

Gebrüder MARTIN GmbH & Co. KG
Product management Operating lights /
camera systems / DVE

March 2013

Sven Zehnder
Director of Product Management
Operations Management
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Important safety information

Inspection and modification of our KLS Martin double-TFT monitor support arm system

Dear Customer and Operator,

Within the scope of our product surveillance, and in consequence of an incident, it is our duty to inform you of the risks that may occur when handling the affected products of Gebrüder Martin GmbH & Co. KG.

According to our knowledge the two M6 retaining screws between the crossbeam and receptacle pin can dissolve, with the result that the crossbeam and the monitors sink down by around 10 cm (falling off, is prevented by the connecting cables).

Advice on safety and conduct and measures for modification:

To exclude unnecessary risks, Gebrüder Martin must call upon you to inspect all double-TFT-monitor support arm systems supplied to you. For this purpose please inspect the units supplied to you by Gebrüder Martin.

An overview of the potentially affected products supplied to you can be found in Appendix 1.

We kindly ask you to perform the corresponding modification (safety measure) on the affected screws, following the enclosed rework instruction (Appendix 2).

Please ensure that your clients (concerns only specialist trade partners) or your operator and the staff responsible for the issue are notified of this safety information and the instructions it contains.

We apologize for the inconvenience that we have caused you. The described measures are of a preventative nature with the purpose of ensuring the safety of patients and operators.

Please keep this information at least until the measure has been finalized.

We are, of course, pleased to be at your disposal at all times, should queries arise.

Kind Regards

Gebrüder Martin GmbH & Co. KG,
a company of the KLS Martin Group



Michael Martin

Marketing Executive Board
Management

Safety Officer pursuant to the German Medical Devices Act (MPG)

p.p.



Sven Zehnder

Director of Product Management Operations

Fax reply
Appendix 1:
Appendix 2:

**FAX reply to +49 7461 706-190
to Gebrüder Martin GmbH & Co. KG**

V.-ID:Client:

We herewith confirm:

- 1) receipt of the letter "Important safety information" from the company Gebrüder Martin from March 2013 with appendices 1 and 2.
- 2) that the situation and risk have been understood.
- 3a) as specialist trade partner:
to forward in the short term the content of the letter "Important safety information" with appendices 1 and 2 to the end customer / operator, with the objective of inspection and modification of the supplied and affected double-TFT-monitor support arm systems
- 3b) as user/operator:
to carry out in the short term an inspection and modification of the supplied and affected double-TFT-monitor support arm systems in accordance with appendix 2

Place, date:

Name / Position of the signatory:

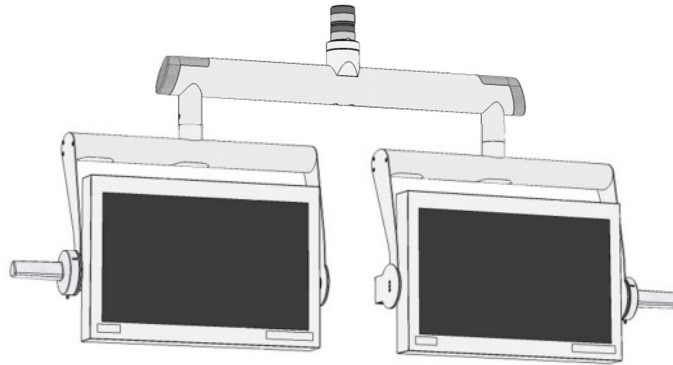
Company / stamp and signature:

Attachment 1a / Anlage 1a

Aufstellung Artikel TFT DUO Comfortbrücke / article TFT DUO comfort bridge

Material	Materialkurztext	Materialkurztext	UMDNS	UMDNS-CODE Bezeichnung	GMDN	GMDN-Code Bezeichnung	CND	CND-Code Bezeichnung	CE
84-300-14-04	ARM KOMFORT FUER 21' DUO-TFT, Ø 24MM	SUSP.ARM COMFORT F. 21" DUO-TFT, Ø 24MM	16-603	Video-Monitor	36612	Image display monitor, colour	Z11900802	MONITOR VISUAL. BIOIMAGING	MP1 CE
84-300-23-04	ARM ECO. 23' TFT-DUO, OBEN, Ø 1X24MM	ARM ECO. 23" TFT-DUO, ON TOP, Ø 1X24MM	16-603	Video-Monitor	36612	Image display monitor, colour	Z11900802	MONITOR VISUAL. BIOIMAGING	MP1 CE
89-417-21-04	TFT DUO KOMFORT BRUECKE F. ONDASPACE	TFT DUO COMFORT BRIDGE FOR ONDASPACE	16-603	Video-Monitor	36612	Image display monitor, colour	Z11900802	MONITOR VISUAL. BIOIMAGING	MP1 CE
89-417-22-04	TFT DUO ECO BRUECKE FUER ONDASPACE	TFT DUO ECO BRIDGE FOR ONDASPACE	16-603	Video-Monitor	36612	Image display monitor, colour	Z11900802	MONITOR VISUAL. BIOIMAGING	MP1 CE
89-417-24-04	TFT DUO KOMFORT BRUECKE 26' AN OSP	TFT DUO COMFORT BRIDGE 26" FOR OSP	16-603	Video-Monitor	36612	Image display monitor, colour	Z11900802	MONITOR VISUAL. BIOIMAGING	MP1 CE
92-860-69-04	TFT-MONITOR-DUO-AUFHAENGUNG,OHNE MONITOR	TFT-MONITOR-DUO-AUFHAENGUNG,OHNE MONITOR	16-603	Video-Monitor	36612	Image display monitor, colour	Z11900802	MONITOR VISUAL. BIOIMAGING	MP1 CE
92-862-05-04	DUO-TFT-BRUECKE 26 ZOLL	DUO-TFT-BRUECKE 26 ZOLL	16-603	Video-Monitor	36612	Image display monitor, colour	Z11900802	MONITOR VISUAL. BIOIMAGING	MP1 CE

Instructions for rework on the TFT-DUO carrier system



1. Identification of the affected TFT-DUO crossbeam

TFT-DUO crossbeam affected version:

→ CAUTION Crossbeam requires rectification!
Follow the advice on the following pages.

Connecting port, long, 2-
component

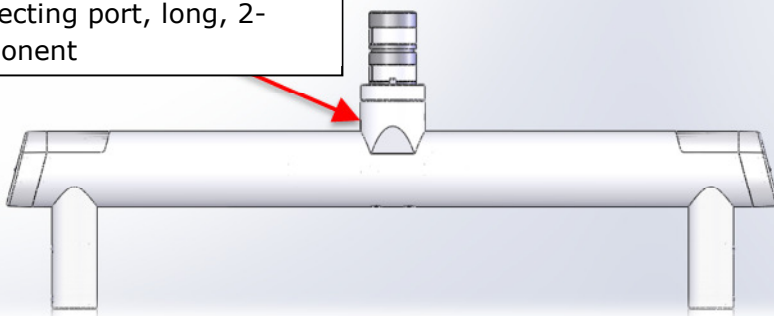
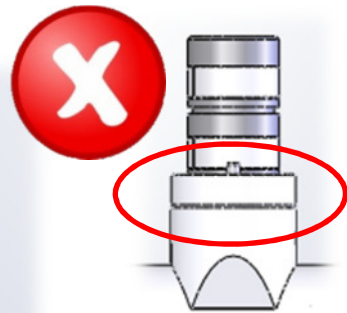


Image 1



TFT-DUO crossbeam non-affected new version:

→ no rectification necessary!

Connecting port, short, 1-
component

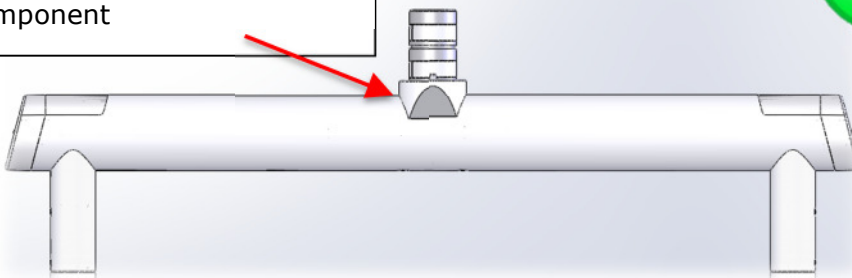
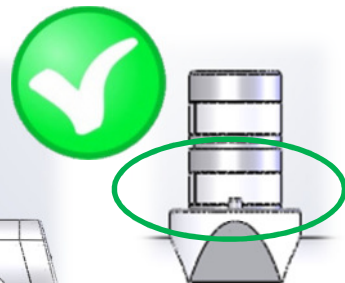
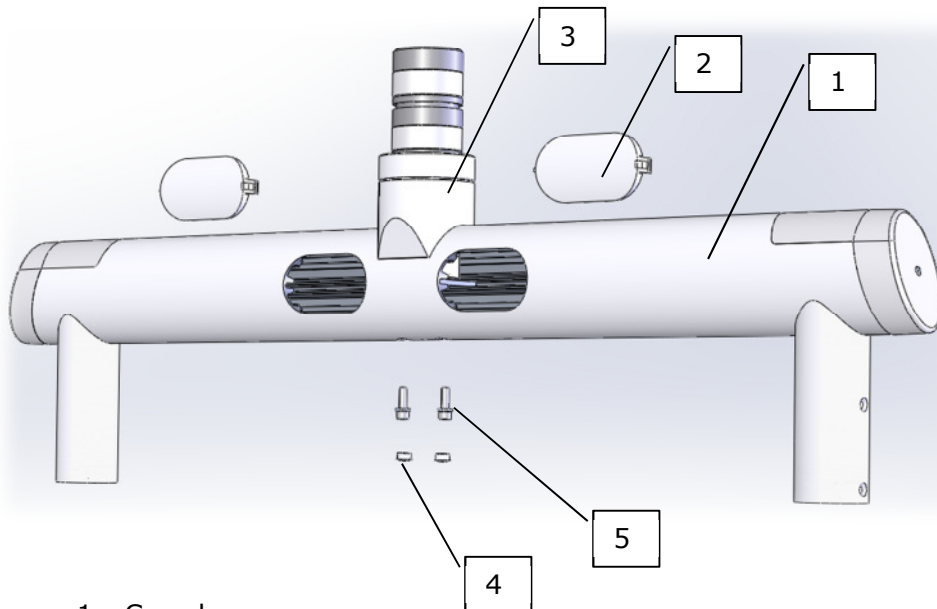


Image 2



2. Description of all components:



1. Crossbeam
2. Cover
3. Connecting port
4. Plastic cap
5. Screw DIN912 M6x20 with washer and serrated lock washer

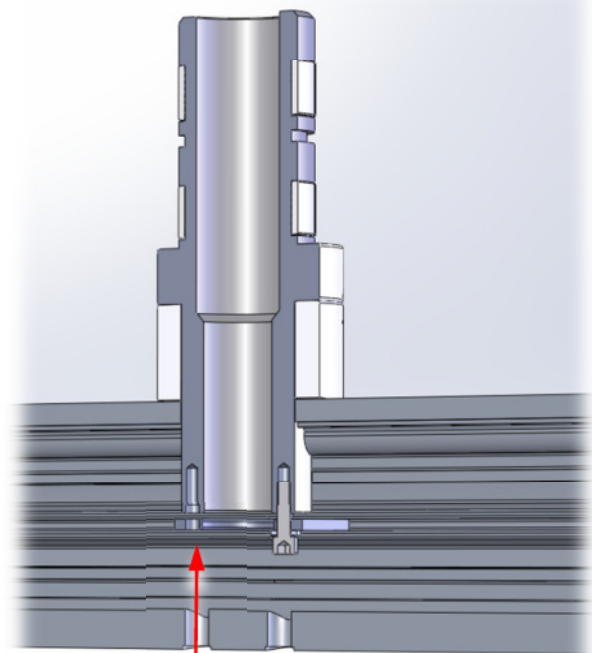
3. Required tools and accessories

1. Small screwdriver for removing the covering caps
2. Inbus socket spanner for M6 DIN912 → spanner size 5
3. Torque wrench 10Nm
4. Liquid screw retaining compound type: "high-strength" e.g. Loctite 270

4. Directions for modification:

1. Remove covering caps 2
2. Remove covering caps 4
3. If necessary, push the laid cable a little to the side in order to access the screw with the socket spanner.
4. CAUTION: Never unfasten both screws at the same time.
5. First tighten screw 1 and in doing so secure the crossbeam.
6. Afterward unfasten screw 2, apply screw retaining compound, screw in screw and tighten 10Nm.
7. Unscrew screw 1, apply screw retaining compound to thread, screw in screw. Tighten screw 10Nm.
8. Affix covering caps 4 and 2
9. The rework is now finished.

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Apply screw retaining compound to thread.
Tighten with torque wrench 10Nm

Gebrüder Martin GmbH & Co. KG

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