can be traced to a number of causes.

For example, cardiac disease or the aging process can interfere with the heart's natural rhythm. Malfunctions in the cardiac conduction system up to its complete blockade are very common.



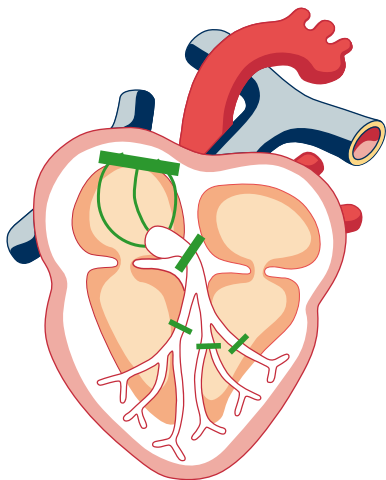
❖ The cardiac conduction system of the heart

The consequence of these pathological phenomena can be an irregular or slowed heartbeat. In such cases, the body is – especially under physical stress – not supplied with enough oxygen, which can lead to dizziness, fatigue, or faintness. The medical term for these kinds of rhythm disturbances is bradycardia.

Two common bradycardic arrhythmias are the sick sinus syndrome and AV block. With sick sinus syndrome, the function of the sinus node is disturbed; electric pulses are generated irregularly or too slowly. Especially under stress, the heart is then no longer capable of adjusting the heart rate to the increased demands.

With AV block, the conduction of the electric signals of the sinus node through the AV node into the ventricles is disturbed. If the conduction between atrium and ventricle is completely interrupted, we speak of a total AV block. In response, additional electric centers in the heart usually generate a very slow auxiliary rhythm to support vital functions.

In such cases, the heart function can be meaningfully supported or supplemented by a pacemaker.




- ❖ With the help of a pacemaker system, carefully calibrated electric pulses stimulate the heart muscle in such a manner that the heart rhythm is once again similar to that of a healthy heart.



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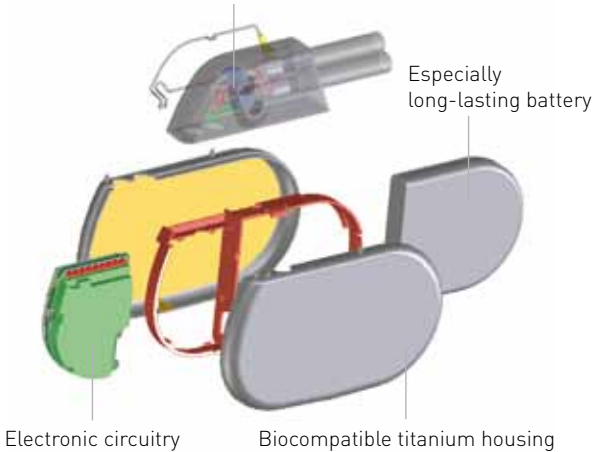
## The Pacemaker

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Modern pacemaker systems can be adapted to any specific malfunction of the heart. They consist of the pacemaker and the leads connected to it. The pacemaker contains miniaturized electronic circuitry and a battery. It becomes active whenever the patient exhibits a disturbed heart rhythm.

For this to happen, the system must be able to detect the heart's intrinsic activity. When the pacemaker sends an electric pulse, the heart muscle contracts. The connection between pacemaker and heart is established by one or two leads. A lead is a very thin, electrically insulated wire that is anchored in the right atrium or the right ventricle.

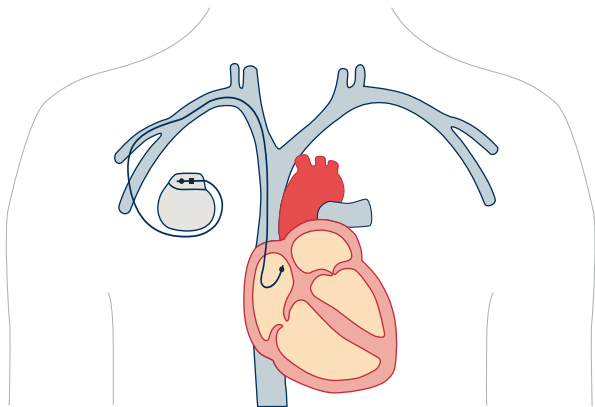
Transparent connection head part (header)



❖ The pacemaker

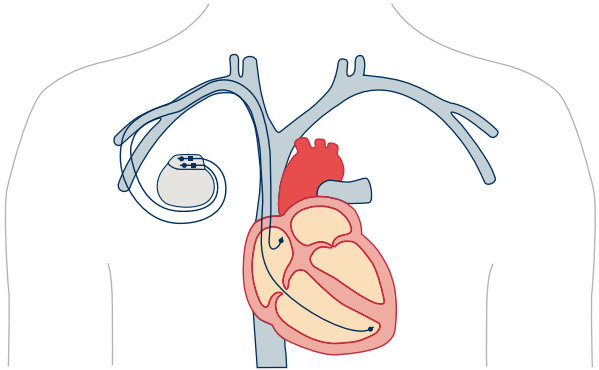
The leads detect the cardiac activity, transmit this information to the pacemaker, and send the electric pulse to the heart.

Depending on the therapeutic requirements, single-chamber or dual-chamber pacemakers can be implanted. The terms relate to the pacemaker's feature of pacing and sensing intrinsic activities in



### ❖ The single-chamber pacemaker

either one or both chambers. In a dual-chamber system, one lead is usually positioned in the atrium, and another one in the ventricle. Thus, the activities of the two chambers are synchronized, and optimal contraction of the heart muscle is ensured.



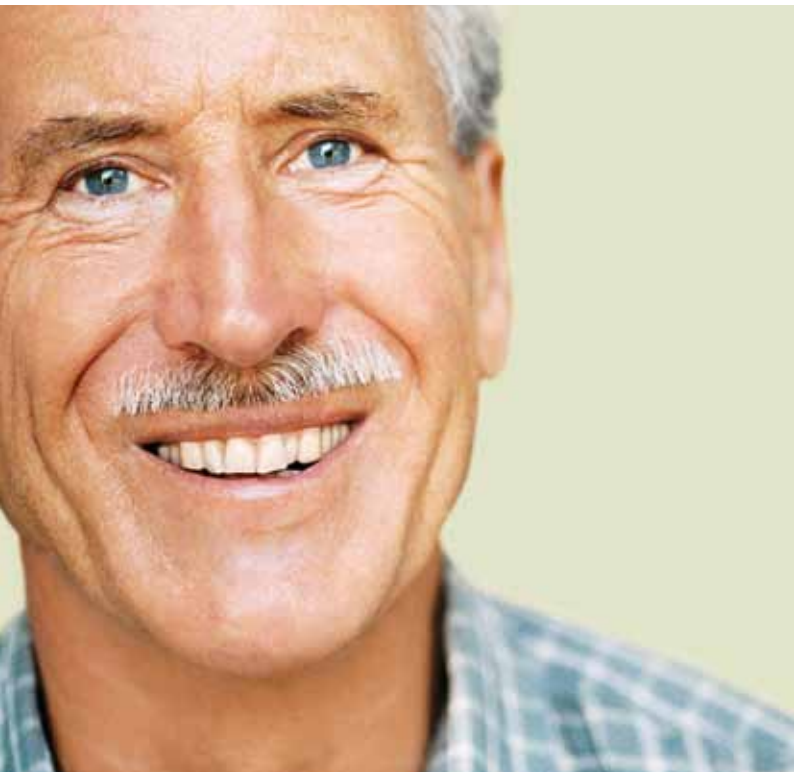
#### ❖ The dual-chamber pacemaker

Many pacemakers are capable of automatically adapting the rate, with which they send out electric pulses, in response to changing needs and activities of the patient. Such so-called rate-adaptive functions of pacemakers are possible due to special sensors in the pacemaker that react to changed conditions. Changed physical needs, as they are created, for instance, by running, swimming, or gardening, are compensated for by the pacemaker with an increasing heart rate.

The latest generation of BIOTRONIK pacemakers is also capable of reacting to changed emotions.

For example, if you watch a very thrilling movie or something unexpected surprises you, your heart-beat may speed up – and your blood pressure rises. The Closed Loop Stimulation system, a special feature of some pacemakers, allows adjustment even to such forms of emotional stress.

The wide range of BIOTRONIK products enables the physician to diagnose cardiac rhythm disturbances correctly and to treat them safely. Thanks to intensive research, these pacemakers stand for the current state of technological development; they are very small, safe and light-weight. Your physician will tell you which pacemaker is most suitable for you.



❖ Hans M., born in 1932, pensioner from Berlin,  
retired cardiologist

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“As a physician, I used to implant pacemakers myself. Later, when I experienced the same symptoms as my former patients and had an ECG recorded by my successor, my suspicion turned into certainty: I needed a pacemaker. Since I have had the device, I have not fainted once. I feel fit and awake again. And to my great joy, I can be active in my rowing club again.”



Philos II DR-T

Home Monitoring

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## The Implantation

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The implantation usually takes less than an hour. Normally, a place below the collar bone is numbed by local anesthesia, and a small incision is made into the skin. The lead of the pacemaker is then carefully advanced to the heart through a vein. Since blood vessels have no pain perception, no additional anesthesia is needed for this procedure. The physician monitors the correct positioning of the lead in the heart on an X-ray screen.

After the function of the lead has been tested, it is connected to the pacemaker. The pacemaker is then implanted in a small “pocket” below the collar bone. As a last step, the physician sutures the incision site with a few stitches.

## After the Implantation

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Normally, you will have recovered a short time after the implantation procedure. You might experience minor wound pain at the implantation site. This discomfort usually eases quickly, and soon you will barely feel your pacemaker at all.

Please be sure to consult your attending physician if:

- ❖ the wound at the implantation site becomes red, hot, or swollen, or if it excretes fluids;
- ❖ you develop a fever, feel dizzy, notice chest pains or persistent fatigue and faintness.

in the first days after the intervention, you should also avoid far sweeping movements with your shoulder on the pacemaker side. Soon after the implantation, you will visit your physician for the first follow-up examination to check your cardiac activity and the pacemaker's function.



### ❖ Programmer ICS 3000

The settings of your pacemaker are adjusted to your individual needs if and as necessary. This does not require any additional surgical intervention because your physician uses an external device for programming.

In most cases, you will not notice that a reprogramming has been performed. From then on, your physician will schedule you for follow-ups in regular intervals – usually every six months. During these examinations, the physician checks the functioning of your pacemaker, the state of the battery, and the excitation threshold of your heart.

## Living with a Pacemaker

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Following the intervention, you can slowly return to your daily routine, as agreed with your physician.

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Please note the following:

- ❖ If you should need medication in addition to having a pacemaker, please take it as prescribed by the physician.
- ❖ Always go to the follow-up examinations.
- ❖ Always carry your pacemaker ID card with you – whether traveling or in familiar surroundings.
- ❖ Contact your physician if you notice anything abnormal in connection with your pacemaker.

## Returning to a Normal Life

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Normally, you will be able to return to your usual lifestyle soon after the implantation. You can do gardening work or household chores or drive a car.

Showering, bathing, and swimming are also possible. After consultation with your physician, you will in most cases be able to work in your profession and follow your hobbies, as well as take up your athletic or sexual activities again without any problems.

If you should be uncertain or experience difficulties, please inform your physician.



# Electric Devices

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BIOTRONIK pacemakers are protected against the impact of electric devices and their radiation to the greatest extent possible. However, if you should experience symptoms, such as an increased heartbeat, irregular pulse, or dizziness, in the vicinity of electric devices, please move away from the device immediately and/or turn off the external device. If in doubt, inform your physician about this incident.

You can use the following devices without hesitation:

- ❖ television sets, radios, wireless headphones, stereos, 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 headphone and pacemaker.

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 at the side opposite from the implanted pacemaker. Even when not in use, you should not keep it close to the pacemaker.

**Attention:** Always check that your electric devices are in good working order and have them maintained and repaired professionally. If possible, do not place portable devices directly above the pacemaker.

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

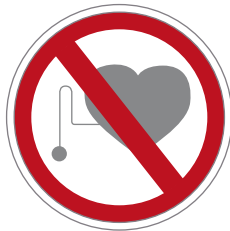
- ❖ machines that generate strong vibrations (electric drills, etc.)
- ❖ firearms
- ❖ electric devices with strong electric fields, high-voltage cables, transmission facilities for radio, television and radar, electric, unshielded ignition systems

- ❖ electric welders
- ❖ induction stoves
- ❖ body fat scales

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This sign warns pacemaker patients  
against using the following:

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- ❖ Prohibited for persons with pacemakers

## Traveling

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

If you need addresses for follow-up clinics or physicians domestically or abroad, for instance for your vacation, please contact BIOTRONIK, Tel +49 (0) 30 68905-0 directly or per e-mail: [patients@biotronik.com](mailto:patients@biotronik.com).

If you should travel by plane, inform the security and ground personnel at the airport and show them your pacemaker ID card if required. You will be informed in detail about how to behave during the security check (see also p. 34).

Traveling by car is uncomplicated. For your own safety, you should always wear a safety belt – it will not damage the pacemaker.

## The Doctor's Visit

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Before any examination, please inform the physician, dentist, or the office or hospital personnel that you are a pacemaker patient.

The following examination methods are harmless for you:

- ❖ X-ray examinations
- ❖ the usual dental treatment – such as drilling and teeth cleaning with ultrasound

**Attention:** For special examination methods and therapies, such as lithotripsy, transcutaneous electric nerve stimulation, magnetic resonance imaging, radiation therapy, or electrocautery, a risk-benefit assessment should be done first. If they are necessary nevertheless, the clinical personnel must take the necessary precautions.

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Some pacemaker models are designed to undergo MR scans under specific conditions. Your pacemaker ID card will indicate if this is the case with your pacemaker. Please inform your physician of the possibility of undergoing an MR scan.

# Answers to Frequently Asked Questions

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Can I pass the security checks at the airport or anti-theft devices in department stores with my pacemaker?

Yes, BIOTRONIK pacemakers are shielded against external influences. Do not stop within such facilities, but pass through them rapidly. You might want to point out that you carry a pacemaker because the metal housing of the pacemaker could trigger an alarm (see also p. 32).

Will I notice the operation of the pacemaker?

No. The pacemaker produces only a small electric current, which affects only the heart. However, if you should note anything abnormal (e.g. persistent hiccups), please inform your physician.

### What happens when my pacemaker is replaced?

The pacemaker is removed during a minor surgical intervention. Functioning leads remain in the heart, and a new pacemaker is connected. Normally, only a short hospital stay is necessary.

### Does the pacemaker need to be reprogrammed after the implantation?

Possibly. This depends on the respective disease manifestation and/or the needs of the patient. Corrections can also be made at a later time.

### Is the pacemaker capable of keeping a human being alive artificially?

A heart works only if it is sufficiently supplied with blood and energy. In case of death, the small electric pulses that the pacemaker sends to the heart no longer impact 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 you need to follow some precautions: Discuss your individual situation with your physician. Do not carry your cellular phone close to your pacemaker, such as in a shirt pocket. Use the phone on the side opposite from the pacemaker.

### How long does the pacemaker's battery last?

The service lifetime of the battery depends on the pacemaker type, the disease manifestation, and the frequency of pacing. In general, pacemakers work for several years. Your physician will provide you with details.

Will the pacemaker still treat me sufficiently when the battery gets weaker?

Yes. Also, the physician checks the state of the battery every time during the regular follow-ups. If it should get weaker, your pacemaker will be replaced by a new one.

How often do I have to go to a follow-up examination?

Your physician will inform you about the next follow-up appointment. In general, the examinations take place every six months. Always keep these appointments.

Can I use electric devices, such as microwave, hair dryer, electric blankets, or massage devices?

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

Can the pacemaker trigger allergic reactions?

Normally it does not. BIOTRONIK only uses such materials that are tolerated by the human body. This includes, for example, titanium and medically compatible and tested plastics.



## The BIOTRONIK Group

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The origins 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 de-fibrillators, have made BIOTRONIK a respected partner for physicians and patients.

# Medical Terms

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**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:** The atrioventricular node, the area of the heart which conducts 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.

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**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.

**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.

**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.

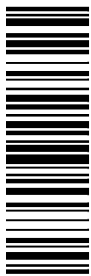


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