



**Queensland
Government**

**Magnetic Resonance Imaging (MRI) Scan with
an MRI-Conditional Pacemaker/Implantable
Cardioverter Defibrillator (ICD) Consent**

Facility:

(Affix identification label here)

URN:

Family name:

Given name(s):

Address:

Date of birth:

Sex: M F I

A. Does the patient have capacity to provide consent?

Complete for ADULT patient only

- Yes → **GO TO section B**
 No → **COMPLETE section A**

You must adhere to the Advance Health Directive (AHD), or if there is no AHD, the consent obtained from a substitute decision-maker in the following order: Category 1. Tribunal-appointed guardian; 2. Enduring Power of Attorney; or 3. Statutory Health Attorney.

Name of substitute decision-maker:

Category of substitute decision-maker:

Complete for CHILD/YOUNG PERSON patient only

- Yes Although the patient is a child/young person, the patient may be capable of giving informed consent and having sufficient maturity, understanding and intelligence to enable them to fully understand the nature, consequences and risks of the proposed procedure and the consequences of non-treatment – ‘Gillick competence’ (*Gillick v West Norfolk and Wisbech Area Health Authority* [1986] AC 112)
 → **GO TO section B**

- No Parent/legal guardian/other person* with parental rights and responsibilities to provide consent and complete this form
 → **COMPLETE section A**

*Formal arrangements, such as parenting/custody orders, adoption, or other formally recognised carer/guardianship arrangements. Refer to the Queensland Health ‘Guide to Informed Decision-making in Health Care’ and local policy and procedures. Complete the source of decision-making authority as applicable below.

If applicable, source of decision-making authority (*tick one*):

- Court order → Court order verified
 Legal guardian → Documentation verified
 Other person → Documentation verified

Name of parent/legal guardian/other person:

Relationship to child/young person:

B. Is an interpreter required?

- Yes No

If yes, the interpreter has:

- provided a sight translation of the informed consent form in person
 translated the informed consent form over the telephone

It is acknowledged that a verbal translation is usually a summary of the text on the form, rather than word-by-word translation.

Name of interpreter:

Interpreter code:

Language:

C. Patient OR substitute decision-maker OR parent/legal guardian/other person confirms the following procedure(s)

I confirm that the referring doctor/clinician has explained that I have been referred for the following procedure:

Magnetic Resonance Imaging (MRI) scan with an MRI-conditional pacemaker: Yes No

MRI scan with an MRI-conditional implantable cardioverter defibrillator (ICD): Yes No

Site/side of procedure:

Make and model:

Name of referring doctor/clinician:

D. Risks specific to the patient in having a Magnetic Resonance Imaging (MRI) scan with an MRI-conditional pacemaker/Implantable Cardioverter Defibrillator (ICD)

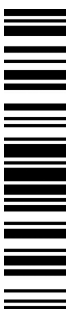
(*Doctor/clinician to document additional risks not included in the patient information sheet*):

E. Risks specific to the patient in *not* having a Magnetic Resonance Imaging (MRI) scan with an MRI-conditional pacemaker/Implantable Cardioverter Defibrillator (ICD)

(*Doctor/clinician to document specific risks in not having a Magnetic Resonance Imaging [MRI] scan with an MRI-conditional pacemaker/Implantable Cardioverter Defibrillator ([CD])*):

DO NOT WRITE IN THIS BINDING MARGIN

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SW9563

MRI SCAN WITH AN MRI-CONDITIONAL PACEMAKER/ICD CONSENT



Magnetic Resonance Imaging (MRI) Scan with an MRI-Conditional Pacemaker/Implantable Cardioverter Defibrillator (ICD) Consent

(Affix identification label here)

URN:

Family name:

Given name(s):

Address:

Date of birth:

Sex: M F I

F. Alternative procedure options

(Doctor/clinician to document alternative procedure not included in the patient information sheet):

Empty box for alternative procedure options.

G. Information for the doctor/clinician

The information in this consent form is not intended to be a substitute for direct communication between the doctor/clinician and the patient OR substitute decision-maker OR parent/legal guardian/other person.

I have explained to the patient OR substitute decision-maker OR parent/legal guardian/other person the contents of this form and am of the opinion that the information has been understood.

Name of doctor/clinician:

Box for doctor/clinician name.

Designation:

Box for doctor/clinician designation.

Signature:

Date:

Box for doctor/clinician signature.

Box for doctor/clinician date.

H. Patient OR substitute decision-maker OR parent/legal guardian/other person consent

I acknowledge that the doctor/clinician has explained:

- the 'Magnetic Resonance Imaging (MRI) Scan with an MRI-Conditional Pacemaker/Implantable Cardioverter Defibrillator (ICD)' patient information sheet
• the medical condition and proposed treatment, including the possibility of additional treatment
• the specific risks and benefits of the procedure
• the prognosis, and risks of not having the procedure
• alternative procedure options
• that there is no guarantee the procedure will improve the medical condition
• that if a life-threatening event occurs during the procedure:
- an adult patient will be treated based on documented discussions (e.g. AHD or ARP [Acute Resuscitation Plan])
- a child/young person's health care will be provided in accordance with good clinical practice and in the best interests of the patient
• that a doctor/clinician other than the consultant/specialist may assist with/conduct the clinically appropriate procedure; this may include a doctor/clinician undergoing further training under supervision
• that if the doctor/clinician wishes to record video, audio or images during the procedure where the recording is not required as part of the treatment (e.g. for training or research purposes), I will be asked to sign a separate consent form. If I choose not to consent, it will not adversely affect my access, outcome or rights to medical treatment in any way.

I was able to ask questions and raise concerns with the doctor/clinician.

I understand I have the right to change my mind regarding consent at any time, including after signing this form (this should be in consultation with the doctor/clinician).

I/substitute decision-maker/parent/legal guardian/other person have received the following consent and patient information sheet(s):

'Magnetic Resonance Imaging (MRI) Scan with an MRI-Conditional Pacemaker/Implantable Cardioverter Defibrillator (ICD)'

'Magnetic Resonance Imaging (MRI) scan'

'About Your Anaesthetic' (Adult patient only)

'About Your Child's Anaesthetic' (Child/young person patient only)

On the basis of the above statements,

1) I/substitute decision-maker/parent/legal guardian/other person consent to having a Magnetic Resonance Imaging (MRI) scan with an MRI-conditional pacemaker/Implantable Cardioverter Defibrillator (ICD).

Name of patient/substitute decision-maker/parent/legal guardian/other person:

Box for patient name.

Signature:

Date:

Box for patient signature.

Box for patient date.

If the patient is a child/young person:

I am not aware of any legal or other reason that prevents me from providing unrestricted consent for this child/young person for this procedure (not applicable if the child/young person is Gillick competent and signs this form).

2) Student examination/procedure for professional training purposes:

For the purpose of undertaking training, a clinical student(s) may observe medical examination(s) or procedure(s) and may also, subject to patient OR substitute decision-maker OR parent/legal guardian/other person consent, assist with/conduct an examination or procedure on a patient while the patient is under anaesthetic.

I/substitute decision-maker/parent/legal guardian/other person consent to a clinical student(s) undergoing training to:

- observe examination(s)/procedure(s) Yes No
• assist with examination(s)/procedure(s) Yes No
• conduct examination(s)/procedure(s) Yes No

Magnetic Resonance Imaging (MRI) Scan with an MRI-Conditional Pacemaker/Implantable Cardioverter Defibrillator (ICD)

Adult and Child/Young Person | Informed consent: patient information

A copy of this patient information sheet should be given to the patient or substitute decision-maker or parent/legal guardian/other person of a child or young person to read carefully and allow time to ask any questions about the procedure. The consent form and patient information sheet should be included in the patient's medical record.

In this information sheet, the word 'you' means the patient unless a substitute decision-maker, parent, legal guardian or other person is providing consent on behalf of the patient, in which case the word 'you' means the substitute decision-maker, parent, legal guardian or other person when used in the context of the person providing consent to the procedure.

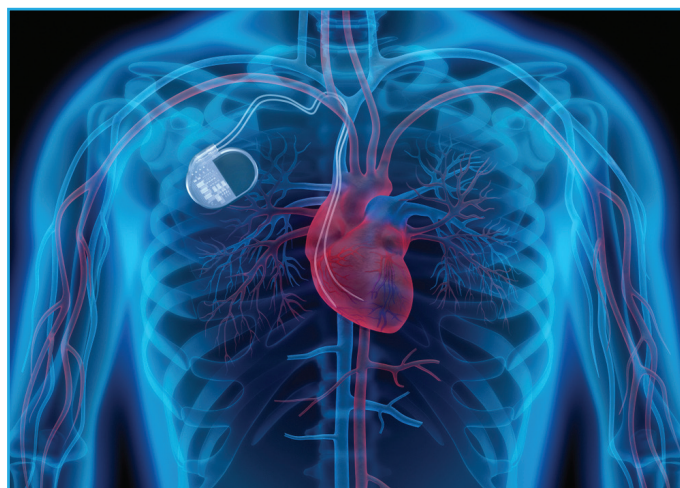


1. What is a Magnetic Resonance Imaging (MRI) scan with an MRI-conditional pacemaker/Implantable Cardioverter Defibrillator (ICD) and how will it help me?

A Magnetic Resonance Imaging (MRI) scan uses a strong magnetic field, radio waves and a computer to produce images of the body. MRI does not use x-rays. MRI images are very detailed and they can show bones and soft tissues in the body. The information from the MRI scan may provide information on your condition.

In the past MRI was not performed on patients with pacemakers/Implantable Cardioverter Defibrillators (ICD) due to the perceived risk from the powerful magnetic and radio frequency field generated by the MRI scanner. A special group of pacemakers and ICDs have been developed for which there are minimal risks when having an MRI scan when appropriate steps are followed. This group is known as "MRI-conditional" devices. If an MRI scan is performed under the particular conditions (different for each device), the risks are minimised.

It is important to always tell your doctor/clinician that you have a cardiac device. An MRI with a *conditional* pacemaker or ICD still requires strict protocols to be followed, and coordination between the cardiac and MRI teams. The device needs to be programmed before and after the MRI and carefully monitored during the scan. For this reason, an MRI is only appropriate when no other diagnostic imaging test can reasonably provide the same information.



*Image: Medical illustration of a permanent pacemaker implant.
ID: 1487085152. www.shutterstock.com*

MRI safety

- No one is permitted into the scanning room until they have answered a series of safety questions and taken off all removable metal objects from their body (e.g. jewellery, piercings, glasses and mobile phones). Your removable metal objects and personal items must be left outside the MRI scan room. You will be allocated a place to store your belongings safely.
- You will be required to change into a hospital gown.
- It is important you answer the safety questions as correctly as possible to avoid injury.

- If you have an implant, foreign body (e.g. shrapnel) or inserted medical device, MRI staff will work to determine if it is safe for you to go into the strong magnetic field of an MRI scanner.
 - If you have an implant, foreign body or device that is not safe to go into an MRI scanner, you may not be able to have an MRI scan.
 - If you have an implant or device that is safe to enter a strong magnetic field under certain conditions, MRI staff will determine if your device or implant is safe to go into the MRI scanner at this hospital.
 - For some devices and implants, it may not be possible to have an MRI scan at one hospital, while it is possible at another hospital. This is because the strength of the magnetic field is not the same for all MRI scanners. The MRI scanner at one hospital might be able to meet the special conditions of your implant or device, whereas the MRI scanner at another hospital cannot.
 - MRI safety also depends on the risk versus benefit for each individual; no one will be refused an MRI without a thorough review.
 - If you have an implanted device you may have received a Patient Implant Card (PIC) with details of the device. The PIC will help MRI staff determine if and how the scan can be performed safely.

Preparing for the procedure

The Medical Imaging department will give you instructions on how to prepare for your procedure. Your procedure might be delayed if you don't follow all of your preparation requirements.

Please tell the doctor/clinician if you are pregnant, or suspect that you may be pregnant.

The MRI staff will ensure that there are no issues in you having the MRI scan before booking your appointment. These include:

- a non MRI-conditional pacing or defibrillation system
- presence of any other MRI unsafe implants
- presence of abandoned or additional leads

- system implanted less than 6 weeks ago
- incomplete system (both the device and leads must be MRI-conditional)
- device implanted outside the pectoral region.

For a parent/legal guardian/other person of a patient having an MRI scan with an MRI-conditional pacemaker/ICD

To prepare the patient for this procedure and to ease their concerns, tell them what they can expect to happen during the procedure. This information sheet will assist you with this.

We welcome your help and support in preparing the patient for the procedure and in explaining why it's so important to lie still.

At the discretion of the procedure staff:

- a parent/guardian/adult (unless pregnant) may be invited into the procedure room to support the patient. MRI staff will need to determine that this support person does not have an implant, foreign object or device that is not safe to go into an MRI scan room
- if the patient is having a general anaesthetic you may be able to see them off to sleep. Once they are asleep you will be asked to leave the procedure room and wait in the waiting area.

Other children are not allowed into the procedure room, and they must be supervised at all times by another parent/guardian/adult.

During the procedure

Before the scan, your pacemaker or ICD will need to be programmed to the MRI settings. While your pacing system is programmed to these settings, your heart rate may be different to what you are used to.

Your heart rate and blood oxygen levels will be monitored during the scan. To do this, the MRI staff will place Electrocardiogram (ECG) leads to record your heartbeat, on your chest and a pulse oximeter (probe) on your finger.

Your pacemaker or ICD system will need to stay within settings for MRI the whole time the MRI scan is being performed. We will advise you, or your caregiver, of the length of time the MRI scan is expected to take, as well as how long your system will operate under the special settings for the MRI scan.

You may see signs at the MRI facility that warn you not to enter if you have a pacemaker. These signs apply to pacing systems that are not eligible, programmed or cleared to have an MRI scan. You are only allowed to enter the room on the instruction from the MRI radiographer.

During the MRI scan, you may experience the following (these are normal):

- Loud noises – the noises are not coming from your pacemaker or generator.
- Slight movement, vibration, or a warm sensation from the pacemaker or generator.

MRI staff will not be in the room during the scan, but they will be able to see you and talk to you between images.

Before the scan starts, you will be given a call button which you can press if there is an urgent concern.

To assist in reducing the risk of thermal injuries, it is very important you remain in the position MRI staff placed you in at the start of the scan. At the end of the scan, you should still be in this same position.

MRI staff will make sure you are positioned to avoid skin-to-skin contact (e.g. you cannot have your arms or legs crossed) and they may place padding around you, so you don't touch the walls of the scanner.

Depending on the body parts being imaged, the procedure may take between 15–90 minutes.

For more information about MRI please see the *Magnetic Resonance Imaging (MRI) Scan* patient information sheet.



2. What are the risks?

In recommending the procedure, the doctor/clinician believes that the benefits to you from having the procedure exceed the risks involved. There are risks and possible complications associated with the procedure which can occur with all patients – these are set out below. There may also be additional risks and possible complications specific to your condition and circumstances which the doctor/clinician will discuss with you. If you have any further concerns, please ensure that you raise them with the doctor/clinician prior to giving consent to the procedure.

Common risks and complications

- no known common risks and complications.

Uncommon risks and complications

- mild local heating around the device and potential small risk of burns
- the scan may not be possible due to medical and/or technical reasons.

Rare risks and complications

- thermal burns are extremely rare due to precautionary measures taken by MRI staff
- risk of device failure or device complication. This would cause the return of an underlying cardiac condition
- injury, severe injury or death because of an undeclared metal implant or if an implant is scanned without the necessary conditions for safety
- death because of an MRI scan is extremely rare.

What are the risks of not having an MRI scan with an MRI-conditional pacemaker/ICD?

There may be adverse consequences for your health if you choose not to have the proposed procedure. Please discuss these with the referring doctor/clinician.

If you choose not to have the procedure, you will not be required to sign a consent form.

If you have signed a consent form, you have the right to change your mind at any time prior to the procedure. Please contact the doctor/clinician to discuss.



3. Are there alternatives?

Making the decision to have a procedure requires you to understand the options available. Please discuss any alternative procedure options with your doctor/clinician before signing the consent form.



4. What should I expect after the procedure?

Your healthcare team will talk to you about what to expect after your procedure and upon discharge from hospital.

After the scan, follow the directions provided by your doctor/clinician or healthcare provider.

Your pacemaker or ICD system may be checked to ensure it is working normally. The system may be programmed manually by your doctor/clinician to your normal pacing settings, or it may return to your normal pacing settings automatically after a specific period of time set by your doctor.

If you experience any new symptoms after the scan, contact your doctor/clinician or healthcare provider.

If you need additional MRI scans, you and your pacemaker or ICD system must be checked for eligibility for a scan each time. If your implanted system has changed (e.g. a new pacemaker or generator or lead wires), or if aspects of your health have changed, it is possible that you are no longer eligible for an MRI scan.

The radiologist (doctor) will review the final images after the scan and send the report to your treating team.

You will receive the results of the scan from your treating team at your next follow-up appointment. Please make an appointment if you do not already have one.



5. Who will be performing the procedure?

Radiographers, doctors, nuclear medicine technologists, sonographers, nurses and medical imaging assistants make up the medical imaging team. All or some of these professionals may be involved in your procedure. A cardiologist and/or cardiac scientist may be present for your MRI scan.

A doctor/clinician other than the consultant/specialist may assist with/conduct the clinically appropriate procedure. This could include a doctor/clinician undergoing further training, however all trainees are supervised according to relevant professional guidelines.

If you have any concerns about which doctor/clinician will be performing the procedure, please discuss this with the doctor/clinician.

For the purpose of undertaking professional training in this teaching hospital, a clinical student(s) may observe medical examination(s) or procedure(s) and may also, subject to your consent, assist with/conduct an examination or procedure on you.

You are under no obligation to consent to an examination(s) or a procedure(s) being undertaken by a clinical student(s) for training purposes. If you choose not to consent, it will not adversely affect your access, outcome or rights to medical treatment in any way.

For more information on student care, please visit www.health.qld.gov.au/consent/students.



6. Where can I find support or more information?

Hospital care: before, during and after is available on the Queensland Health website www.qld.gov.au/health/services/hospital-care/before-after where you can read about your healthcare rights.

Further information about informed consent can be found on the Informed Consent website www.health.qld.gov.au/consent. Additional statewide consent forms and patient information sheets are also available here.

Staff are available to support patients' cultural and spiritual needs. If you would like cultural or spiritual support, please discuss this with your doctor/clinician.

Queensland Health recognises that First Nations People's culture must be considered in the patient's clinical care to ensure their holistic health and individual needs are met.



7. Questions

Please ask the doctor/clinician if you do not understand any aspect of this patient information sheet or if you have any questions about your proposed procedure.

If you have further questions prior to your appointment, please contact the Medical Imaging department via the main switchboard of the facility where your procedure is booked.



8. Contact us

In an emergency, call Triple Zero (000).

If it is not an emergency, but you have concerns, contact 13 HEALTH (13 43 25 84), 24 hours a day, 7 days a week.