

Cardiac Rhythm Management // BIOTRONIK Home Monitoring®

BIOTRONIK Home Monitoring®

Patient information





Table of Contents

| | |
|--|----|
| Introduction | 4 |
| About BIOTRONIK Home Monitoring® | 6 |
| ▪ Why would you need BIOTRONIK Home Monitoring®? | 7 |
| ▪ How does BIOTRONIK Home Monitoring® technology work? | 10 |
| ▪ What information does your doctor receive with BIOTRONIK Home Monitoring® and how is it used? | 11 |
| Daily life with BIOTRONIK Home Monitoring® | 13 |
| ▪ The CardioMessenger Smart | 14 |
| ▪ The bedside CardioMessenger II-S and II-S T-Line | 18 |
| ▪ Daily life with the CardioMessenger (at home, at work and while traveling) | 19 |
| Frequently Asked Questions | 22 |
| Further Information | 29 |
| ▪ Studies confirming the benefits of BIOTRONIK Home Monitoring® | 29 |

Introduction

Pacemakers, implantable cardioverter-defibrillators (ICDs), heart failure therapy systems for cardiac resynchronization and insertable cardiac monitors have been used for decades to improve the quality of life of cardiac patients. These small devices are now a common form of treatment.

If you have or if you are about to have one of these devices implanted, you might know that you will need to visit your doctor regularly to have checkups made on your health conditions and your cardiac device. But what if your health condition or cardiac device status changes between checkups? BIOTRONIK Home Monitoring® technology will assist your doctor by monitoring it remotely from where you are.

This booklet provides you with useful information about the BIOTRONIK Home Monitoring® system and answers patients' most frequently asked questions. In addition to reading this brochure, be sure to speak with your doctor to make sure you have all the information you need for your particular condition.





About BIOTRONIK Home Monitoring®

BIOTRONIK Home Monitoring® is the world's most advanced telemonitoring solution for patients with cardiac devices. It allows your doctor to continuously access information about your implanted system.

Based on BIOTRONIK Home Monitoring® information, your physician may be able to respond much earlier to critical changes in your heart or device condition – and, therefore, perform your follow-ups in line with your medical needs.

BIOTRONIK Home Monitoring® regularly provides your physician with helpful information about your current health care and device status – without any required interaction from you.

Via a secure website, your doctor is able to remotely check your device status around the clock, independently from what you do and where you are.

PLEASE NOTE: BIOTRONIK Home Monitoring® is not a substitute for appropriate medical attention in the event of an emergency and should only be used as directed by a physician. BIOTRONIK Home Monitoring may be unavailable at times due to maintenance or updates, or due to cellular coverage being unavailable in your area.



Why would you need BIOTRONIK Home Monitoring®?

With BIOTRONIK Home Monitoring®, every day your doctor is sent information about your heart condition and how your implanted device has functioned. Most of the information will be good news: Your heart is beating normally, no arrhythmias occurred, the device is operating appropriately and the battery of your implanted device has plenty of energy left.

Sometimes, however, between traditional in-office follow-up appointments, your health condition may change silently – and your doctor would not know about it until your next routine checkup. With BIOTRONIK Home Monitoring®, your doctor can be informed about your status daily – allowing him or her to contact you immediately and, if necessary, adjust your therapy or device settings sooner than if you did not use the system.

Using BIOTRONIK Home Monitoring® may improve your cardiac device's safety¹ as well as your quality of care² in general. The following advantages usually can be seen in clinical practice.

Therapy optimization

The physiology and condition of the heart is continuously changing. Those changes may require your doctor to adjust your therapy from time to time, e.g., your medication, device programming or lifestyle. BIOTRONIK Home Monitoring® allows your doctor to monitor your disease progression and intervene earlier than conventional in-office follow-ups.

For example, if you have a pacemaker, your physician may be keen to avoid unnecessary device stimulations in the ventricle to minimize the risk of atrial fibrillation – a main cause for strokes. If you are a defibrillator (ICD) patient, your device will deliver electrical shocks if life-threatening arrhythmias occur. Shock deliveries, however, represent a considerable burden for a patient and should be avoided unless absolutely necessary.

About BIOTRONIK Home Monitoring®

With BIOTRONIK Home Monitoring®, your physician has the option of being informed after a therapy occurs – particularly a shock delivery. For instance, your physician can check why the therapy was delivered and whether the device behaved correctly. Having all this information at his or her fingertips, your physician may adjust your therapy settings not only in accordance with your health condition, but also in ways that minimize your risk for hospitalization.

Early detection

Imagine your heart beat is frequently affected by serious arrhythmias or technical complications, which are not noticeable to either you or your doctor. Untreated arrhythmias like atrial fibrillation may increase the incidence of stroke or heart failure progression. Lead failures may result in inappropriate device therapies, which could cause anxiety and other emotional problems that can compromise a patient's overall treatment effect. With BIOTRONIK Home Monitoring®, your physician may receive an alert about changes in your health and see you for an evaluation sooner. The diagnosis of such events may enable your physician to react promptly and thereby prevent subsequent health damages.

Patient follow-ups

Most in-clinic routine follow-ups do not require any device change or other medical adaptations. They do, however, involve effort from you and your physician. As long as your heart and device conditions are judged stable, your physician may decide to replace the device interrogation from your in-clinic routine follow-ups with remote follow-up information. With BIOTRONIK Home Monitoring®, your physician can perform these remote follow-ups according to your individual needs at just the right time.

Is there anything wrong with me?

Even knowing that your doctor will be informed when anything out of the ordinary occurs, you might sometimes wonder whether the device implanted in your chest is working properly. Or, you may experience symptoms that make you feel insecure. Sometimes in these cases, patients schedule a follow-up appointment to clarify the reason for their symptoms – only to arrive at the clinic and have the symptoms seem to disappear.

With BIOTRONIK Home Monitoring®, your physician can easily check to see whether your symptoms were related to a clinical event. If you feel dizzy, feel your heart beat racing or feel a strange sensation in your heart, try to note the date and time of the episode and contact your doctor's office. With the help of BIOTRONIK Home Monitoring®, your physician can match your symptoms with the data stored on the Home Monitoring platform to determine what happened.

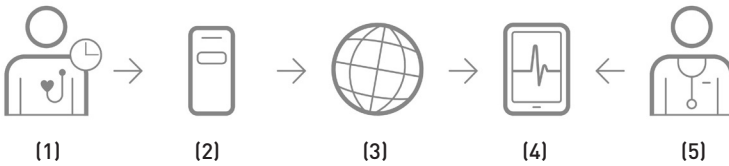


About BIOTRONIK Home Monitoring®

How does BIOTRONIK Home Monitoring® technology work?

BIOTRONIK Home Monitoring® works together with a transmitter called the CardioMessenger. The CardioMessenger communicates with your cardiac implant through an antenna that is built inside the device. Once the CardioMessenger receives the data from the device, it forwards them to your doctor via a secure website.

Here is how the data transmission works, step by step:



(1) Every day your device communicates what your heart is doing. The data transmissions usually take place at night while you are asleep. All data are transmitted wirelessly, silently and automatically to the CardioMessenger.

(2) The CardioMessenger receives the data and **(3)** forwards them to the BIOTRONIK Home Monitoring® Service Center. All data is encrypted and transmitted via the worldwide cell phone network (GPRS) or via standard landline.

(4) At the Service Center, all your data are processed automatically and summarized into special reports. All reports are stored for your physician on a protected website. Most of the time, the reports confirm normal activity.

(5) Only your doctor and his or her team are authorized to review the data online. Your doctor is also alerted by email, fax or text message if something unusual is detected. If your doctor needs to see you based on the transmitted data, he or she will notify you to make an appointment.

What information does your doctor receive with BIOTRONIK Home Monitoring® and how is it used?

Every day, the BIOTRONIK Home Monitoring® system provides useful information about your device and heart condition to your physician. The information includes:

- Any irregular heart rhythm (arrhythmia) that might occur
- All device activities (electrical stimulations, impulses, shocks and battery status)
- Certain values assessing an underlying heart failure condition
- Periodic and event-triggered electrocardiograms (ECGs) from the inside of your heart (IEGM)
- Technical information about the reliability of your leads and implanted device

With this information at hand, your physician can assess not only your device status, but also your heart condition.

In addition to that, your doctor has the possibility to define what he or she wants to focus on: Your doctor can assign a color coding similar to a traffic light concept, where he or she determines in advance which events will be classified as "important" or "very important."



Daily life with BIOTRONIK Home Monitoring®

After your device implantation, you will receive your CardioMessenger. Your CardioMessenger will be in a ready-to-operate state. The CardioMessenger is the device that is required so that your data can be transmitted to your physician when you are at home.

All CardioMessenger devices have the same functionality, and depending on your health condition and your lifestyle, your doctor will decide with you which CardioMessenger would fit best for you. The CardioMessenger devices are very easy to set up, and each transmits your data automatically to your doctor via the cell phone network or landline. Your doctor or a nurse can explain to you how to set up the CardioMessenger at home and what the LED lights mean. During this explanation, you can also verify whether your CardioMessenger works properly. To ensure data transmission, remember to place the CardioMessenger no less than 8 inches (20 cm) away from you and no more than 6 feet (2 meters) away from your bed.

Please also refer to the user's manual for further information.

Daily life with BIOTRONIK Home Monitoring®

The CardioMessenger Smart

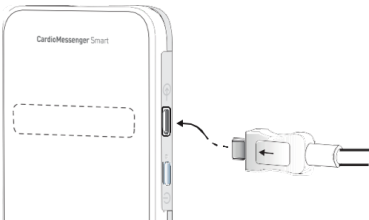
CardioMessenger Smart is a small, lightweight, portable Home Monitoring transmitter. It receives information from your implanted device and forwards these messages to your doctor. This normally occurs during the nighttime while you are sleeping. In general, you simply need to place your CardioMessenger close to where you sleep to ensure that the data will be transmitted properly.

CardioMessenger Smart is designed for use at home or while away from home. Your doctor will advise you if it is necessary to take the device with you while you are away from home.

Here is how you should set it up:

After unboxing CardioMessenger Smart, locate the power adapter cable. Plug the power adapter into an ordinary wall outlet (120/220V).

1. Connect the small plug (micro USB plug) into the right side of the CardioMessenger Smart. Make sure that the marking (white arrow) is on the upper side of the plug.



The connector port is labeled with the following symbol:



2. Insert the power plug into the wall outlet.

Make sure that the outlet is easily accessible and not connected to a light switch in order to prevent the CardioMessenger Smart from accidentally being turned off.

The CardioMessenger Smart will now power on automatically and perform a self-test. It is

ready for use once the self-test is completed and the following icons are displayed indicating that the device has successfully completed the self-test and the battery is charging:



At night, the CardioMessenger Smart should be placed close to your bed to ensure the nightly data transfer from the implanted device. The bedside table or headboard are ideal locations for your CardioMessenger Smart, as they typically meet the following conditions:

- The CardioMessenger Smart is placed on a solid base and cannot fall.
- The distance to the implanted device is less than 2 m (6 feet), so that the CardioMessenger Smart is within communication range of your implanted device.

You should leave the device connected to the power adapter at all times unless instructed by your doctor to take the device with you when away from home. Be sure to take the power adapter with you to recharge the CardioMessenger Smart if you plan to be away from home for more than 48 hours.


Check once a day (typically before going to sleep) if the CardioMessenger Smart is switched on and ready for use. This is indicated by the following icons:








Turning Off the CardioMessenger Smart

Since the CardioMessenger Smart contains a mobile ("cellular") module, you may need to switch off the CardioMessenger Smart for safety reasons in areas where the use of mobile phones is prohibited (e.g., airplanes).

Daily life with BIOTRONIK Home Monitoring®

Press and hold the blue  key on the right side of the CardioMessenger Smart for two seconds until the display turns off.

The CardioMessenger Smart has the following icons:

| | |
|--|--|
|  | Operation icon. The CardioMessenger Smart is ready for use. |
|  | Call back icon. If this icon flashes, contact your physician during normal office hours. Refer to Section 4 of the CardioMessenger Smart Product Manual for more information. |
|  | Information icon. If this icon flashes, a cellular connection cannot be established. Please try relocating the device in the room. Refer to Section 5 of the CardioMessenger Smart Product Manual for more information. |
|  | The battery icon is always displayed with 1-3 bars according to the charging status. Refer to Section 6 of the CardioMessenger Smart Product Manual for more information. |
|  | The CardioMessenger Smart is connected to the power supply and charging. |

During charging, the individual segments of the battery icon flash alternately and a small power plug is displayed. The three bars on the battery icon flash successively until the CardioMessenger Smart is fully charged. Once it is fully charged, all three bars are completely filled. The charging process usually takes three hours.



Your CardioMessenger Smart needs to be charged immediately when the battery monitor light contains no bars and is flashing.



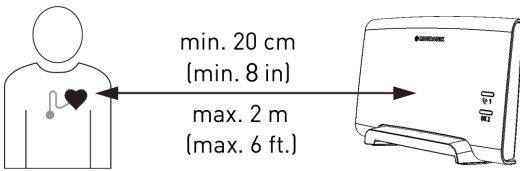
Please consult the Product Manual included with your CardioMessenger Smart for additional instructions on the use of this product.

Daily life with BIOTRONIK Home Monitoring[®]

The bedside CardioMessenger II-S and II-S T-line

The CardioMessenger II-S and II-S T-line are home-based transmitters used to facilitate the once daily transmission of cardiac and technical implant data to your physician. Both models perform the same data transmission function; however, they do it in slightly different ways. The CardioMessenger II-S uses a mobile network (cellular GSM network) to transmit data to your physician, as opposed to the T-line model, which uses a standard household telephone line for data transmission.

Since your implanted device usually communicates with the CardioMessenger II-S at night while you are sleeping, choose a location near your bed to keep your CardioMessenger II-S – usually on your nightstand or headboard. You will also need to connect the CardioMessenger II-S to a power outlet.



As soon as you connect your CardioMessenger II-S to the power supply, data will be transmitted automatically to your physician starting the following night.



Here is how you should set it up:

- (T-line only) Connect your Cardiomesenger II-S to your telephone line connection, following the instructions included with the device.
- Plug the bigger plug of the power supply cable to an ordinary wall outlet (120/220V) and the smaller plug of the same cable into the left side of the CardioMessenger II-S.
- The CardioMessenger II-S will automatically turn on and conduct a self-test. The "OK 2" light will illuminate yellow for about fifteen minutes.
- As soon as the self-test has been performed successfully, the "OK 2" light will turn green and data should be transmitted without any problem.
- If the "OK 2" light remains yellow, the CardioMessenger II-S is not able to establish a connection to the service center. After 48 hours, if a connection can not be established, please contact BIOTRONIK Technical Services.

Usually, only the lower operating "OK 2" light is green and the upper call-back light (📞 1) is not illuminated. If the call-back light blinks yellow, your doctor turned it on to ask you to call him or her. Please call your doctor as soon as you realize that the call-back light is blinking. The call-back light will blink yellow for a maximum of three days. If you want to turn it off earlier, just disconnect power from your CardioMessenger II-S for a few seconds and then reinsert it.

The bedside CardioMessenger II-S does not have an on/off button. Simply leave your device plugged into the electrical wall outlet at all times.

Daily life with the CardioMessenger (at home, at work and while traveling)

The CardioMessenger devices were designed to easily integrate into your normal, everyday routine. They work almost anywhere there is reliable cellular data access or a household telephone line.

Daily life with BIOTRONIK Home Monitoring®

In general, you simply need to place your CardioMessenger, regardless of whether it is the portable or the bedside transmitter, close to your bed to ensure that the data will be transmitted properly. You can take the CardioMessenger Smart with you when you spend a night away from home - such as when you go on vacation or need to stay overnight in the hospital.

You can carry the CardioMessenger Smart with you at any time, although it should not be carried directly over the implant (for example, in your jacket pocket). Your doctor will advise you if you need to carry your CardioMessenger with you when you travel away from home.



If you plan to travel for an extended period of time or travel out of the country, discuss your plans in advance with your doctor. He or she will ensure that your CardioMessenger will work properly during this time period. For example, if you are traveling outside of your time zone, your doctor may want to reset the time when Home Monitoring sends its daily report.

Keep in mind that BIOTRONIK Home Monitoring® works in more than 160 countries. To check where BIOTRONIK Home Monitoring® works, please visit www.biotronik.com or ask your doctor.

Please note that your CardioMessenger Smart will not be damaged by airport security X-ray or anti-theft devices in shops or libraries. And, like you would do with your mobile phone, don't forget to turn it off on an airplane.



Frequently Asked Questions

Why do some people have BIOTRONIK Home Monitoring® and others don't?

BIOTRONIK Home Monitoring® is only available with certain pacemakers, defibrillators and cardiac resynchronization therapy devices from BIOTRONIK. Your physician will help you decide whether BIOTRONIK Home Monitoring® is right for you.

Can BIOTRONIK Home Monitoring® reduce the number of necessary checkup appointments?

In general, since BIOTRONIK Home Monitoring® allows your doctor to monitor your heart condition remotely, BIOTRONIK Home Monitoring® can extend the time between routine in-office follow-up visits. However, every patient is different and a great deal depends on your overall health, your cardiac condition, other complications you might have, and your physician. Discuss this with your doctor; he or she is the expert on your particular medical condition.

Is there a lower risk of going back to the hospital for people with heart failure who use BIOTRONIK Home Monitoring®?

Yes, there is a lower risk of going back to the hospital.² Heart failure is a progressive disorder, meaning that a person with heart failure has a permanently changing cardiac condition. People with heart failure may need frequent adjustments to their prescriptions or need to change or add new drugs, and those with cardiac resynchronization therapy devices may need to have frequent adjustments made to their devices. To make those adjustments, the doctor must be able to regularly assess the patient's condition. People with heart failure are often rehospitalized because their condition has gotten worse and because therapy was either not adjusted, or not adjusted quickly enough. BIOTRONIK Home Monitoring® can help change that by providing the physician with frequent updates on a patient's status, letting him or her identify trends that indicate the need for therapy adjustment.

What happens if my doctor finds something wrong with my heart using BIOTRONIK Home Monitoring®?

It might be possible that your doctor will be notified about problems before you as the patient even know something is wrong. If something like this should happen, the doctor's office will contact you and schedule an appointment for an in-office follow-up. Your doctor may then want to adjust the device, change your medications or suggest some other therapy to address what is going on.

What are the advantages of BIOTRONIK Home Monitoring®?

BIOTRONIK Home Monitoring® works automatically and silently, so it is not difficult to use. There is no required interaction from you and there is no complicated technology to operate. It's completely painless; in fact, you will not even be aware that it's working. You may even forget that you have it after a while, since your physician will have no reason to contact you – provided that all reports come back normal. You can easily travel to many parts of the world without compromising your care. And, should you enter an environment where electronic devices must be turned off (such as an airplane), it's very simple to turn the CardioMessenger on and off. Even if you are one of the people who is "not good with technology," you'll still be able to work with BIOTRONIK Home Monitoring® and the CardioMessenger with ease and confidence from the very start.

Frequently Asked Questions

Will BIOTRONIK Home Monitoring® affect my implant device's performance?

BIOTRONIK Home Monitoring® has no negative effect on your device's performance. It has minimal impact on your device's battery longevity.³

What is the difference between BIOTRONIK Home Monitoring® and CardioMessenger?

BIOTRONIK Home Monitoring®, the world's most advanced monitoring solution, is the system that allows your implanted BIOTRONIK cardiac device to communicate directly with your doctor. While the technology is called BIOTRONIK Home Monitoring®, the CardioMessenger is the small device that receives the data from your implant and forwards it to your doctor.

How can I see if my CardioMessenger is working properly?

Your CardioMessenger is working properly if the you see "OK". On the CardioMessenger Smart, the "OK" icon illuminates on the LCD screen to indicate normal operation. On the CardioMessenger II-S, a green light next to "OK 2" indicates normal operation. If any other lights flash or illuminate, please refer to the user's manual or call your doctor's office.

How often will the data be transmitted and how long will it take?

Normally, your CardioMessenger will transmit your data every night around 2 a.m. (Your physician can program at what time the daily transmission will occur.) Your physician can program the device so that it will transmit additional alerts – for example, if you experience an episode of extended atrial fibrillation or if your device battery starts to get low. Your doctor may choose to receive an additional alert via email, text message or fax.

The data transmission takes only a few seconds. If it is interrupted, your CardioMessenger will try retransmitting the data a few minutes later.

What kind of information is transmitted to my doctor?

The data transmitted to your doctor includes:

- Any irregularities of the heart rhythm (arrhythmia)
- All device activities (electrical stimulations, impulses, shocks, battery status)
- Certain values to monitor the underlying condition of heart failure
- Periodic and event-triggered electrocardiograms (ECGs) from inside of your heart (IEGM)
- Technical information about the reliability of your leads and the implanted device



Frequently Asked Questions

Is the data transmission secure?

Yes, the transmission is secure. The data will be transmitted as an encrypted medical message and will be only accessible via a secure, password-protected website.

Who can access my data?

Only your doctor, or persons authorized by him or her, are able to access your data and will be alerted if something unusual is detected.

Do I need to recharge my CardioMessenger?

Your bedside CardioMessenger doesn't need to be recharged, but if you use CardioMessenger Smart, you'll need to charge it just like you would charge a cell phone. A fully charged mobile CardioMessenger Smart lasts for up to 48 hours before you need to recharge it. To recharge it, just plug it into the power adapter; it will recharge automatically.

Will the transmitter interfere with my cell phone?

No, the transmitter will not interfere with your cell phone.

What happens if my CardioMessenger loses cell phone connection?

You will probably not notice if your CardioMessenger loses cell phone connection. If it does, it's not a problem; as soon as the cell phone network is available again, your CardioMessenger will reestablish the connection.

What happens if I forget to take my CardioMessenger with me?

From a technical point of view, it's not a problem; your CardioMessenger Smart will operate as usual as soon as you come back. But if your doctor told you to carry your CardioMessenger Smart with you the whole day, please make sure you do so. If you forget to take your CardioMessenger Smart with you while traveling, for instance, you should call your doctor right away, because after a few days he or she will receive a notification that there is no data being transmitted anymore.

Can I travel with my Cardio Messenger Smart?

Yes. Traveling with your CardioMessenger Smart is fine, and BIOTRONIK Home Monitoring® works in more than 160 countries – nearly anywhere there is cell phone access. But as a person with an implanted pacemaker, defibrillator, cardiac resynchronization device, or insertable cardiac monitor, you should always discuss your travel plans in advance with your doctor – especially if you are traveling out of the country or will be traveling for extended periods of time. In addition, if you are traveling outside of your home time zone, your doctor may want to reset when BIOTRONIK Home Monitoring® sends its daily report.

Your CardioMessenger Smart will not be damaged by airport security X-ray, but note that similar to what you would do with your mobile phone, be sure to turn it off while on an airplane.



Frequently Asked Questions

What should I do if I'm experiencing certain symptoms such as a dizzy spell, heart racing, strange sensations or similar symptoms?

If you ever experience symptoms such as these and are unsure whether they are serious or not, simply note the date and time when you experienced them and call your doctor's office. He or she can get information from BIOTRONIK Home Monitoring® for the past few hours or days and assess what is happening with your heart and your implantable device.



Further Information

Studies confirming the benefits of BIOTRONIK Home Monitoring®

BIOTRONIK Home Monitoring® has been the subject of numerous clinical studies. The first such study was published in 2002 and demonstrated that Home Monitoring works safely and reliably.² This study also showed that for patients with heart failure, using BIOTRONIK Home Monitoring® actually decreased their risk of having to go back to the hospital and improved their overall quality of care. In addition, a clinical study presented at the American Heart Association in 2008 found that BIOTRONIK Home Monitoring® could safely decrease the number of checkups that device patients had to have.¹

Another clinical study (ECOST Trial) confirmed again that BIOTRONIK Home Monitoring® decreased the patient's risk of having to go back to the hospital. Furthermore, the study found that BIOTRONIK Home Monitoring® reduces the number of inappropriate shocks - and that reducing the number of charges has a positive impact on battery longevity.³

BIOTRONIK, Inc.
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- 1 Varma, et al., American Heart Association (AHA) Scientific Sessions, Late-Breaking Clinical Trial Abstracts 2008, *Circulation* 2008, 118, 2309-2317.
- 2 Wallbrueck K, Stellbrink C, Santini M et al., The value of permanent follow-up of implantable pace-makers - first results of a European trial, *Biomed Tech (Berlin)* 2002; 47 (Suppl.1, Pt. 2): 950-3.
- 3 Guédon-Moreau L et al., A randomized study of remote follow-up of implantable defibrillators. Safety and Efficacy report of the ECOST trial. *Eur. Heart J.*, Dec. 2012, doi: 10.1093/eurheartj/ehs425-



BIOTRONIK Home Monitoring®

Patient information

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