Medtronic

Micra™ MC1VR01

MRI procedural information for Micra Model MC1VR01 MR Conditional single chamber transcatheter pacing device (VVIR)

MRI Technical Manual

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

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1 Introduction

The Medtronic Micra Model MC1VR01 transcatheter pacing device is an MR Conditional device and, as such, is designed to allow patients to be safely scanned by a magnetic resonance imaging (MRI) machine when used according to the specified MRI conditions for use. When the MRI SureScan feature is programmed to On, the patient implanted with the Micra device can be safely scanned while the device continues to provide appropriate pacing.

Before an MRI scan is performed on a patient with this device, the cardiology and radiology professionals involved in the MRI procedure should read this manual and understand the requirements, instructions, and MRI-specific warnings and precautions specific to their tasks. If you have questions about the information in this manual, contact your local Medtronic representative.

For instructions on non-MRI related use of this device, such as the implant procedure and programming instructions, cardiologists should refer to the clinician manual Medtronic provided for this device.

2 MRI conditions for use

The Micra transcatheter pacing device is MR Conditional and, as such, allows the patient to undergo an MRI scan when used according to the instructions in this manual.

Warning: Do not scan a patient who has an active Micra device without first programming MRI SureScan to On. Scanning an active Micra device without programming MRI SureScan to On may result in patient harm.

Note: MRI SureScan cannot be programmed to On if the device reaches the Recommended Replacement Time (RRT).

Note: Micra devices can be safely scanned if the device is programmed to Device Off, or if the device has reached End of Service (EOS). For more information about EOS conditions, refer to the implant manual Medtronic provided for this device.

2.1 Cardiology requirements

Patients implanted with the Micra device must be screened to meet the following requirements:

- No abandoned leads are present.
- For patients who have multiple MR Conditional devices present, the MR labeling conditions for all implanted devices are satisfied.
- The active SureScan device is operating within the projected service life.
  - Pacing amplitude is ≤ 4.5 V at the programmed pulse width.
  - No diaphragmatic stimulation is observed when MRI SureScan is programmed to On.
- The SureScan device that is beyond its projected service life is programmed to Device Off.

2.2 Radiology requirements

Scanning patients who have multiple MR Conditional devices present is acceptable when the MR labeling conditions for all implanted devices are satisfied.

The safety and reliability of the Micra device have been evaluated for scanning patients, using MRI equipment that has the following operating characteristics:

Scanner type	Horizontal field, cylindrical bore, clinical system
Scanner characteristics	• Hydrogen proton magnetic resonance imaging equipment with a static magnetic field of 1.5 T or 3.0 T and a maximum spatial gradient of ≤ 25 T/m (2500 gauss/cm) • Gradient systems with maximum gradient slew rate performance per axis of ≤ 200 Tesla per meter per second (T/m/s)
Scanner operation	MRI radio frequency (RF) power. The whole body averaged specific absorption rate (SAR) must be ≤ 4.0 W per kilogram (W/kg). The head SAR must be ≤ 3.2 W/kg.

2.3 Training requirements

The following training is required:

- A health professional who has completed cardiology SureScan training must be present during the programming of the SureScan feature.
- A health professional who has completed radiology SureScan training must be present during the MRI scan.

2.4 Patient monitoring and rescue requirements

Proper patient monitoring must be provided during the MRI scan.

An external defibrillator must be immediately available during the MRI scan.

3 MRI warnings and precautions

Warnings:

- Do not scan a patient who has an active Micra device without first programming MRI SureScan to On. Scanning an active Micra device without programming MRI SureScan to On may result in patient harm.
- Do not leave the device in MRI SureScan mode after the scan is complete. Be sure to program MRI SureScan to Off as soon as the scan is complete.
- Do not scan patients with abandoned leads. Patients with abandoned leads may be harmed if an MRI scan is performed.
- Do not scan patients with a Micra device implanted in a location other than the right ventricle.

Cautions:

- Do not scan patients with programmed outputs > 4.5 V.
- Do not scan patients who exhibit diaphragmatic stimulation when the device is pacing asynchronously during the MRI SureScan mode.
- It is not recommended to perform MRI scans during the implant maturation period because MRI scans during this period have not been prospectively studied by Medtronic.
- Scanning patients who have multiple MR Conditional devices present is acceptable as long as the MR labeling conditions for all implanted devices can be satisfied.
- Do not bring the Medtronic programmer into the examination room (magnet room). It is MR Unsafe.

4 Potential adverse events

The Micra device has been designed to minimize the potential adverse events that may cause patient harm. The following potential adverse events may occur in the MR environment:

- potential for VT/VF induction when the patient is programmed to an asynchronous pacing mode during MRI SureScan
- damage to the device causing the device to fail to detect or treat irregular heartbeats, or causing the device to treat the patient's condition incorrectly

5 Patient monitoring requirements

Proper patient monitoring must be provided during the MRI scan. This includes continuous monitoring of the patient's hemodynamic function and both of the following actions:

- maintaining continuous visual and verbal contact with the patient
- continuous monitoring of the patient's heart rate using instrumentation such as pulse oximetry (plethysmography) or electrocardiography

Preparation for patient rescue – In the event that patient rescue is required, an external defibrillator must be available during the MRI scan.

Note: If the patient's hemodynamic function is compromised during the MRI scan, discontinue the scan, remove the patient from the magnet room, program MRI SureScan to Off, and take the proper measures to restore the patient's hemodynamic function.

Note: Monitoring is required whether the device is active, or if the device is programmed to Device Off.

6 Cardiology-specific considerations

Device maturation – It is not recommended to perform MRI scans during the device maturation period (6 weeks by default) because MRI scans during this period have not been prospectively studied by Medtronic.

VT/VF induction – If an asynchronous MRI SureScan pacing mode is selected for a patient, be aware that the patient may be susceptible to cardiac arrhythmia induced by competitive pacing and other mechanisms. To avoid VT/VF induction, confirm that the patient needs asynchronous pacing, select a pacing rate that avoids competitive pacing, and minimize the period of time during which MRI SureScan is programmed to On.

Note: If the patient does not need pacing support, select a nonpacing mode (OVO).

Device information and records – All pertinent information about the implanted SureScan device such as model name, model number, and serial number should be recorded in the patient record and on the Patient Information screen on the programmer. This information will help with device identification in the future.

Patient ID card – Reference materials, such as an ID card, should be provided to all patients with an implanted SureScan device. These reference materials should indicate that the patient has a SureScan device.

Note: Be sure to advise patients to notify medical personnel that they have a pacemaker before entering the MR environment and to present their patient ID cards.

Multiple implanted devices – Scanning patients who have multiple MR Conditional devices present is acceptable when the MR labeling conditions for all implants are satisfied. Scanning patients who have multiple MR Conditional Micra devices is also acceptable when the MR labeling conditions for Micra are satisfied.

7 Radiology-specific considerations

7.1 MRI considerations

Patient positioning – There are no patient positioning restrictions relative to the MRI isocenter landmark.

Use of transmit/receive and receive-only coils – There are no restrictions on the use of local transmit/receive coils for MRI scanning of the head or of the extremities, and there are no restrictions on the placement of receive-only coils.

Image artifact and distortion – Image artifact and distortion can result from the presence of the Micra device within the field of view. Image artifact and distortion resulting from the presence of the device within the field of view must be considered when selecting the field of view and imaging parameters. These factors must also be considered when interpreting the MRI images.

Multiple implanted devices – Scanning patients who have multiple MR Conditional devices present is acceptable when the MR labeling conditions for all implants are satisfied. Scanning patients who have multiple MR Conditional Micra devices is also acceptable when the MR labeling conditions for Micra are satisfied.

8 Pre-MRI scan operations

The steps in the following sections are required before performing an MRI scan.

8.1 Identification of the SureScan device

You can verify that the patient has the SureScan device required for an MRI scan in the following ways:

1. **X-ray of the implanted device:** Take an x-ray of the implanted device to verify that it is a Micra device. Although this device is MR Conditional, the wavy line for the radiopaque MRI symbol is not present on the device due to the small size of this device. An x-ray also indicates whether the patient has any implanted devices that are contraindicated for an MRI scan.
2. **Patient records or patient ID cards (if applicable):** Use the patient records or patient ID cards, if applicable, to verify that the patient has a SureScan device. The patient records or patient ID cards must be complete and accurate if they are to be used for the identification of the SureScan device. The patient may have implanted devices that are MRI contraindicated, but not noted on the Medtronic patient ID card.
3. **Patient information on the programmer:** Use the patient information on the programmer, such as the Patient Information screen, to verify that the patient has a SureScan device. The patient information available on the programmer must be complete and accurate if this information is to be used for the identification of the SureScan device. The patient may have implanted devices that are MRI contraindicated, but not noted in the patient information on the programmer.

8.2 Required patient care

Before programming MRI SureScan to On, perform the following actions to help ensure patient safety:

Verify that the pacing amplitude is ≤ 4.5 V before programming MRI SureScan to On. – If the programmed output exceeds 4.5 V, do not scan the patient.

Evaluate the patient to determine whether or not pacing support is needed while MRI SureScan is programmed to On. – For patients who require pacing support, set the MRI SureScan pacing mode to VOO when programming MRI SureScan to On. For patients who do not require pacing support, set the MRI SureScan pacing mode to OVO when programming MRI SureScan to On. Asynchronous pacing may increase the risk of arrhythmia.

If the patient will require pacing support, ascertain an appropriate pacing rate. – An appropriate pacing rate is one that will help avoid competitive pacing while MRI SureScan is programmed to On.

Prepare to provide proper patient monitoring during the MRI scan. – Proper patient monitoring includes maintaining continuous visual and verbal contact with the patient and continuous monitoring of the patient's heart rate using instrumentation such as pulse oximetry (plethysmography) or electrocardiography.

Prepare for patient rescue. – In the event that patient rescue is required, an external defibrillator must be available during the MRI scan.

9 Performing an MRI scan

Warning: Do not scan a patient who has an active Micra device without first programming MRI SureScan to On. Scanning an active Micra device without programming MRI SureScan to On may result in patient harm.

Note: Micra devices can be safely scanned if the device is programmed to Device Off, or if the device has reached EOS.

Warning: Do not leave the device in MRI SureScan mode after the scan is complete. Be sure to program MRI SureScan to Off as soon as possible after the scan is complete.

Note: The device automatically programs MRI SureScan to Off 24 hours after it is programmed to On. Before you program MRI SureScan to On, ensure that the MRI scan will be completed before this 24-hour timeout occurs. Refer to the MRI SureScan report for information about when MRI SureScan was programmed to On.

Caution: Do not bring the Medtronic programmer into the examination room (magnet room). It is MR Unsafe.

When programming MRI SureScan to On, you must select parameters that are appropriate for the patient. Pacing mode and rate (if applicable) are to be programmed per the physician's discretion. Based on whether or not the patient needs pacing support, an asynchronous pacing mode (VOO) or sensing only mode can be programmed. Sensed events will be ignored by the device when MRI SureScan is programmed to On, regardless of the programmed mode. The device maintains the selected parameters until MRI SureScan is programmed to Off after the MRI scan has been completed. After MRI SureScan is programmed to Off, the permanent device parameters are restored.

9.1 SureScan device integrity verification

The SureScan device provides automatic verification that no device issues that may compromise patient safety during an MRI scan are detected. Before allowing the user to initiate the SureScan feature, the SureScan device application software checks for the following issues:

Insufficient battery longevity – If the device is at Recommended Replacement Time (RRT), the device software prevents the SureScan feature from being initiated.

Note: Micra devices can be safely scanned if the device is programmed to Device Off, or if the device has reached EOS.

High pacing amplitude – If the patient's amplitude is greater than 4.5 V, the device software prevents the SureScan feature from being initiated.

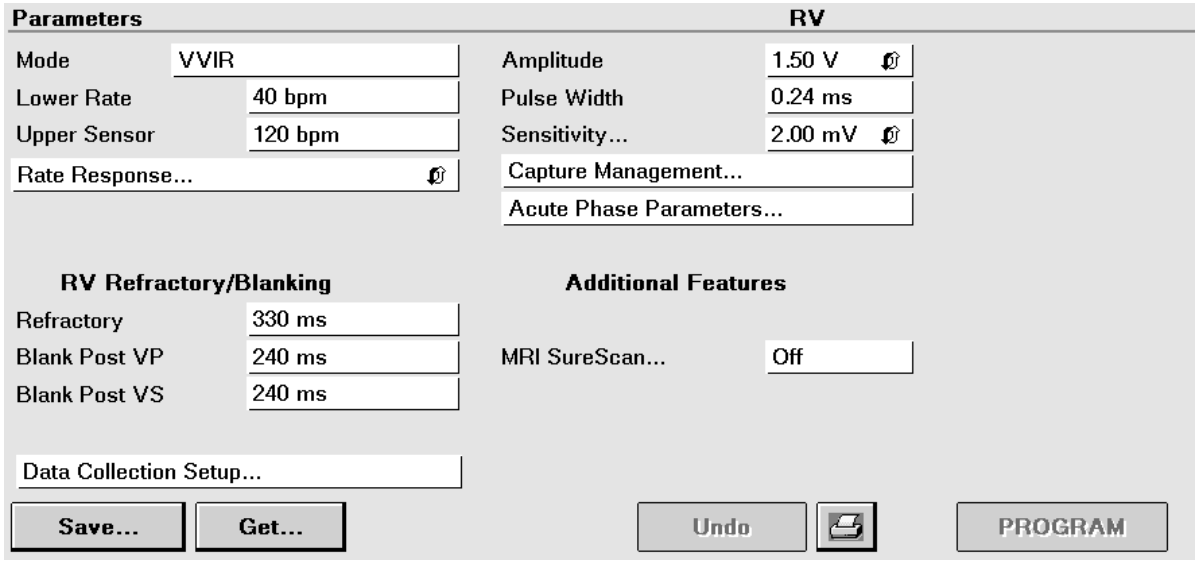
Lockout for implant maturation period – If the device has been implanted for less than 6 weeks, the device software prevents the SureScan feature from being initiated.

9.2 Programming the MRI SureScan feature to On

To program the MRI SureScan feature for operation, follow these instructions:

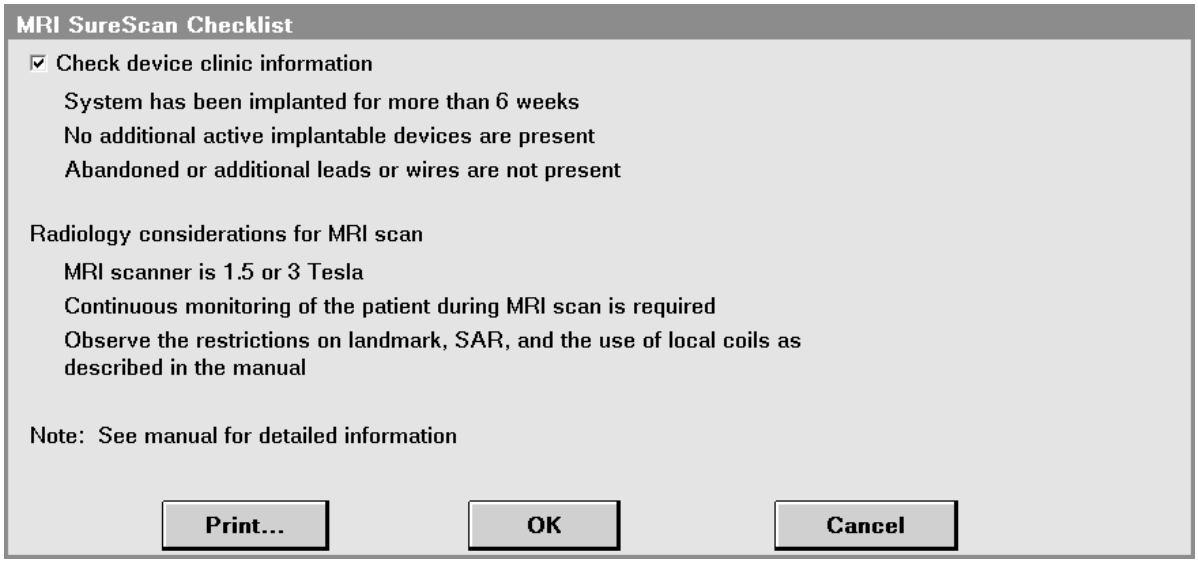
1. Select the Params icon from the tool palette on the programmer. The Parameters screen opens.
2. Select the MRI SureScan… parameter field to open the MRI SureScan Checklist window. See Figure 1.

Figure 1. MRI SureScan… selection screen



3. Make sure that all the items on the MRI SureScan Checklist window are satisfied for the patient. Then, select the check box in the upper left corner. See Figure 2.

Figure 2. MRI SureScan Checklist window



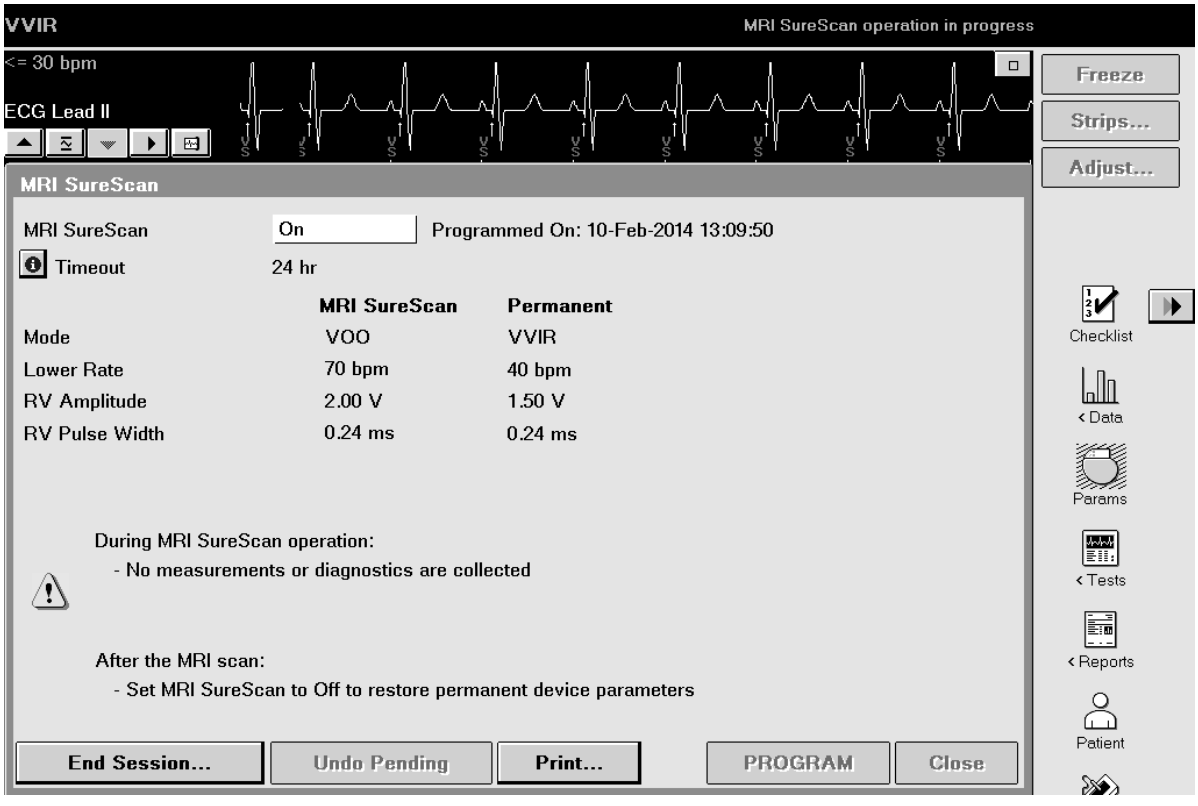
Note: Print the MRI SureScan Checklist, if preferred.

4. Select [OK] on the checklist window. The MRI SureScan screen opens.
5. Select the MRI SureScan parameter field to change the setting to On. See Figure 3.
6. Select the Mode field to open the MRI Pacing Mode window. Then, select the VOO or OVO pacing mode, as appropriate for the patient during the SureScan operation.
   To select the MRI pacing mode and, if required, the MRI pacing rate, appropriate for the patient, use the following information:
   - For patients who require pacing support, the device should be programmed to the asynchronous pacing mode (VOO).

Note: An MRI SureScan pacing rate must be selected for the asynchronous pacing mode to avoid competitive pacing during the operation of the SureScan feature.

- For patients who do not require pacing support during the MRI scan, the device should be programmed to the nonpacing mode (OVO).
  Note: If the patient's device is programmed to the nonpacing mode (OVO), the MRI SureScan pacing rate (Lower Rate) is not available for programming.

Figure 3. MRI SureScan parameters screen



7. Select [PROGRAM] to program the MRI SureScan parameters. The MRI SureScan screen shows the date and time when these parameters are programmed. Also, the Status bar shows the message "MRI SureScan operation in progress."
   Notes:
   - After the MRI SureScan parameter settings are programmed for an MRI scan, the available options are [End Session…], [Print…], and [Emergency]. MRI SureScan can be programmed to Off.
   - If the [Emergency] button is selected while the device is in the MRI SureScan mode, the MRI SureScan setting is restored to Off.
   - To confirm the status of the MRI SureScan feature and the programmed parameters, print the MRI SureScan parameters screen.
   - After 24 hours, the MRI SureScan mode is timed out automatically, and the MRI SureScan parameter is restored to Off.

The device is now ready for the MRI scan.

9.3 Device considerations

Suspension of diagnostic data – When MRI SureScan is programmed to On, all device diagnostic measurements and collection are suspended.

Asynchronous bradyarrhythmia pacing therapy – Asynchronous bradyarrhythmia pacing therapy is provided when an asynchronous pacing mode is selected for MRI SureScan operation.

Automatic amplitude selection for MRI SureScan pacing mode – When MRI SureScan is programmed to On and the pacing mode is VOO, the device may automatically reset the amplitude values. If the permanently programmed RV Amplitude is ≤ 4.5 V, the amplitude is temporarily set to the current pacing amplitude plus 0.5 V.

Automatic canceling of MRI SureScan with Emergency programming – If you deliver any emergency therapy when MRI SureScan is programmed to On, MRI SureScan is automatically programmed to Off. After an Emergency feature is programmed, MRI SureScan must be programmed to On again before the patient can be scanned safely.

10 Following the MRI scan of an active device

Warning: Do not leave the device in SureScan mode after the scan is complete. Be sure to program MRI SureScan to Off as soon as possible after the scan is complete.

24-hour timeout period – The device automatically programs the MRI SureScan parameter to Off 24 hours after it was programmed to On.

Check the pacing capture threshold – Check the pacing capture threshold of the active device after the scan is complete, and be sure that the pacing parameters are programmed adequately for the patient based on the threshold.

10.1 Returning the active device to the pre-MRI configuration

Note: The device maintains the parameters that were set while initiating the SureScan feature until the MRI SureScan parameter is programmed to Off after the MRI scan. After 24 hours, MRI SureScan is restored to Off automatically.

After the MRI scan is completed, program MRI SureScan to Off to restore the device parameter settings to pre-MRI SureScan configuration.

To program MRI SureScan to Off, follow these steps:

1. Select the MRI SureScan parameter field to switch the setting to Off.
2. Select [PROGRAM].
3. Select [Close] to return to the Parameters screen.

The device parameter settings are now restored to the pre-MRI SureScan configuration. If MRI SureScan is not programmed to Off within 24 hours after it is programmed to On, the SureScan operation ends and the MRI SureScan parameter settings are restored to pre-MRI SureScan configuration.

Note: During each interrogation, the device is monitored for possible electrical reset conditions and disabled therapies. If a condition that requires attention is detected, the programmer displays a Device Status Indicator warning in a message window and on the Quick Look II screen.

11 Medtronic warranty information

Please see the literature enclosed with the products for information regarding the product warranty or disclaimer of warranty as applicable.

12 Explanation of symbols

The following symbols are related to the magnetic resonance (MR) environment and are used to indicate the safety of devices and components in the MR environment.

SureScan symbol

MR Conditional symbol. The Medtronic SureScan pacing device is MR Conditional and, as such, is designed to allow implanted patients the ability to undergo an MRI scan under the specified MRI conditions for use.

MR Unsafe symbol. An item that is known to pose hazards in all MR environments. The Patient Assistant, Medtronic Programmer, and the Medtronic Home Monitor are MR Unsafe.

13 Service

Medtronic employs highly trained representatives and engineers located throughout the world to serve you and, upon request, to provide training to qualified hospital personnel in the use of Medtronic products. Medtronic also maintains a professional staff to provide technical consultation to product users. For more information, contact your local Medtronic representative or call or write Medtronic at the appropriate telephone number or address listed on the back cover.

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