

## **Customer Safety Notification**

### **To the users of the G-scan Brio Magnetic Resonance System**

Dear Healthcare Professional,

Esaote SpA, in consultation with Health Sciences Authority (HSA), is issuing the letter to provide you with additional safety instructions for the safe use of the Magnetic Resonance System G-scan Brio (Part Number 101002000). If not addressed, the issue described below could lead to an unsafe exam condition.

#### **Description of the problem**

A potential weakness of a part of the patient table has been determined. This weakness may lead to a fracture of the patient table within the foot rest and the left bed rail. In particular this may happen if a heavy weigh patient applies a strong dynamic stress to that part of the table to access or descend to the bed

Breaking of the bed is detectable. If breaking occurs, the patient table must not be used any longer.

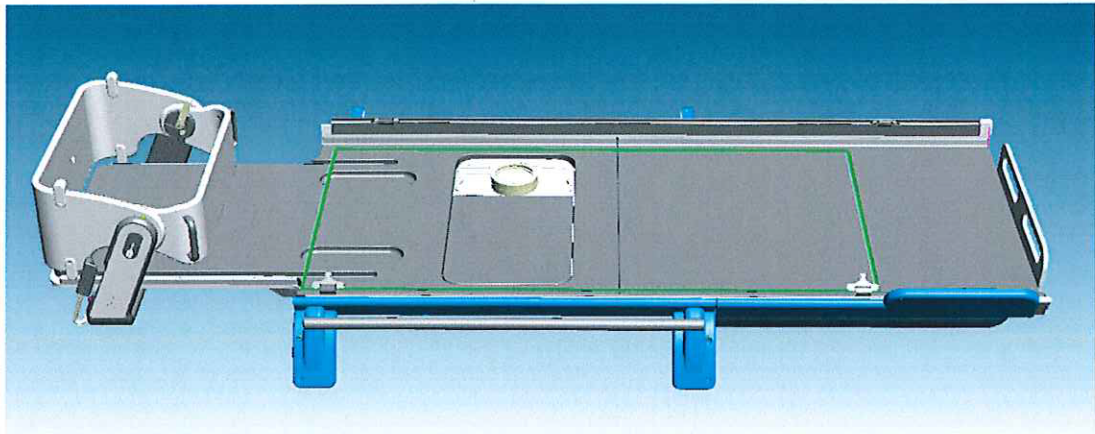
It is important to note that to-date no patient injury has been reported with regards to this issue.

#### **Advice on action to be taken by the users**

To use the device to perform the exam on the following anatomical regions:

- Shoulder
- Hip
- Lumbar Spine
- Thoracic Spine
- Cervical Spine
- Temporomandibular joint

the patient must access to the table and descend from it inside the area delimited by the green rectangle shown in the figure below.



Performing a weight bearing examination of the following anatomical regions:

- Shoulder
- Cervical Spine
- Temporomandibular joint

the patient must access to the table and the descend from it with the patient table in vertical position.

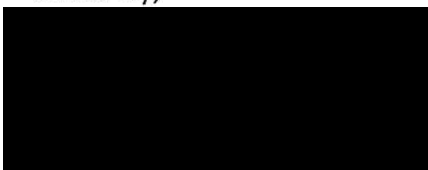
The possible completion of the examination in supine position must be executed only after that the patient gets off from the table and the table is rotated in horizontal position; the patient can access the table again, inside the area delimited by the green rectangle, and must be positioned with the "head on left".

A revision of the instructions for use dedicated to the correct use of the area delimited by the green rectangle during the patient access to the table and the descent from it will be sent soon.

Please distribute this information to all appropriate personnel in your organization organization and forward this information to all parties that may use the G-scan Brio system, including others to whom you may have transferred the product, in which case you are kindly requested to inform Esaote about the new owner.

We sincerely regret any inconvenience this issue may cause in your daily operations.

Sincerely,



Head of Quality Assurance