

Using a Magnet to Suspend or Deactivate Tachy Therapy in CRM ICDs and CRT-Ds

BACKGROUND INFORMATION

A magnet can be used to determine a Boston Scientific defibrillator's current therapy status via audible tones and to suspend or deactivate tachyarrhythmia therapy (depending on available device features and programming).

Note: Unlike standard pacemakers, magnet application does not affect bradycardia pacing in an ICD or CRT-D.

ICD: implantable cardioverter defibrillator

CRT-D: cardiac resynchronization therapy defibrillator

CRM PRODUCTS REFERENCED

All ICDs and CRT-Ds

CRM CONTACT INFORMATION

Technical Services - U.S.
1.800.CARDIAC (227.3422)
TechServices@guidant.com

Technical Services - Europe
+32 2 416 9357
eurtechservice@guidant.com

Technical Patient Support Services - U.S.
1.866.484.3268
TechServices@guidant.com

Boston Scientific Corporation acquired Guidant Corporation in April 2006. During the transition, both the Boston Scientific and/or Guidant names may appear on communication materials.

1. To determine whether magnet functions are enabled:

Position a doughnut magnet over the device and listen for tones (beeping or continuous).

- No tones implies that: 1) The magnet is not properly positioned over the device, or 2) the device is programmed to ignore a magnet, in which case a programmer is required, or 3) the device may not be manufactured by Boston Scientific.
- If tones are heard: The Enable Magnet Use feature is programmed On, meaning that magnet functions are enabled.

2. To suspend or deactivate tachyarrhythmia therapy if magnet functions are enabled:

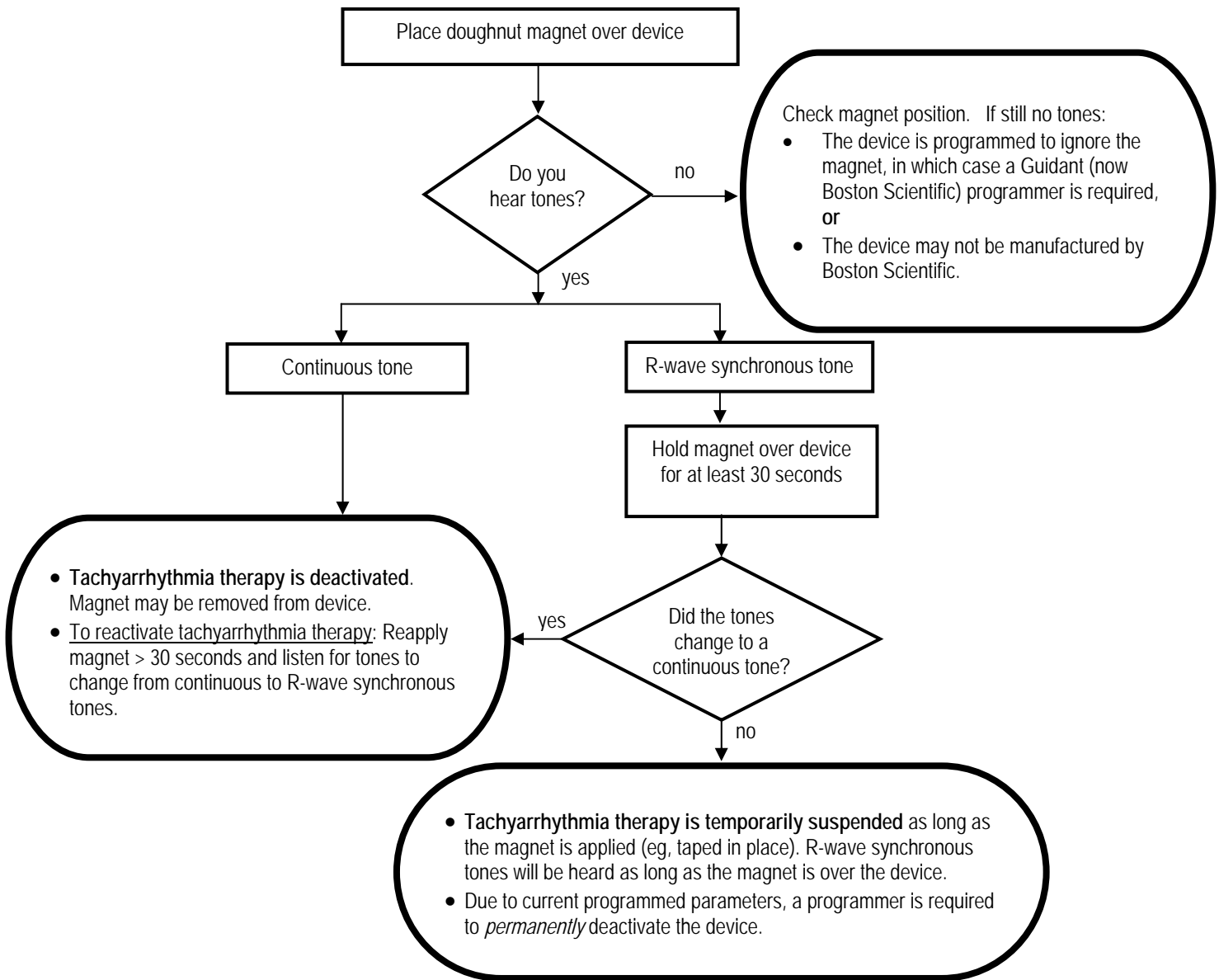
Depending on available device feature(s) and respective programming, this table describes how to suspend or deactivate tachyarrhythmia therapy using magnet application.

Beginning tones	After 30 seconds of magnet application
R-wave synchronous tones indicate tachyarrhythmia therapy is ON (Monitor+Therapy).	<p>Scenario 1: R-wave synchronous tones remain As long as the magnet is applied and R-wave synchronous tones are heard, tachyarrhythmia therapy is suspended. A programmer is required to permanently change the Tachy Mode.</p> <p>Scenario 2: R-wave synchronous tones switch to a continuous tone Tachyarrhythmia therapy is deactivated.</p>
Continuous tone indicates tachyarrhythmia therapy is OFF .	<p>Scenario 1: Continuous tone remains Tachyarrhythmia therapy remains deactivated. A programmer is required to permanently change the Tachy Mode.</p> <p>Scenario 2: Continuous tone switches to R-wave synchronous tones The Tachy Mode has been changed from OFF to ON (Monitor+Therapy), and the magnet can be removed. Tachyarrhythmia therapy is available.</p>

To reactivate tachyarrhythmia therapy: If the device therapy status was changed and you want to change the status again, remove the magnet for at least two seconds. Reapply the magnet for more than 30 seconds and listen for a change in tones, as described above. Contact your local representative or Technical Services with further questions.

Important Notice: Guidant (now Boston Scientific) issued a physician communication, dated June 23, 2005, regarding important safety information and corrective actions for specific CRT-Ds (CONTAK RENEWAL[®] 3 & 4, RENEWAL 3 & 4 AVT[®] and RENEWAL RF devices, Models H170/H173/H175/ H177/ H179/H190/ H195/H197/H199/M150/M155/ M157/M159/M170/M175/ M177/M179/H230/ H235/H239). As a part of this communication, Guidant recommended that physicians consider programming the Enable Magnet Use feature OFF in these devices. If the Enable Magnet Use feature is programmed OFF, suspension of tachyarrhythmia therapy can only be performed with a Guidant programmer. Contact your local representative or Technical Services for assistance and/or to determine if a specific device is included in the communication.

To suspend or deactivate tachy therapy in a Boston Scientific ICD or CRT-D using a magnet:



NOTES:

- Magnet application does not affect bradycardia pacing in an ICD or CRT-D.
- As described in the physician communication dated June 23, 2005, regarding specific CONTAK RENEWAL 3 & 4, RENEWAL 3 & 4 AVT and RENEWAL RF devices (Models H170/H173/H175/H177/H179/H190/H195/H197/H199/M150/M155/ M157/M159/ M170/M175/M177/M179/H230/H235/H239): **If tones persist following magnet removal, the patient's following physician should be contacted, or the patient should go to the hospital emergency room immediately.** Contact your local representative or Technical Services for assistance and/or to determine if a specific device is included in the communication.