

MEDICAL DEVICE FIELD NOTIFICATION

[Facility Name]
[Contact Name]
[Address]
[Address]
[Country]

Date:

Subject: ACIST CVi® Angiographic Injection System X-ray Synchronization Feature

Dear [Contact Name],

You are receiving this letter because you are a user of the ACIST CVi® Angiographic Injection System with X-ray synchronization feature with a Toshiba *Infinix™ - i cardiovascular* x-ray system.

It has been determined that when using the ACIST CVi® Angiographic Injection system to synchronize with the Toshiba *Infinix™ - i cardiovascular* x-ray system there is an injection scenario that may result in multiple injections of contrast media when one injection was intended. No other ACIST's Angiographic Injection Systems are affected by this notification.

We want to make you aware of this potential for your patients, especially those with a history of a previous reaction to contrast media. Although these scenarios have a very low probability of occurring, they may result in multiple contrast injections when only one injection was intended.

This situation can only occur when the injection system is being used for "Low Volume Injections" defined as less than 20 mLs total volume of contrast **and** flow rates of less than 10 mLs/second.

Based upon the above potential described injection scenario, you should not use the ACIST CVi® Angiographic Injection system to synchronize with the Toshiba *Infinix™ - i cardiovascular* x-ray system. You may continue to use the CVi® Angiographic Injection system and Toshiba *Infinix™ - i cardiovascular* x-ray system only in the non synchronized mode.

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We are working with Toshiba to resolve this issue. However, in the interim, we wanted to be sure that as our valued customer you are aware of this problem.

Please feel free to contact ACIST Europe B.V. at (+31) (0)43 3545030 or your local Sales Representative or Clinical Applications Specialist if you have any further questions regarding this matter.

ACIST Europe B.V.

Math van Sloun
Director of Operations & Customer Services

ACIST Europe B.V.

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