

PRACTITIONER'S CORNER

Update on MRI safety in patients with stents, prosthetic heart valves and cardiovascular implantable electronic devices

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Abstract: Due to recent technical developments, magnetic resonance imaging (MRI) has become one of the most attractive imaging modalities for a multitude of pathologies, offering unique information with the potential to modify diagnosis and treatment strategies in a cost-effective manner. Cardiovascular magnetic resonance (CMR) in particular has dramatically evolved to a reliable diagnostic tool bringing unique information for virtually all cardiovascular pathologies¹. Patients with coronary stents, prosthetic heart valves or pacemakers and others cardiac implanted electronic devices (CIEDs) have been historically denied the opportunity to undergo clinically indicated MRI scans. As the population ages, it has been suggested that 50% to 75% of patients with CIEDs will have a clinical indication for MRI examination in their lifetimes^{2,3}. As we are facing a growing need for MRI scans in the large population of patients with implanted cardiac devices, it is crucial to accurately inform healthcare professionals about the actually low risk of performing MRI in these patients. As a rule of thumb, virtually all patients with coronary stents, prosthetic heart valves, annuloplasty rings and MR-conditional CIEDs can safely undergo MRI scanning at 1.5 tesla, and some of them at 3 tesla³⁻⁵. Moreover, recent studies have led the scientific societies to allow MRI scanning even for patients with non-conditional CIEDs under special circumstances.

This review aims to inform physicians of all specialties on how to safely indicate clinical MRI in patients with implanted cardiovascular devices based on an evidence-based approach.

Keywords: magnetic resonance imaging, safety, stents, prosthetic heart valves, cardiac implanted electronic devices.

Rezumat: Datorită evoluției tehnologice recente, imagistica prin rezonanță magnetică (MRI) a devenit una dintre cele mai atractive tehnici imagistice pentru evaluarea a numeroase patologii, oferind informații unicate cu potențialul de a modifica diagnostice și strategii terapeutice într-o manieră cost-eficientă. În mod particular, rezonanța magnetică cardiovasculară (CMR) a evoluat spectaculos, devenind o tehnică imagistică de încredere ce oferă informații utile în absolut toate patologiile cardiovasculare¹. Până în trecutul foarte recent, MRI era considerată o investigație contraindicată pentru pacienții cu stenturi coronariene, proteze valvulare, sau stimulatori cardiace și alte dispozitive cardiace electronice implantabile (CIED). Pe măsură ce populația globului îmbătrânește, se estimează că aproximativ 50-75% dintre pacienții cu CIED vor avea nevoie de o examinare MRI pe parcursul vieții^{2,3}. Dat fiind că asistăm la un necesar tot mai mare de examinări MRI în rândul pacienților cu dispozitive cardiace aflați în continuă creștere este foarte important ca personalul medical să știe că riscul examinării MRI a acestor bolnavi este de fapt mic. În principiu, toți pacienții cu stenturi coronariene, proteze valvulare, inele de anuloplastie, și CIED condiționale pentru MR pot efectua în siguranță MRI la 1.5 tesla, și o parte dintre aceștia chiar la 3 tesla³⁻⁵. Mai mult decât atât, studiile recente au convins societățile științifice să recomande examinările MRI chiar la pacienții cu CIED care nu sunt condiționale pentru MR, desigur cu precauții specifice. Această lucrare își propune să informeze într-o manieră bazată pe dovezi științifice, medicii din toate specialitățile cum să indice în siguranță examinări MRI la pacienții cu dispozitive cardiace.

Cuvinte cheie: imagistica prin rezonanță magnetică, siguranță, stenturi, proteze valvulare, dispozitive cardiace electronice implantabile.

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VERY BASIC MRI PHYSICS

MRI is an imaging method relying on the nuclear magnetism properties of the atoms. These properties can be used for detecting compounds with an odd number of nuclear particles (nucleons). In living organisms, the atoms with magnetic properties are: ^1H , ^{13}C , ^{19}F , ^{31}P , ^{23}Na . From these compounds, only ^1H (the proton) is generally responsible for playing the major role in MRI. Therefore, MRI might be considered as proton imaging⁶.

In order to perform an MRI examination, several events should be considered. First, the patient is positioned in a high-intensity, static and homogenous magnetic field (the magnet itself). Then, a short radio-frequency (RF) wave is transmitted from the scanner to the patient, producing a radio-magnetic transfer of energy⁷. This energy transfer will result in levels of magnetization that are different in each tissue and organ of the body according to their intrinsic physical properties. Following this radiofrequency impulse, the tissues of the patient will generate a radio signal, „returning” the energy received during the RF impulse towards the scanner (by use of specific receiver coils). During this stage of the process (called relaxation), each tissue and organ will gradually return to the previous balanced state, but this process will be accomplished at different times and levels throughout the body. The scanner is detecting this latter relaxation signal that is subsequently used for producing the images⁷. Therefore, in MRI, unlike in other imaging modalities, the very body of the patient represents the origin of energy required for data processing and ultimately for image reconstruction.

In order to spatially locate the anatomical structures of the body, the system uses specially tailored ancillary variable magnetic fields, called gradients. There are several types of gradients, each serving different purposes, the most widely used being the slice-coding gradients (perpendicular to the slices to be acquired) and the phase and readout (frequency-encoding) gradients, used for the spatial location of structures within one slice^{6,7}.

From these basic principles, multiple types of acquisitions, sequences and applications have been developed, each having special indications and features, according to the required area of examination, patient condition and specific study items and methods⁸.

To summarize, in order to obtain MR images, the following are necessary: the static magnetic field (1.5 tesla, 3 tesla, etc.), the RF waves and the gradient mag-

netic fields. All these can interfere with ferromagnetic objects in the body.

MRI IN PATIENTS WITH CORONARY AND PERIPHERAL STENTS

There used to be a historical excessive precaution among radiologists in performing MRI in patients with implanted coronary or peripheral stents, especially when closer to the implantation date. Most coronary and peripheral stents are made of 316L stainless steel or nitinol (Nickel-Titanium alloy) and exhibit non-ferromagnetic or weakly ferromagnetic properties. The forces caused by the magnetic field on the implanted stent are proportional to its length and mass, but they seem to be insufficient to provoke any shifting even in the case of weakly ferromagnetic stents^{11,5}.

There was a consensus that suggested to wait around 4 to 8 weeks after stent implantation before performing an MRI. The reason behind this recommendation was the additional anchoring of the stent to vessel wall due to endothelization, process that take longer in patients with drug eluting stents. However, there are studies that showed no differences in terms of all-cause deaths, myocardial infarction, and revascularization in the 30 days after MRI examination between patients who had undergone MRI soon after stent implantation and those who had waited 4 to 8 weeks^{20,21}. There is only one case report of a patient with ostial left main lesion treated with a stent that was partially retracted in the aorta that was completely dislodged after MRI, performed 2 weeks after stent implantation²². So, we must bear in mind that a short stent at an aorto-ostial location, especially a drug-eluting stent with delayed endothelial coverage, and a short time of MRI after stenting may be high-risk features for an adverse effect in a strong magnetic field²².

Other clinical trials demonstrated the safety of performing a 1.5 T MRI within 1 to 14 days after stents implantation^{23,24}. Similar evidences came from ex vivo studies that showed the safety of 3 tesla MRI performed early after stent implantation²⁵.

The following guidelines apply to using MRI in all patients with coronary artery stents (including two or more overlapped stents):

- 1) Patients with all commercially available coronary artery stents (including drug-eluting and non-drug eluting or bare metal stents) can be scanned at 1.5 tesla or 3 tesla, regardless of the value of the spatial gradient magnetic field.
- 2) Patients with all commercially available coronary

artery stents can undergo MRI immediately after placement of these implants.

AORTIC STENT GRAFTS AND LEFT ATRIAL APPENDAGE OCCLUSION DEVICES

Most endovascular aortic stent grafts, but not all, are made from nonferromagnetic or weakly ferromagnetic materials and several studies have documented the safety of MRI after aortic stent grafts implantation^{26,27}. Only the Zenith AAA endovascular graft (Cook) is considered unsafe for 1.5 tesla MRI. The only problem with aortic stent grafts are the increased number of artifacts induced by the metallic components of stent grafts.

Regarding the cardiac closure and occluder devices, at least one left atrial appendage occlusion device, the Watchman left atrial appendage device (Atritech, Inc), can be safely scanned at 3 tesla⁵.

MRI IN PATIENTS WITH PROSTHETIC HEART VALVES

Several studies have documented the safety of MRI in patients with prosthetic heart valves and annuloplasty rings^{9,10}. No case of a patient incident or injury related to the presence of a heart valve prosthesis or annuloplasty ring in association with an MR examination were reported in the literature⁵.

The materials used for manufacturing prosthetic heart valves include metals, polymers, and carbons^{11,12}. The metals used are Titanium, alloys of Cobalt and Chromium, and alloys of Nickel, Molybdenum, and Tungsten, as well as Aluminum and Vanadium¹¹. However, it was demonstrated that the forces exerted on these valves and rings by the MRI scanner are less

than the forces exerted by gravity and considerably less than those exerted by the beating heart and resultant pulsatile blood flow^{5,6,14}. Moreover, no case of movement of the mobile parts of valves caused by a magnetic field greater than 1.5 tesla has ever been reported^{11,12}.

The heating effect also is not a hazard, as heat from the area involved is dissipated by flowing blood^{15,12,5}.

Similarly, sternal wires do not produce any significant heating effects and their metallic artifacts are usually minor permitting optimal interpretation of the images.

As such, there is no evidence to justify withholding a cardiac or extracardiac MR study at 1.5 tesla just due to the presence of a prosthetic heart valve. Most of the prosthetic heart valves are also safe at 3 tesla, but testing is less widely available⁵.

METALLIC ARTIFACTS FROM THE PROSTHETIC VALVES

Various models of prosthetic valves may induce different degrees of metallic artifacts, depending on the amount of contained ferromagnetic material. However, in most instances accurate and interpretable images may be obtained (Figure 1 A and B).

Bioprosthetic heart valves are composed primarily of nonmetallic materials (usually porcine tissue or bovine pericardium) but may contain small amounts of metal (used for scaffolding rings)⁵. As such, they are also prone to producing metallic artifacts obscuring not only the valve but also the adjacent structures. On contrary, stentless bioprosthetic valves do not cause any artefacts as they do not contain any metal.

In case of severe metal artefacts, specific MRI sequences with less susceptibility to artifacts may be employed resulting in better image quality (Figure 1).

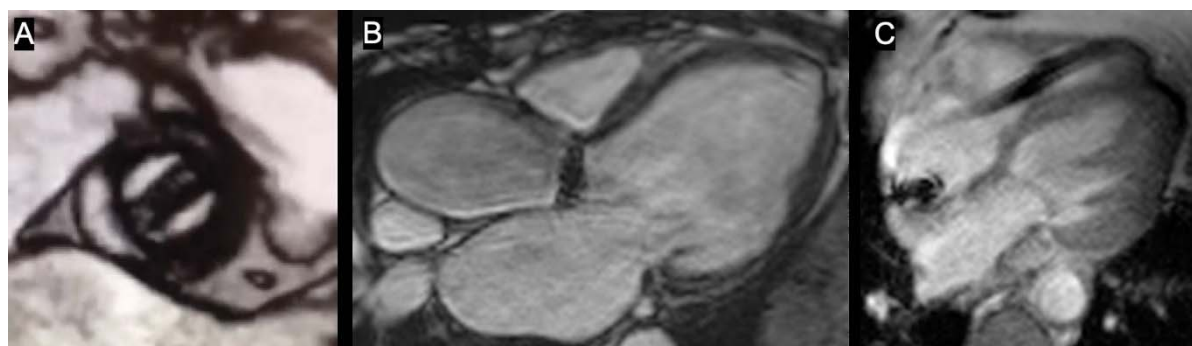


Figure 1. Cardiac MRI in patients with implanted cardiac devices. With careful adjustments, no significant metal artifacts are seen. A. Cine balanced-SSFP in a patient with bileaflet metallic prosthesis in mitral position. B. Cine balanced-SSFP in a patient with bileaflet metallic prosthesis in aortic position. C. Spoiled gradient-echo cine image in a patient with implanted cardiac defibrillator (ICD).

MRI IN PATIENTS WITH CARDIAC IMPLANTED ELECTRONIC DEVICES (CIEDS)

Terminology

The designation MR Safe requires there be no hazard in any MR environment. For example, plastic objects are MR safe¹⁶. On contrary, the designation MR Unsafe refers to an object that is known to pose hazards in all MR environments.

However, no CIED has an MR Safe designation, most of them being labelled as MR conditional. The term MR conditional refers to any device for which a specified MRI environment with specified conditions of use does not pose a known hazard¹⁶. Field conditions that define the MRI environment can include the region of imaging, static magnetic field strength, spatial gradient, time-varying magnetic field (dB/dt), radiofrequency (RF) fields, and specific absorption rate. Additional conditions might be required, including the use of specific leads and generator combinations, as well as MRI mode programming of the CIED system¹⁶.

MR non-conditional - This includes MR conditional generators that have been combined with nonconditional leads or MR conditional systems implanted in patients that do not meet all specified conditions of use, such as patients with abandoned leads.

POTENTIAL HAZARDS WITH MRI SCANNING OF PATIENTS WITH NON-MRI CONDITIONAL CARDIAC IMPLANTED ELECTRONIC DEVICES

There is no risk of CIED generator or leads dislodgement due to magnetic field forces. The CIED generator is confined in the subcutaneous tissues and leads do not contain any significant ferromagnetic materials to cause movement in a magnetic field¹⁶. It has been demonstrated that pacemakers released after 1995 have very low magnetic force values, even lower than the gravity of the earth (the measured acceleration <9.81 N/kg)¹⁷.

However, there are some potential interactions between CIEDs and electromagnetic interference from MRI including the following:

- Gradient magnetic field-induced electrical currents that could lead to myocardial capture and potentially lead to atrial or ventricular arrhythmias
- RF energy pulses or rapidly changing magnetic field gradients might cause oversensing that can

lead to inappropriate inhibition of demand pacing and possibly asystole in a pacing-dependent patient, or induction of therapies such as inappropriate shocks in a patient with an implantable cardioverter defibrillator (ICD).

- RF fields can lead to electrodes heating and subsequent myocardial thermal injury at the lead-tissue interface resulting in detrimental changes in pacing properties (small changes in lead sensing, impedances, and capture thresholds immediately after the MRI)^{16,18,19}.
- Electrical reset: High-energy electromagnetic interference can lead rarely to electrical or power-on reset, a backup demand mode.
- The radiofrequency energy generated during MRI scanning creates a temporary decrease in battery voltage, which has typically been reported to resolve after several weeks¹⁸.

PATIENTS WITH NON-MR-CONDITIONAL CIEDS CAN SAFELY UNDERGO MRI SCANNING

The MagnaSafe Registry was designed to prospectively determine the risks associated with MRI among patients with non-MR-conditional CIEDs who undergo nonthoracic MRI at a magnetic field strength of 1.5 tesla¹⁸. MRI was performed in 1000 cases in which patients had a pacemaker and in 500 cases in which patients had an ICD. No deaths, lead failures, losses of capture, or ventricular arrhythmias occurred during MRI.

At the end of 2017, another study demonstrated the safety of thoracic and nonthoracic MRI examinations in patients with CIEDs¹⁹. No long-term clinically significant adverse events were reported among the 2103 thoracic and nonthoracic MRI examinations. In nine MRI examinations (0.4%; 95% confidence interval, 0.2 to 0.7), the patient's device reset to a backup mode. The most common notable change in device parameters (>50% change from baseline) immediately after MRI was a decrease in P-wave amplitude, which occurred in 1% of the patients.

PRACTICAL RECOMMENDATIONS ON MRI SCANNING OF PATIENTS WITH NON-MR-CONDITIONAL CIEDS

Before the MRI

A full understanding of the implanted hardware is mandatory. The MR conditionality for each of the

Key messages
<ul style="list-style-type: none"> As we are facing a growing need for MRI scans in the large population of patients with implanted cardiac devices, it is crucial to be informed about the actually low risk of performing MRI in this population.
Coronary and peripheral vascular stents
<ul style="list-style-type: none"> All coronary stents can safely undergo MRI scanning at 1.5 tesla and 3 tesla Patients with all commercially available coronary artery stents can undergo MRI immediately after implants Most endovascular aortic stent grafts are safe to undergo MRI after implantation Only the Zenith AAA endovascular graft (Cook) is considered unsafe for 1.5T MRI
Left atrial appendage closure devices
<ul style="list-style-type: none"> The Watchman left atrial appendage device (Atritech, Inc), can be safely scanned at 1.5 tesla or 3 tesla immediately after placement
Prosthetic valves and annuloplasty rings
<ul style="list-style-type: none"> All prosthetic heart valves and annuloplasty rings can safely undergo MRI scanning at 1.5 tesla and 3 tesla as soon as they were implanted Percutaneously implanted cardiac valves and devices (TAVR, MitraClip[®]) can safely undergo MRI scanning at 1.5 tesla and 3 tesla as soon as they were implanted Sternal wires do not produce any significant heating effects and their metallic artifacts are usually minor permitting optimal interpretation of the images
Cardiac implanted electronic devices
<p><i>General principles</i></p> <ul style="list-style-type: none"> A full understanding of the implanted hardware is mandatory. The MR conditionality for each of the components of the CIEDs components (pulse generator, leads) should be established. For up-to-date information on MR conditionality, one can consult company-specific databases or other web-based data sources such as www.mrisafety.com (manufacturer independent)¹⁶. The components of the CIEDs systems may be manufactured by different vendors. In such cases, even if each separate component is labeled MR-conditional, the combined hardware from various vendors does not meet the conditional labeling, and the system should be considered nonconditional. It is crucial to check the presence of abandoned or fractured leads, extenders or adaptors, lead remnants, surgically implanted epicardial leads, all of which would render the system nonconditional. If a medical history is not available and/or there is any suspicion of the presence of abandoned leads, a chest X-ray may be useful to clarify whether such hardware is present. <p><i>MR-conditional CIEDs</i></p> <ul style="list-style-type: none"> All MR-conditional CIEDs can undergo MRI scanning at 1.5 tesla as soon as they were implanted There is no risk of CIED generator or leads dislodgement due to magnetic field forces <p><i>Nonconditional CIEDs</i></p> <ul style="list-style-type: none"> Patients with nonconditional CIEDs can undergo MRI scanning at 1.5 tesla when MRI is determined to be the imaging examination of choice without an acceptable alternate modality for a particular patient or disease entity. When an MRI scan is performed in a patient with nonconditional CIED, special measures should be taken including: predefined institutional protocols, dedicated checklist, additional personnel with the skill to program the CIED and a physician who can establish temporary transvenous pacing. It is vital to emphasize the need for monitoring by qualified personnel, and the availability of an external pacing backup for such patients¹⁹. Implantable loop recorders (ILR) The currently available ILRs are classified as MR conditional by their manufacturers for use at both 1.5 tesla and 3 tesla field strengths¹⁶. It is recommended that prior to MRI scanning patients that the ILR be evaluated and that any desired recorded information be removed/ downloaded from the system and cleared after the MRI¹⁶.

Table 1. Selective recommendations regarding MRI scanning in patients with non-conditional cardiac implanted electronic devices (CIEDs) from the 2017 HRS expert consensus statement on magnetic resonance imaging and radiation exposure in patients with cardiovascular implantable electronic devices¹⁶. The reader is invited to refer to this document as it provides more exhaustive recommendations, which were not entirely covered by our review.

Recommendation	(Class of recommendation, Level of evidence)
It is reasonable for patients with an MR nonconditional CIED system to undergo MR imaging if there are no fractured, epicardial, or abandoned leads; the MRI is the best test for the condition; and there is an institutional protocol and a designated responsible MR physician and CIED physician.	(IIa, B)
It is reasonable to perform an MR scan immediately after implantation of a lead or generator of an MR nonconditional CIED system if clinically warranted.	(IIa, B)
For patients with an MR nonconditional CIED, it is reasonable to perform repeat MRI when required, without restriction regarding the minimum interval between imaging studies or the maximum number of studies performed.	(IIa, C)
It is reasonable to program patients with an MR nonconditional CRT device who are not pacing-dependent to an asynchronous pacing mode (VOO/DOO) with deactivation of advanced or adaptive features during the MRI examination, and with a pacing rate that avoids competitive pacing.	(IIA C)
For patients who are pacing-dependent with an MR nonconditional CIED, additional personnel are needed. Personnel with the skill to program the CIED should be in attendance during MR scanning, a physician who can establish temporary transvenous pacing should be immediately available on the premises, and a physician who can direct CIED programming should be immediately available on the premises, in accordance with reported clinical study protocols.	(I, B)

components of the CIEDs system (pulse generator, leads) should be established. Sometimes older non-conditional leads receive MR conditional approval in combination with certain devices after their initial market release¹⁶. For up-to-date information on MR conditionality, one can consult company-specific databases or other web-based data sources such as www.mrisafety.com (manufacturer independent)¹⁶.

The components of the CIEDs systems may be manufactured by different vendors. In such cases, even if each separate component is labeled MR-conditional, the combined hardware from various vendors does not meet the conditional labeling, and the system should be considered nonconditional.

It is crucial to check the presence of abandoned or fractured leads, extenders or adaptors, lead remnants, surgically implanted epicardial leads, all of which would render the system nonconditional. If a medical history is not available and/or there is any suspicion of the presence of abandoned leads, a chest X-ray may be useful to clarify whether such hardware is present¹⁶.

Before the scan, the electrophysiologist must manually switch the CIED to MR settings. However, some of the new devices have the capacity to activate automatically within the MRI magnet.

The non-MR-conditional CIEDs require special programming before the scan by the skilled personnel. The appropriate device programming will depend on the patient's characteristics, including pacing dependence, but its complexity is beyond the scope of this paper. The 2017 HRS expert consensus statement provides exhaustive recommendations on appropriate device programming in patients with CIEDs¹⁶. As a rule of thumb an asynchronous pacing mode will be chosen for pacing-dependent patients while an inhibited pacing mode will be used for patients without pacing dependence. Tachyarrhythmia functions should be disabled. Patients with a CRT device should be programmed to an asynchronous pacing mode with deactivation of advanced or adaptive features during the MRI examination, and with a pacing rate that avoids competitive pacing (IIA C)¹⁶.

During the MRI scan

ECG and pulse oximetry should be monitored during the MRI scan of patients with both MR conditional and non-conditional systems. Many of the MRI sequences induce significant electrical artifacts, which may render the ECG tracing uninterpretable. However, transcutaneous pulse oximetry is relatively unaffected during

MR sequences, and thus can confirm a change in pulse rate¹⁶.

A defibrillator/monitor (with external pacing function) and a manufacturer-specific device programming system should be immediately available¹⁶.

For patients who are pacing-dependent with an MR-nonconditional CIED, additional personnel are needed: personnel with the skill to program the CIED, a physician who can establish temporary transvenous pacing (I, B)¹⁶.

After the MRI

After completion of the MRI, full device interrogation should be performed and the devices must be reprogrammed to the original settings¹⁹.

Table I shows selective recommendations regarding MRI scanning in patients with non-MR-conditional CIEDs from the 2017 HRS expert consensus statement on magnetic resonance imaging and radiation exposure in patients with cardiovascular implantable electronic devices¹⁶. The reader is invited to refer to this document as it provides more exhaustive recommendations, which were not entirely covered by our review.

METALLIC ARTIFACTS DUE TO CIEDS

Beside the safety issues, CIEDs cause various types of metallic artifacts within MR images, such as image distortions or signal loss near the device. Artifacts cannot be predicted in advance, however most of the MRI scans in patients with a CIED yield interpretable images. (Figure 1C) The images acquisition can be further optimized by using wideband filtering algorithms¹⁶.

MRI SCANS OF PATIENTS WITH IMPLANTABLE LOOP RECORDERS (ILR)

The currently available ILRs are classified as MR conditional by their manufacturers for use at both 1.5 tesla and 3 tesla field strengths¹⁶. It is recommended that prior to MRI scanning patients that the ILR be evaluated and that any desired recorded information be removed/ downloaded from the system and cleared after the MRI¹⁶.

Conflict of interest: none declared.

List of abbreviations and acronyms

CIED - Cardiac Implantable Electronic Device (e.g. pacemaker, implanted cardiac defibrillator)
CMR - Cardiovascular Magnetic Resonance

CRT - Cardiac Resynchronisation Therapy
ICD - Implantable Cardioverter Defibrillator
ILR - Implantable Loop Recorder
MR - Magnetic Resonance
MRI - Magnetic Resonance Imaging
RF - Radiofrequency
SSFP - steady state free precession
TAVR - Transcatheter Aortic Valve Replacement

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