

ANSWERS TO QUESTIONS ABOUT **YOUR CHILD'S HEART DEVICE**



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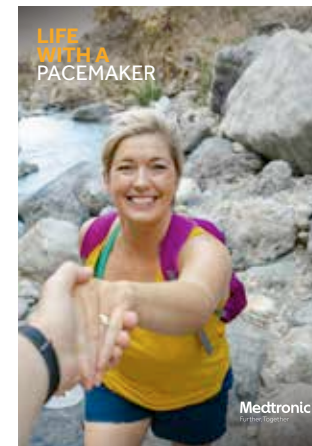
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Your child's doctor has prescribed an implantable heart device for your child because he or she has a **heart rhythm disorder**, or is at risk for a rhythm disorder that may cause the heart to beat too slow, too fast, or in a fast, unstable, and irregular manner.

This brochure provides general information about your child's heart device. More specific information on the various heart devices is provided in the following brochures:

- Life with a **Pacemaker**
- Life with an **Implantable Cardioverter Defibrillator (ICD)**
- Life with a **Cardiac Resynchronisation Therapy (CRT) device**

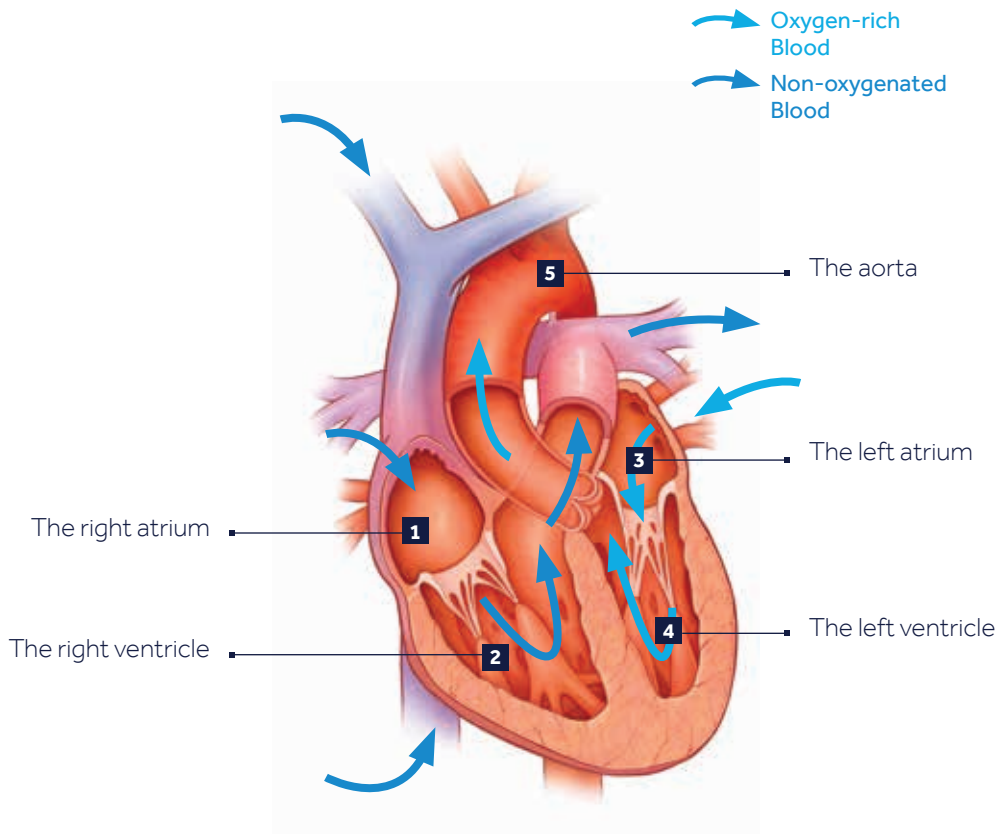


THE HEART

The heart is a fist-sized organ that acts as a **pump** to send oxygen-rich blood throughout the body. Regular, rhythmic electrical signals keep the heart pumping blood. The heart has four chambers:

- Two upper chambers – a right atrium and a left atrium
- Two lower chambers – a right ventricle and a left ventricle

The right atrium (1) takes in oxygen-depleted blood from the rest of the body and pushes it to the right ventricle (2) which then sends it to the lungs. The lungs oxygenate the blood which travels to the left atrium (3), and then onto the left ventricle (4), which pumps oxygen-rich blood to the rest of the body via the aorta (5).



WHAT IS BRADYCARDIA?

Bradycardia is a condition in which the heart beats **too slowly**. A healthy adult heart beats **60 to 100** times per minute, pumping about **280 liters of blood every hour**. With bradycardia, the heart beats fewer than 60 times per minute. At that rate, the heart is not able to pump enough oxygen-rich blood to the body during normal activity or exercise. Children have higher heart rates which gradually drop to the adult values. With bradycardia in children, the heart beats less than 100 times per minute for infants, less than 80 for toddlers and young children and less than 70 for school age children¹.

WHAT IS TACHYCARDIA?

Tachycardia is a condition where the heart beats too fast. Exercise, stress or fear can cause the heart to beat faster, but this is a normal response. With tachycardia, the adult heart beats at **more than 100 beats per minute** and can beat as fast as 400 beats per minute for no specific reason. At this rate the heart is not able to pump blood effectively to the body and brain. With tachycardia in children, the heart beats more than 160 times per minute for infants, more than 140 for toddlers and young children and more than 120 for school age children¹.

There are different types of fast heart rhythms that can occur in either the upper chambers (atria) or lower chambers (ventricles) of the heart:

- Atrial flutter and atrial fibrillation start in the upper chambers of the heart
- Ventricular tachycardia and ventricular fibrillation start in the lower chambers of the heart

WHAT IS HEART FAILURE?

Heart failure is a condition where the heart muscle is not able to efficiently pump blood. The term heart failure does not mean the heart has stopped pumping; rather, the heart muscle is not able to pump enough blood to meet the body's needs. As a result, one may feel tired, lack energy, experience shortness of breath and notice excess fluid collecting in the body.

WHAT IS SUDDEN CARDIAC ARREST?

When the heart muscle must work harder to pump blood to the body, this may cause the heart to beat faster, which can lead to dangerously fast or irregular heart rhythms.

These abnormal heart rhythms can lead to a condition called Sudden Cardiac Arrest (SCA).

Sudden Cardiac Arrest (SCA) results from an **electrical problem** with the heart that triggers a dangerously fast heart rhythm (ventricular fibrillation). The rapid, irregular heart rhythm causes the heart to quiver rather than contract or pump. When the heart stops pumping blood, oxygen cannot reach the body and brain. If not treated immediately, SCA can be fatal.

HEART ATTACK AND SCA: WHAT ARE THE DIFFERENCES?

Sudden cardiac arrest is not the same as a heart attack, although the two are often confused.

	HEART ATTACK	SUDDEN CARDIAC ARREST (SCA)
WHAT KIND OF PROBLEM	A circulation or plumbing problem	An electrical problem
CAUSE	Blockage in a vessel that supplies blood to the heart muscle, which may permanently damage part of the heart	Electrical malfunction of the heart that results in no blood flow to the body and brain
RISK FACTORS	High cholesterol, high blood pressure, obesity, smoking, family history of a heart attack, diabetes	Previous heart attack, heart failure, abnormal heart rhythm, low ejection fraction (EF ≤ 35%), family history of SCA
SYMPTOMS	May be accompanied by pressure in the chest, pain radiating to the arm, shortness of breath, sweating, nausea	Generally no symptoms, may experience racing heartbeat, lightheadedness, dizziness, fainting

The most effective way to treat SCA is through **defibrillation**². Defibrillation involves delivering an electrical shock to the heart to restore a normal heartbeat.

There are two primary forms of defibrillation:

- An **automated external defibrillator**, or AED, is a portable device that is used by emergency response teams or the general public to shock the heart
- An **implantable cardiac device (an ICD or a CRT-D)** that is implanted under the skin. This implantable cardiac device delivers electrical pulses or shocks to treat fast, irregular rhythms

EXAMPLES OF HEART DEVICES

- **Pacemakers** – for slow heartbeats (bradycardia)
- **Implantable Cardioverter Defibrillator (ICD)** devices for fast heartbeats (tachycardia)
- **Cardiac Resynchronisation Therapy (CRT)** devices for heart failure

When people refer to an implantable heart device, they are actually discussing a system, which includes a pulse generator or defibrillator and leads:

- A **pulse generator or defibrillator** is a small device (the size of a matchbox) that is implanted under the skin, typically just below the collarbone
- **Leads** are thin, soft, insulated wires about the size of a spaghetti noodle. The leads carry the electrical impulse from the pulse generator or defibrillator to your child's heart and relays information about the heart's activity back to the pulse generator or defibrillator



Traditional pacemaker and lead



ICD with leads



CRT with leads

HOW IS A HEART DEVICE IMPLANTED?

The procedure to implant a heart device is minimally invasive. Before the surgery, medication may be given to make your child sleepy and comfortable. Generally, the procedure is performed under local anesthesia.

GENERAL STEPS OF AN IMPLANT PROCEDURE:

- A small incision, approximately 5 to 10cm long, will be made in your child's upper chest area, just below the collarbone
- Leads will be guided through a vein into your child's heart, and the leads will be connected to the pulse generator
- The heart device settings will be programmed, and the heart device will be tested to ensure it is working properly
- The pulse generator will be inserted beneath your child's skin, and the incision will be closed

In very young children, the device may be placed into the abdomen and the leads are placed on the heart's surface. This procedure is usually performed in the operating room under general anesthesia.

WILL MY CHILD'S HEART DEVICE NEED TO BE REPLACED?

Yes. The heart device will be replaced depending on many variables including, but not limited to, the amount of therapy provided, changes in heart condition, device technical advances, etc. Because the battery that powers the heart device is sealed, the heart device will have to be replaced when the battery power becomes low. Your child's doctor will monitor your child's health regularly and will check the device, and can give you a general idea of the replacement time.

WHO SHOULD I TELL ABOUT MY CHILD'S HEART DEVICE?

Your child should generally be able to do the same activities as other children from the same age. However your child should avoid getting a blow to the area over the implanted heart device. Ask your child's doctor about his or her underlying health condition and activity limits.

It is important to inform teachers and coaches, school nurses, dentists, and others who have regular contact with your child for extended periods of time. Depending on the kinds of activities your child is involved in, this may include camp counselors, trip organizers, etc.

WILL MY CHILD ALWAYS NEED A HEART DEVICE?

The heart device is not a "cure" for the heart's rhythm problems. The device does, however, help the heart to beat regularly. Sometimes the heart device simply provides backup support when the heart needs it and sometimes the heart device is the only means to provide a heartbeat. There are a few children who only need a heart device temporarily. Most children, however, who receive a heart device will need one throughout their life.



HOW CAN I BE SURE THAT MY CHILD'S HEART DEVICE IS PROVIDING OPTIMAL THERAPY?

After your child's heart device is implanted, its performance will be monitored by their physician or a nurse in a follow-up clinic (doctor's office). The follow-up schedule will be determined by your child's physician.

You may want to ask your child's doctor if **remote monitoring*** is appropriate for your child. This is used to send information from your child's heart device to their clinic. Once received, the clinic can review the information on a secure website. Remote monitoring provides easy access to information that allows the doctor to:

- Manage your child's heart condition
- Monitor your child's implanted heart device
- Obtain information from your child's implanted heart device on an as-needed basis

Your child's implanted heart device has built-in safeguards that protect their device and their device data to prevent any outside parties from accessing the device (often referred to as "hacking"). The data sent to your child's clinic is encrypted. Your child's implanted heart device can only be programmed by doctors using the programmer in their office.

*subject to local availability

MRI SCAN ACCESS

A magnetic resonance imaging (MRI) scan is a type of diagnostic that creates an internal view of the body. Traditionally, most heart devices are not considered safe in an MRI environment because the MRI could change the settings, temporarily affect the normal operation of, or potentially damage the pacemaker. Medtronic heart devices are approved for use in the MRI environment, having a unique design developed so that under specific conditions, people may safely undergo MRI scans.

Your child's doctor should discuss all potential benefits and risks of an MRI scan with you.

WHAT CONCERNS SHOULD I HAVE ABOUT PLAYING, DIET, COLDS, ETC.?

Your child, after consultation with his or her physician, will be able to engage in most activities, including: swimming, riding tricycles or bikes, skipping, and running.

Your child should be careful, however, to avoid activities that may involve a direct blow to the heart device, such as football, wrestling, and other heavy contact sports.

Food, diet, normal immunizations, emotional changes, and colds will not affect heart devices' function. Be sure, however, to consult with your child's physician regarding any special restrictions or concerns.

CAN MY CHILD USE A CELL PHONE?

Yes. When talking on a cell phone keep the phone's antenna six inches/15 centimeters away from the heart device, and use the phone on the ear opposite the heart device. We also recommend to avoid placing the cell phone in a pocket near the heart device.

ARE ELECTRONIC ITEMS IN THE HOME SAFE FOR MY CHILD TO USE AND BE AROUND?

Yes. Most household electronic items are safe for your child to use and be around as long as they are properly maintained and in good working order. This includes microwave ovens, MP3 players, computers (desktop, laptop, and tablets such as an iPad), and other household appliances. As a general precaution, we do recommend keeping electronic items, items that transmit wireless signals, and items with electric motors at least six inches/15 centimeters away from your child's heart device.

WILL MAGNETS AFFECT MY CHILD'S HEART DEVICE?

Items such as magnetic therapy products, stereo speakers, and toys containing magnets may temporarily affect the normal operation of your child's heart device if the magnet is close enough and strong enough. We recommend keeping items with magnets at least six inches/15 centimeters away from your child's heart device. A magnet will not damage your child's heart device and the heart device resumes normal operation once the magnet is moved away.

WHAT IS THE PATIENT IDENTIFICATION CARD?

After surgery, your child will receive an implanted device **identification card**. You and/or your child should carry the card at all times. It will be useful in managing your child's follow-up care or in case of a medical emergency. Use this card to inform your child's doctors, dentists, and other healthcare providers that your child has a heart device.

WILL MY CHILD BE ABLE TO TRAVEL?

Given the short duration of security screening, it is unlikely that your child's heart device will be affected by metal detectors (walk-through archways and hand-held wands) or full body imaging scanners (also called millimeter wave scanners and 3D imaging scanners) such as those found in airports. To minimize the risk of temporary interference with your child's heart device while going through the security screening process, your child should avoid touching metal surfaces around any screening equipment. Your child should not stop or linger in a walk-through archway, but simply walk through the archway at a normal pace. If a hand-held wand is used, ask the security operator not to hold it over your child's heart device and not to wave it back and forth over the heart device. You may also request a hand search as an alternative.

If you or your child have concerns about these security screening methods, show your child's device ID card, request alternative screening, and then follow the instructions of the security personnel.

HOW CAN I LEARN MORE ABOUT HEART DEVICES?

Your child's doctor or cardiology nurse can answer any medical questions you have about your child's medical condition and about the particular device he or she has implanted.

Additionally, you can ask your child's doctor or nurse if there is a heart device support group in your community or online. These groups provide ongoing support and education to patients and their families.

We also encourage you to visit our website at medtronic.eu where you can access information 24 hours a day.

RECOMMENDED PRECAUTIONS

The following tables provide a summary of recommended precautions for different categories:

- Household & Hobby Items
- Tools & Industrial Equipment
- Communications & Office Equipment
- Medical & Dental Procedures

HOUSEHOLD & HOBBY ITEMS

Most household and hobby items are unlikely to affect your child's heart device when the items are in good working condition, used as intended, and the recommended distances are maintained. For items that transmit power through an antenna, it is recommended to follow the noted distances between the antenna and your child's implanted heart device.

SPECIAL CONSIDERATIONS

Maintain at least the recommended distance between the item and your child's heart device:

12-inch/30 centimeters distance

- Car/Motorcycle — from components of ignition system
- Electric Fence
- Transformer Box (green box in yard)

2-foot/60 centimeters distance

- Beach Comber Metal Detector—from search head
- Induction Cooktop Stove

Not Recommended

- Ab Stimulator
- Electronic Body Fat Scale
- Magnetic Mattress Pad/Pillow

MINIMAL RISK

Maintain at least a 6-inch/15 centimeters distance between the item and your child's heart device:

- Electric Grocery Cart/Golf Cart—from motor
- Electric Kitchen Appliances—hand-held (electric mixer or knife)
- Electronic Pet Containment Fence—from collar, remote and base antenna
- Electric Shaver—corded
- Electric Toothbrush Charging Base
- Exercise Bike—from magnet in wheel
- Hair Dryer—hand-held
- Hand-Held Back Massager
- Magnetic Therapy Products
- Radio-Controlled Items—from antenna
- Sewing Machine/Serger—from motor
- Small Magnet (household magnet)
- Speakers
- Tattoo Machine
- Treadmill—from motor
- Ultrasonic Pest Control Device
- Vacuum Cleaner—from motor

NO KNOWN RISK

If the item is used as intended and in good working condition, there is no known risk:

- Battery Charger—for household batteries
- Casino Slot Machine
- CD/DVD or Recorder
- Curling Iron
- Dishwasher
- Electric Blanket
- Electric Guitar
- Electric Toothbrush
- Electronic Weight Scale
- Garage Door Opener
- Hair Straightener
- Heating Pad
- Hot Tub
- Ionized Air Filter
- Iron
- Kitchen Appliances —small and large (blender, can opener, refrigerator, stove, toaster)
- Low Voltage Residential Power Lines
- Massage Chair/Pad
- Medical Alert Necklace
- Microwave Oven
- Remote Control (CD, DVD Player, TV)
- Salon Hair Dryer
- Sauna
- Shaver/Trimmer— battery powered
- Tanning Bed
- Television

TOOLS & INDUSTRIAL EQUIPMENT

It is important that your power tools and/or equipment be in good working order and properly wired (three-prong plug, if applicable) and used as intended by the manufacturer of the product. It is recommended that corded electrical items be plugged into a safety outlet device called a ground fault circuit interrupter (GFCI or GFI).

SPECIAL CONSIDERATIONS

Maintain at least the recommended distance between the item and your child's heart device:

12-inch/30 centimeters distance

- Boat Motor
- Car Battery Charger
- Gasoline Ignition Systems—from components of ignition system
- Gasoline Powered Tools—from components of ignition system (lawn mower, snowblower, weed whacker, chainsaw)

2-foot/60 centimeters distance

- Bench Mounted/Free Standing Tools—for motors 400 horsepower or less (air compressor, drill presses, grinder, pressure washer, table saw)
- Jumper Cables
- Welding Equipment (with currents under 160 amps)

Not Recommended

- Welding Equipment (with currents over 160 amps)

MINIMAL RISK

Maintain at least a 6-inch/15 centimeters distance between the item and your child's heart device:

- Circular Saw—skill saw
- Drills—battery and electric powered
- Electric Chainsaw
- Grinder (hand-held)
- Hedge Trimmer—electric powered
- Lawn Mower— electric powered
- Leaf Blower—electric powered
- Reciprocating Saw (Sawzall™*)
- Router
- Sander
- Screwdriver— battery powered
- Soldering Gun
- Weed Whacker—electric powered

NO KNOWN RISK

If the item is used as intended and in good working condition, there is no known risk:

- Calipers—battery powered
- Flashlight—battery powered
- Laser Level
- Soldering Iron
- Stud Finder

COMMUNICATIONS & OFFICE EQUIPMENT

Guidelines for safe operation of communications and office equipment include such factors as transmitting power, frequency and antenna type. For items that transmit wireless signals through an antenna, it is recommended to follow the noted distances between the antenna and your child's implanted heart device.

SPECIAL CONSIDERATIONS

Maintain at least the recommended distance between the item and your child's heart device:

12-inch/30 centimeters distance

- Amateur Radio, Ham Radio, Marine Radio, Walkie Talkie —between 3-15 watts —from antenna
- Citizens Band (CB) Radio—5 watts or less—from antenna
- Uninterrupted Power Source (UPS)

2-foot/60 centimeters distance

- Amateur Radio, Ham Radio, Marine Radio, Walkie Talkie —between 15-30 watts—from antenna

MINIMAL RISK

Maintain at least a 6-inch/15 centimeters distance between the item and your child's heart device:

- Amateur Radio, Ham Radio, Marine Radio, Walkie Talkie —3 watts or less—from antenna
- Cellular Phone—3 watts or less—from antenna
- Cordless Headphone Sending Unit (i.e., T V Ears™*)
- Digital Music Player (iPod™*) —transmitting
- Disney Magic Bands (6" from band reader, band itself has no known risk)
- Electronic Reader/Reading Devices
- Electronic Tablets (i.e., Kindle™*, iPad™*, Surface™*)
- Home Wireless Electronics—from antenna
- On Star™* Technology—from antenna
- Remote Keyless Entry—key fob (such as Smart Key)
- Remote Car Starter
- Smart Meter (utility companies)
- Security Badge Wall Scanner
- Wireless Communication Devices (computers, headsets, modems, routers, smartphones, Bluetooth™*)
- Wireless Controllers (video game consoles, Xbox™*, Playstation™*, Nintendo™*)

NO KNOWN RISK

If the item is used as intended and in good working condition, there is no known risk:

- Activity bands (FitBit™*, Body Bug™*, Nike+™*, Jawbone™*)
- Calculator
- Copy Machine
- Desktop/Laptop Computer
- Digital Music player (iPod™*)—non-transmitting
- Fax Machine
- Global Positioning System (GPS)
- Barcode Scanner
- Medical Alert Pendant
- Printer
- Radio AM/FM
- Scanner

MEDICAL & DENTAL PROCEDURES

Many medical procedures will not affect your child's heart device; however, certain medical procedures can result in serious injury, damage to your child's heart device, or device malfunction. Before undergoing any medical procedure, it is recommended that you advise your child's treating doctor or dentist that he or she has an implanted heart device and consult with his or her heart doctor to evaluate any possible associated risk.

NOT RECOMMENDED

- Diathermy (high frequency, short wave and microwave)
- MRA (Magnetic Resonance Angiography) for Non MR-Conditional Devices
- MRI*
- Virtual Colonoscopy with MRI* for Non MR-Conditional Devices

ACCEPTABLE WITH PRECAUTIONS

Inform your treating physician that your child has an implanted heart device and/or consult with your child's heart doctor/clinic. Medical procedures that require some precautions:

- Ablation (specifically, microwave ablation and radiofrequency ablation)
- Acupuncture with AC-Alternate Current Stimulus
- Argon Plasma Cautery
- Blood Bag Dielectric Sealing Equipment
- Bone Growth Stimulator Alternating Magnetic Field
- Bone Growth Stimulator Introducing AC Current
- Colonoscopy—polyp removal
- Computerized Axial Tomography (CT or CAT) Scan
- ECT (Electroconvulsive Shock Therapy)
- Electrolysis
- Electrosurgery and Other Procedures That Use an Electric Probe to Control Bleeding, Cut Tissue or Remove Tissue
- EMG Electromyography—automated sequence
- EMG Electromyography—single stimulus
- External Defibrillation, AED and Elective Cardioversion
- Hyfrecator
- Hyperbaric Oxygen Therapy (HBOT)
- Interferential Electrical Current Therapy
- Lithotripsy
- Magnetic Therapy
- MET (Microcurrent Electrical Therapy) Alpha-Stim 100™*
- Mechanical Ventilation with a Respiration Rate Monitor
- Muscle Stimulators and Other Devices Sending Current into Your Body
- Neutron Radiation
- Radiation Therapy (external x-ray, Gamma Knife™* or radiosurgery)
- Radiotherapy (Including high-energy radiation therapy)
- Stereotaxis
- Therapeutic Ultrasound
- TMS (Transcranial Magnetic Stimulation)
- Transcutaneous Electrical Nerve Stimulation (TENS) (including Neuro Muscular Electrical Stimulation (NMES))
- Transmitting Loop for Digital Hearing Aid
- Transurethral Needle Ablation (TUNA™* Therapy)
- TUMT (Transurethral Microwave Thermotherapeutic Device)
- TURP Prostate Test (Transurethral Resection of the Prostate)
- Virtual Colonoscopy Performed with CAT Scan (CT Scan)

ACCEPTABLE

If the item is used as intended and in good working condition, there is no known risk:

- Acupuncture—no electrical stimulus
- Acupuncture DC— direct current
- Bone Density Test (x-ray)
- Bone Density Ultrasound—on heel or hand
- Bone Growth Stimulator Direct Current
- Capsule Endoscopy
- Colonoscopy—diagnostic only
- Dental Apex Locator (root locator)
- Dental Drills
- Dental Pulp Tester
- Dental Ultrasonic Scalers/Cleaners
- Dental X-Ray
- Diagnostic Ultrasound (Sonogram)
- Diagnostic X-Rays (fluoroscopy)
- Digital Infrared Thermal Imaging (DITI)
- Echocardiogram
- EECF—Enhanced External Counter Pulsation Therapy
- Electrocardiogram (ECG/EKG)
- Electroencephalography— EEG
- Electronystagmography (Audiology—ENG)
- Hearing Aid (in or behind ear)
- Heart Rate Monitor
- Iontophoresis (drug patch)
- Laser Surgery
- Lasik Eye Surgery
- Lie Detector Test
- Mammography
- Medical Helicopter
- Nuclear Stress Test
- PH Capsules
- Positron Emission Tomography (PET Scan)
- Relief Band™*
- Sleep Apnea Machine

*Unless the device is MR Conditional, then see MRI guidelines for that device.
Visit www.mrisurescan.com for more information.

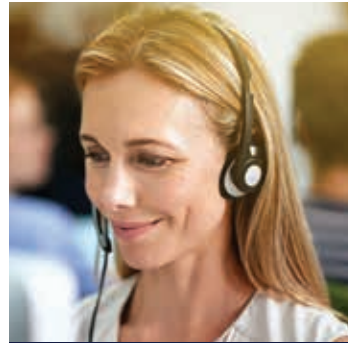
EDUCATIONAL RESOURCES & SUPPORT

You can rely on Medtronic as your experienced partner when you have a question around your child's heart device or remote monitoring solution†.

00800-266-632-82*

Official country language(s)
Monday-Friday 8am-4pm**

medtronic.eu
asktheicd.com
bhf.org.uk



BECONNECTED

† Subject to local availability
* Free-of-charge number
** Ability to leave voicemail outside of office hours

Reference:

1. Adapted from Fleming S. Lancet 2011; 377(9770): 1011-1018)
2. Priori S et al. 2015 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: The Task Force for the Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death of the European Society of Cardiology (ESC). Eur Heart J 2015 ; 36(41) : 2793-2867



Information contained herein does not replace the recommendations of your healthcare professional. See the device manual for detailed information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your Health Care Professional.

For applicable products, consult instructions for use on www.medtronic.com/manuals. Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

Important Reminder: This information is intended only for users in markets where Medtronic products and therapies are approved or available for use as indicated within the respective product manuals. Content on specific Medtronic products and therapies is not intended for users in markets that do not have authorization for use.

ANSWERS TO QUESTIONS ABOUT YOUR CHILD'S HEART DEVICE

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