

URGENT – FIELD SAFETY NOTICE

Unexpected image mixture of Hitachi MRI Systems – AIRIS Vento with Software V2.1B /

**No. : FCO-MR-15-0001Z
Control No. : QAM15-013
Type of Action : Recall
Aug. 17, 2015**

Dear customer,

Hitachi Medical Corporation has identified a potential issue that an unexpected image has been mixed into the output series are created in AIRIS Vento with Software Version V2.1B.

When the issue occurs, one of image in scanned series is replaced by an analysis image. It looks like the following figures.

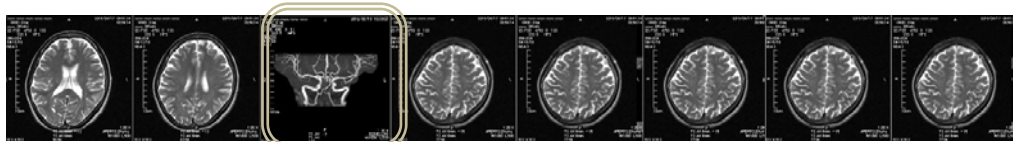


Fig. The example that MIP processing image was mixed into the third slice eight slices of scanned series.

Hitachi recommends that all users of the product follow the instruction or recommendation in this Safety Notice. And also, we carry out the software updates for the purpose of the improvement of function, stabilization and usability on your MRI system.

Details of Affected Devices :

Product Name	Software Version
AIRIS Vento	V2.1B, or V2.1B Service Pack1 to V2.1B Service Pack7

Description of problem :

In above software version, there is a rare possibility of mixing other images into the output series created by scanning or post-processing. This problem has no health hazard. If this problem occurs, it may cause misdiagnosis. This phenomenon may also occur when MPR and filter task are used, and the mixed image side will be lost.

Other software updates have the following contents that are for the purpose of the improvement of function, stabilization and usability.

- Improvement of input series behavior
- Improvement of the processing to apply clipping of MIP/VR
- Prevention of the measurement stop process in the Reconstruction board
- Improvement of MIP task
- Improvement of creating VR image
- Improvement for unusual close of examination windows
- Improvement of database maintenance

Action to be taken by the users:

No immediate actions by you are required, other than being aware of potential issue related to image mixture in the affected devices.

Actions planned by Hitachi:

In order to resolve the above problem, we will install service pack software to the system. It will be performed by our service engineer at your site and will contact you to arrange for this installation.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected device has been transferred.

Geographic Distribution :

AIRIS Vento: Japan, China, UAE, Yemen, Egypt, Lebanon, India, Nepal, Oman, Bangladesh, Vietnam, Malaysia, Myanmar, Philippines, Argentina, South Korea, Turkey, Kazakhstan, Ecuador, Columbia, Peru, Italy, Spain

Contact Information:

If you require any further clarification, please contact our local sales organization.

We confirm that this item has been reported to the responsible National Competent Authority.
We sincerely apologize for any inconvenience and thank you in advance for your cooperation.

Yours sincerely
HITACHI MEDICAL CORPORATION.

Rev.1.5

URGENT – FIELD SAFETY NOTICE

Unexpected image mixture of Hitachi MRI Systems AIRIS Vento LT with Software V2.1A

No. : FCO-MR-15-0001Z
Control No. : QAM15-014
Type of Action : Recall
Aug. 17, 2015

Dear customer,

Hitachi Medical Corporation has identified a potential issue that an unexpected image has been mixed into the output series are created in AIRIS Vento LT with Software Version V2.1A.

When the issue occurs, one of image in scanned series is replaced by an analysis image. It looks like the following figures.

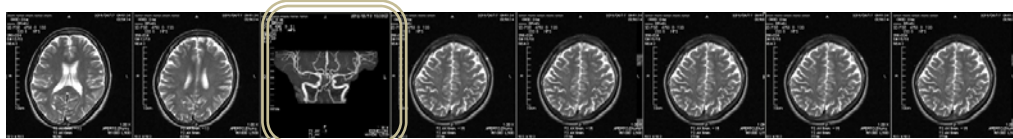


Fig. The example that MIP processing image was mixed into the third slice eight slices of scanned series.

Hitachi recommends that all users of the product follow the instruction or recommendation in this Safety Notice. And also, we carry out the software updates for the purpose of the improvement of function, stabilization and usability on your MRI system.

Details of Affected Devices :

Product Name	Software Version
AIRIS Vento LT	V2.1A, or V2.1A Service Pack1 to V2.1A Service Pack4

Description of problem :

In above software version, there is a rare possibility of mixing other images into the output series created by scanning or post-processing. This problem has no health hazard. If this problem occurs, it may cause misdiagnosis. This phenomenon may also occur when MPR and filter task are used, and the mixed image side will be lost.

Other software updates have the following contents that are for the purpose of the improvement of function, stabilization and usability.

- Improvement of the processing to apply clipping of MIP/VR
- Prevention of the measurement stop process in the Reconstruction board
- Improvement of MIP task
- Improvement of creating VR image
- Improvement for unusual close of examination windows
- Improvement of database maintenance

Action to be taken by the users:

No immediate actions by you are required, other than being aware of potential issue related to image mixture in the affected devices.

Actions planned by Hitachi:

In order to resolve the above problem, we will install service pack software to the system. It will be performed by our service engineer at your site and will contact you to arrange for this installation.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected device has been transferred.

Geographic Distribution :

AIRIS Vento LT: Japan, Nigeria, India, Singapore, South Korea, Turkey, Tajikistan, Peru, Italy, Germany, Spain, Russia, Ukraine, Serbia

Contact Information:

If you require any further clarification, please contact our local sales organization.

We confirm that this item has been reported to the responsible National Competent Authority.
We sincerely apologize for any inconvenience and thank you in advance for your cooperation.

Yours sincerely
HITACHI MEDICAL CORPORATION.

Rev.1.5

URGENT – FIELD SAFETY NOTICE

Unexpected image mixture of Hitachi MRI Systems Aperto Eterna LT with Software V2.1A

No. : FCO-MR-15-0001Z
Control No. : QAM15-016
Type of Action : Recall
Aug. 17, 2015

Dear customer,

Hitachi Medical Corporation has identified a potential issue that an unexpected image has been mixed into the output series are created in Aperto Eterna with Software Version V2.1A.

When the issue occurs, one of image in scanned series is replaced by an analysis image. It looks like the following figures.

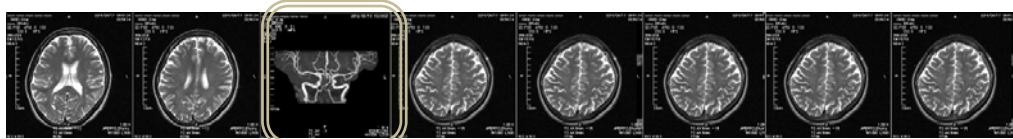


Fig. The example that MIP processing image was mixed into the third slice eight slices of scanned series.

Hitachi recommends that all users of the product follow the instruction or recommendation in this Safety Notice. And also, we carry out the software updates for the purpose of the improvement of function, stabilization and usability on your MRI system.

Details of Affected Devices :

Product Name	Software Version
Aperto Eterna	V2.1A, or V2.1A Service Pack1 to V2.1A Service Pack7

Description of problem :

In above software version, there is a rare possibility of mixing other images into the output series created by scanning or post-processing. This problem has no health hazard. If this problem occurs, it may cause misdiagnosis. This phenomenon may also occur when MPR and filter task are used, and the mixed image side will be lost.

Other software updates have the following contents that are for the purpose of the improvement of function, stabilization and usability.

- Improvement of the opacity processing of VR task
- Improvement of the display processing of VR task
- Displayed WW/WL after restoring ADC map
- Improvement of the processing to apply clipping of MIP/VR
- Prevention of the measurement stop process in the Reconstruction board
- Improvement of MIP task
- Improvement of creating VR image
- Improvement for unusual close of examination windows
- Improvement of database maintenance

Action to be taken by the users:

No immediate actions by you are required, other than being aware of potential issue related to image mixture in the affected devices.

Actions planned by Hitachi:

In order to resolve the above problem, we will install service pack software to the system. It will be performed by our service engineer at your site and will contact you to arrange for this installation.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected device has been transferred.

Geographic Distribution :

Aperto Eterna: Japan, Italy, Germany, Russia, Spain, Poland, Romania, Ukraine, Greece, China, UAE, Qatar, Saudi Arabia, Jordan, India, Singapore, Philippines, South Korea, Turkey

Contact Information:

If you require any further clarification, please contact our local sales organization.

We confirm that this item has been reported to the responsible National Competent Authority.
We sincerely apologize for any inconvenience and thank you in advance for your cooperation.

Yours sincerely
HITACHI MEDICAL CORPORATION.

Rev.1.5

URGENT – FIELD SAFETY NOTICE

Unexpected image mixture of Hitachi MRI Systems Aperto Lucent with Software V2.1A

No. : FCO-MR-15-0001Z
Control No. : QAM15-015
Type of Action : Recall
Aug. 17, 2015

Dear customer,

Hitachi Medical Corporation has identified a potential issue that an unexpected image has been mixed into the output series are created in Aperto Lucent with Software Version V2.1A.

When the issue occurs, one of image in scanned series is replaced by an analysis image. It looks like the following figures.

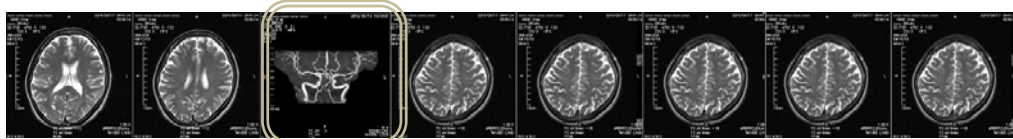


Fig. The example that MIP processing image was mixed into the third slice eight slices of scanned series.

Hitachi recommends that all users of the product follow the instruction or recommendation in this Safety Notice. And also, we carry out the software updates for the purpose of the improvement of function, stabilization and usability on your MRI system.

Details of Affected Devices :

Product Name	Software Version
Aperto Lucent	V2.1A, or V2.1A Service Pack1 to V2.1A Service Pack4

Description of problem :

In above software version, there is a rare possibility of mixing other images into the output series created by scanning or post-processing. This problem has no health hazard. If this problem occurs, it may cause misdiagnosis. This phenomenon may also occur when MPR and filter task are used, and the mixed image side will be lost.

Other software updates have the following contents that are for the purpose of the improvement of function, stabilization and usability.

- Improvement of GC control against GC output stop issue in the repetition scan of fMRI
- Improvement of the processing to apply clipping of MIP/VR
- Prevention of the measurement stop process in the Reconstruction board
- Improvement of MIP task
- Improvement of creating VR image
- Improvement for unusual close of examination windows
- Improvement of database maintenance

Action to be taken by the users:

No immediate actions by you are required, other than being aware of potential issue related to image mixture in the affected devices.

Actions planned by Hitachi:

In order to resolve the above problem, we will install service pack software to the system. It will be performed by our service engineer at your site and will contact you to arrange for this installation.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected device has been transferred.

Geographic Distribution :

Aperto Lucent: Japan, Italy, Spain, Germany, Bulgaria, Netherlands, Czech Republic, UAE, Egypt, India, Pakistan, Bangladesh, Philippines, Myanmar, South Korea, Turkey, Mauritius

Contact Information:

If you require any further clarification, please contact our local sales organization.

We confirm that this item has been reported to the responsible National Competent Authority.
We sincerely apologize for any inconvenience and thank you in advance for your cooperation.

Yours sincerely

HITACHI MEDICAL CORPORATION.

Rev.1.5

URGENT – FIELD SAFETY NOTICE

Unexpected image mixture of Hitachi MRI Systems – Echelon with Software V2.1B / Echelon with Software V2.2A

No. : FCO-MR-15-0001Z
Control No. : QAM15-017
Type of Action : Recall
Aug. 17, 2015

Dear customer,

Hitachi Medical Corporation has identified a potential issue that an unexpected image has been mixed into the output series are created in Echelon with Software Version 2.1B or Echelon with Software Version 2.2A. When the issue occurs, one of image in scanned series is replaced by an analysis image. It looks like the following figures.

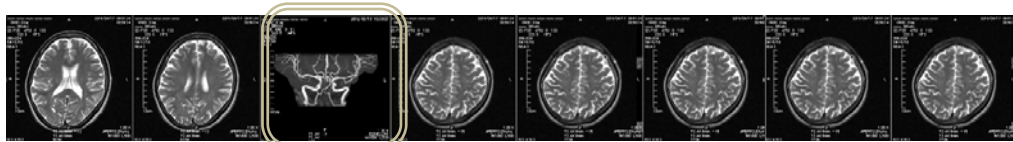


Fig. The example that MIP processing image was mixed into the third slice eight slices of scanned series.

Hitachi recommends that all users of the product follow the instruction or recommendation in this Safety Notice. And also, we carry out the software updates for the purpose of the improvement of function, stabilization and usability on your MRI system.

Details of Affected Devices :

Product Name	Software Version
Echelon	V2.1B, or V2.1B Service Pack1 to V2.1B Service Pack8
Echelon	V2.2A, or V2.2A Service Pack1 to V2.2A Service Pack7

Description of problem :

In above software version, there is a rare possibility of mixing other images into the output series created by scanning or post-processing. This problem has no health hazard. If this problem occurs, it may cause misdiagnosis. This phenomenon may also occur when MPR and filter task are used, and the mixed image side will be lost.

Other software updates have the following contents that are for the purpose of the improvement of function, stabilization and usability.

V2.1B and V2.2A

- Improvement of Database maintenance
- Improvement with consideration of the load of GPA
- Improvement of the processing to apply clipping of MIP/VR
- Improvement for unusual close of examination windows
- Improvement of shutdown process on MonitorMode.
- Improvement of MIP task
- Improvement of the property of the simple stitching image
- Improvement of creating VR image

V2.2A

- Improvement of image quality in FSE sequence with DE pulse

Action to be taken by the users:

No immediate actions by you are required, other than being aware of potential issue related to image mixture in the affected devices.

Actions planned by Hitachi:

In order to resolve the above problem, we will install service pack software to the system. It will be performed by our service engineer at your site and will contact you to arrange for this installation.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected device has been transferred.

Geographic Distribution :

Echelon V2.1B:	Japan, Italy, Germany, Russia, Ukraine, Indonesia, Singapore, Bangladesh, Vietnam, China, South Korea
Echelon V2.2A:	Japan, USA, Vietnam, China

Contact Information:

If you require any further clarification, please contact our local sales organization.

We confirm that this item has been reported to the responsible National Competent Authority.
We sincerely apologize for any inconvenience and thank you in advance for your cooperation.

Yours sincerely
HITACHI MEDICAL CORPORATION.

Rev.1.5

URGENT – FIELD SAFETY NOTICE

Unexpected image mixture of Hitachi MRI Systems OASIS with Software V2.1B

No. : FCO-MR-15-0001Z
Control No. : QAM15-012
Type of Action : Recall
Aug. 17, 2015

Dear customer,

Hitachi Medical Corporation has identified a potential issue that an unexpected image has been mixed into the output series are created in OASIS with Software Version 2.1B.

When the issue occurs, one of image in scanned series is replaced by an analysis image. It looks like the following figures.

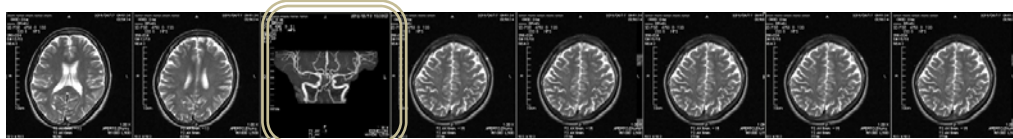


Fig. The example that MIP processing image was mixed into the third slice eight slices of scanned series.

Hitachi recommends that all users of the product follow the instruction or recommendation in this Safety Notice. And also, we carry out the software updates for the purpose of the improvement of function, stabilization and usability on your MRI system.

Details of Affected Devices :

Product Name	Software Version
OASIS	V2.1B, or V2.1B Service Pack1 to V2.1B Service Pack7

Description of problem :

In above software version, there is a rare possibility of mixing other images into the output series created by scanning or post-processing. This problem has no health hazard. If this problem occurs, it may cause misdiagnosis. This phenomenon may also occur when MPR and filter task are used, and the mixed image side will be lost.

Other software updates have the following contents that are for the purpose of the improvement of function, stabilization and usability.

- Improvement of GC control against GC output stop issue in the repetition scan of fMRI
- Improvement in system startup reliability
- Improvement of shutdown process on MonitorMode.
- Improvement of the processing to apply clipping of MIP/VR
- Improvement of database maintenance

Action to be taken by the users:

No immediate actions by you are required, other than being aware of potential issue related to image mixture in the affected devices.

Actions planned by Hitachi:

In order to resolve the above problem, we will install service pack software to the system. It will be performed by our service engineer at your site and will contact you to arrange for this installation.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected device has been transferred.

Geographic Distribution :

OASIS: Japan, USA, United Kingdom, Germany, Spain, Russia, Italy, Netherland

Contact Information:

If you require any further clarification, please contact our local sales organization.

We confirm that this item has been reported to the responsible National Competent Authority.
We sincerely apologize for any inconvenience and thank you in advance for your cooperation.

Yours sincerely

HITACHI MEDICAL CORPORATION.

Rev.1.5