



**Lasersystems for
patient alignment**

Zeppelinstrasse 23
21337 Lüneburg, Germany
Phone: +49 (0)4131 951166
Fax: +49 (0)4131 951196

www.lap-laser.com

16.10.2013

LAP GmbH Laser Applikationen, Zeppelinstr. 23, 21337 Lüneburg

Urgent field safety notice Corrective action concerning the operating instructions of CARINAsim + CARINAiso

Dear Customer:

According to our information, you are currently using one of our CARINAsim / CARINAiso systems. In the course of our continuing quality control, we have found two safety-relevant errors in the operating instructions (CARINAsim MAN-1236 Rev. 2 / CARINAiso MAN-1237 Rev. 2) that we want to inform you about. We have not learned of any incidents in the field that are connected with these errors.

Systems concerned:

1. CARINAsim and CARINAiso with DORADO 1 or DORADO 3 laser systems and the "relative marking" workflow in which the patient is repositioned for a second marking session.
2. CARINAsim systems that use files in the LAP file format and CARINAiso systems

Description of issues:

Issue 1:

In the manual's description of the "relative marking" workflow involving two sessions (CARINAsim chapter 8.6.2.3 and 8.6.2.4, CARINAiso chapter 8.6.2.3), there is no clear instruction to the fact that the table must be "zeroised" at the reference positions of the lasers after the patient is positioned and **before** the patient is marked. This applies only to the DORADO 1 and DORADO 3 laser systems. In this context, "zeroising" the table means that the displayed table position is set to "0".

The values displayed by CARINAsim / CARINAiso in the prompt to adjust the table are only valid if the table was previously zeroised at the reference position. If this step is neglected, the patient may be marked incorrectly and consequently positioned and irradiated incorrectly at the linear accelerator.

Systems concerned:

CARINAsim and CARINAiso with DORADO 1 or DORADO 3 laser systems and the "relative marking" workflow in which the patient is repositioned for a second marking session

Issue 2:

In the descriptions of the “absolute marking” and “relative marking” workflow the step “entering the table deviation” is wrong respectively not included (CARINAiso manual Rev. 2 p 78 and p. 83, CARINAsim manual Rev. 2 p. 87 und p. 92).

- If a laser reference position other than LAP zero is used to position the patient, this position must be defined as zero position in the planning system. This definition is based on the adhesive, X-ray-proof markers and is required for the subsequent exchange of data via the LAP file format to ensure that all planned positions reference this zero position. In this case, the user must **not** enter a table deviation – contrary to the instructions in the manual of CARINAsim p. 87– as the deviation has already been factored into the planning by means of the defined zero position.

Systems concerned:

CARINAsim with LAP file format and workflow "relative marking".

- If, however, LAP zero is used as reference position and this position is not defined as zero position in the planning system, then the table deviation must be entered in CARINAsim / CARINAiso. This step is not described in the manual.

Systems concerned:

CARINAsim with LAP file format in the "absolute marking" workflow

CARINAiso with LAP file format or DICOM in the "absolute marking" and “relative marking” workflow

Whether there is a table deviation for a data set that must be considered depends on the table used, the patient's weight etc. and can be determined by means of the CT scans based on the adhesive, X-ray-proof markers positioned at LAP zero.

If the table deviation is not taken into account as required by the selected process, the patient may be marked incorrectly and consequently positioned and irradiated incorrectly at the linear accelerator.

Please remember that only files in the LAP file format and DICOM files may be transmitted to CARINAsim / CARINAiso.

Measures to be taken by the user:

- Replace the user manual (CARINAsim MAN-1236 Rev. 2 / CARINAiso MAN-1237 Rev. 2) with the manual that has been corrected by LAP (CARINAsim MAN-1236 Rev. 3 / CARINAiso MAN-1237 Rev. 3). You will find relevant changes in chapter 8.6.
- Review your current operational steps with regard to the aforementioned issues
- Validate your entire operating sequence. Remember that the operating sequence must be revalidated after every relevant change to the system configuration (e.g. changes to the setup of CARINAsim / CARINAiso, modifications at the CT, changed settings in the therapy planning system etc.).
- You will receive a modified software version (1.2.0.0) in January 2014, which holds an information message to set the table to zero (issue 1). Update your current version to version 1.2.0.0.



Forwarding the information in this document:

Please ensure that all users of the aforementioned products and any other relevant persons receive this Field Safety Corrective Notice. If you have passed the products on to third parties, please forward a copy of this document or notify the contact person below.

Please keep this document for reference at least until the corrective action has been completed.

The German Federal Institute for Drugs and Medical Devices has received a copy of this "Field Safety Corrective Notice".

Contact:

If you have any further questions, please address them to [REDACTED] (Service Center).

Phone: +49 4131 9511339

E-mail: [REDACTED]

Fax: +49 4131 951196

You can reach [REDACTED] Monday through Friday from 8:00 to 16:00.

We apologise for any inconvenience caused and thank you for your understanding in this matter.

With best regards

[REDACTED]
Safety officer
LAP GmbH Laser Applikationen



Please return this confirmation letter by mail or fax to:

LAP GmbH

██████████
Zeppelinstraße 23
21337 Lüneburg

E-Mail: ██████████

Fax: +49 4131 951196

Confirmation

- We hereby confirm that we have received and understood the corrective notice for the operating instructions for CARINAsim and CARINAiso
- The relevant manuals (CARINAsim MAN-1236 Rev. 2 / CARINAiso MAN-1237 Rev. 2) have been replaced by the revised version (CARINAsim MAN-1236 Rev. 3 / CARINAsim MAN-1237 Rev. 3)

Name: _____

Organization: _____

Address: _____

Contact Nr: _____

Date, Signature