

August 28, 2017

To: Surgeons/ Hospitals

Subject: **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE- CORRECTION**

Reference: ZFA 2015-01

**Affected Product:** A.T.S® 2200TS and A.T.S® 4000TS

Zimmer Biomet Surgical is initiating a Medical Device Field Safety Notice (Correction) for the A.T.S® 2200TS and A.T.S® 4000TS to provide an on-device label and 3 pages of an updated Operator/Service Manual.

In a typical Operation Room (OR) setting, Zimmer Biomet originally recommended a minimum separation distance of 3.8 meters (m) between Radio Frequency (RF) communication equipment to mitigate the potential for electromagnetic interference and to achieve optimal performance of the tourniquet machines.

RF equipment consists of, but is not limited to, electrosurgical equipment, including any consoles, wiring, and pencil units. This distance recommendation originates from IEC 60601-1-2. As a result of customer feedback, additional internal testing was performed to see if this distance could be shortened, and it was determined that **1.0 meter provided adequate distance** to avoid interference. Notably, this newly established 1.0m separation distance is a *reduction* from the previously recommended 3.8m distance and therefore does not contradict or nullify previous revisions of product Operator/Service Manuals.

Zimmer Biomet is now communicating this newly shortened separation distance of 1.0m between RF communication equipment to mitigate the potential for electromagnetic interference and achieve optimal performance of the tourniquet machines. We are providing an on-device label and updated Operator/Service Manual pages to notify our customers of this newly established separation distance to allow for a smaller distance between equipment, suitable for smaller OR settings. The proper on-device label placement is to have the label placed directly above the IV Pole label on the side of the device, as shown below on Figure 1.

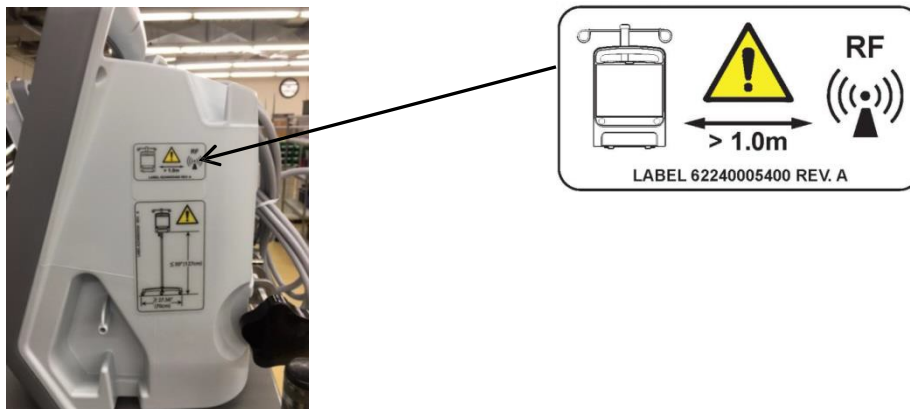


Figure 1. Proper on-device label placement

If the user does not comply with the recommended separation distance of either 3.8m or 1.0m and experiences an event, the likelihood of injury is 'Less than remote,' with the most likely outcome being a spontaneous inflation event resulting a delay in surgery of less than 30 minutes. Further, cuff inflation will trigger an inflation timer on the ATS which is set to a

default of 60 minutes. The ATS will monitor the elapsed time of inflation and alarm when the timer expires, mitigating an unnoticed spontaneous cuff inflation.

Our records indicate you may have received one or more of the affected products. The affected units were distributed between the dates of January 2014 and June 2017 and have serial numbers that begin with the prefixes shown in attachment 2.

#### **Risk Manager Responsibilities:**

1. Review the notification and ensure affected personnel are aware of the contents.
2. Confirm that you have received the on-device label and 3 pages of the updated Operator/Service Manual, included in this package.
3. **Place the label** on the device in the location specified in Figure 1 above.
4. **Replace the 3 pages of the Operator/Service Manual with the updated pages.**
5. Email a completed copy of the Attachment 1 form to [fieldaction.netherlands@zimmerbiomet.com](mailto:fieldaction.netherlands@zimmerbiomet.com) to confirm that you have placed the label in the specified location on the device and replaced the 3 pages of the Operator/Service Manual with the updated pages.
6. If after reviewing this notification you have further questions or concerns please contact your Zimmer Biomet Sales Representative.

#### **Other Information**

This voluntary medical device Field Safety Notice was reported to all relevant Competent Authorities and the related Notified Body as required under the applicable regulations for Medical Devices.

The undersigned confirms that this notice has been delivered to the appropriate Competent Authorities, as per MEDDEV 2.12-1 revision 8.

Please be aware that the names of user facilities notified are routinely provided to the Competent Authorities for audit purposes. Your urgent cooperation is needed.

Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing [SurgicalRegulatoryReporting@zimmerbiomet.com](mailto:SurgicalRegulatoryReporting@zimmerbiomet.com) or to your local Zimmer Biomet contact.

We would like to thank you for your cooperation in advance and regret any inconveniences caused by this medical device correction.

Sincerely,

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## ATTACHMENT 1 Certificate of Acknowledgement

By signing below, I acknowledge that the required actions have been taken in accordance with the Medical Device Correction Notice.

Hospital Facility     Surgeon

**Please confirm the following by checking the boxes:**

- I fixed the new label to the device(s) as instructed.
- I replaced 3 pages of the Operator/Service Manual with the current copies.

Printed Name: \_\_\_\_\_ Signature: \_\_\_\_\_

Title: \_\_\_\_\_ Telephone: (    ) \_\_\_\_\_ - \_\_\_\_\_ Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Facility Name: \_\_\_\_\_

Facility Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ ZIP: \_\_\_\_\_

**Note:** This form must be returned to Zimmer Biomet before this action can be considered closed for your account. It is important that you complete this form and email a copy to:

[fieldaction.netherlands@zimmerbiomet.com](mailto:fieldaction.netherlands@zimmerbiomet.com) or to your Zimmer Biomet representative.

## ATTACHMENT 2

### Affected Product List

Item Number	Serial Number prefix	Item Description
60220030101	2214	ATS2200TS WITH HOSES-ZH S
60220030103	2214-2216	ATS2200TS WITH HOSES-DA
60220030104	2214-2216	ATS2200TS WITH HOSES-NL
60220030105	2214-2216	ATS2200TS WITH HOSES-FI
60220030106	2214-2216	ATS2200TS WITH HOSES-FR
60220030107	2214-2216	ATS2200TS WITH HOSES-DE
60220030108	2214-2216	ATS2200TS WITH HOSES-IT
60220030110	2214-2216	ATS2200TS WITH HOSES-KO
60220030112	2214-2216	ATS2200TS WITH HOSES-ES
60220030113	2214-2216	ATS2200TS WITH HOSES-SV
60400030101	4014-4016	ATS4000TS WITH HOSES-ZH S
60400030103	4014-4016	ATS4000TS WITH HOSES-DA
60400030104	4014-4016	ATS4000TS WITH HOSES-NL
60400030105	4014-4016	ATS4000TS WITH HOSES-FI
60400030106	4014-4016	ATS4000TS WITH HOSES-FR
60400030107	4014-4016	ATS4000TS WITH HOSES-DE
60400030108	4014-4016	ATS4000TS WITH HOSES-IT
60400030109	4015-4016	ATS4000TS WITH HOSES-JA
60400030110	4014-4016	ATS4000TS WITH HOSES-KO
60400030111	4015	ATS4000TS WITH HOSES-PT
60400030112	4014-4016	ATS4000TS WITH HOSES-ES
60400030113	4014-4016	ATS4000TS WITH HOSES-SV