

CH-3110 Münsingen, March 27, 2017

FIELD SAFETY NOTICE

Please forward this information to all your relevant staff and potential users of the Schaerer arcus 501, 601 and 701 Surgical tables.

PREVENTIVE CORRECTIVE ACTION CONCERNING SCHAERER ARCUS 501-701 SURGICAL TABLES

Dear Valued Customer

With this letter, we inform you about a potential issue concerning the hydraulic system of the Schaerer Arcus 501-701 surgical tables. Every Schaerer arcus 501, 601 or 701 surgical table is equipped with a large hydraulic valve block (see figure 1) which is mounted on the upper part of the column of the table (see figure 2). This valve block is designed to control and coordinate the various hydraulic movements of the surgical table. The potential defect of the valve block may result in slow movements or complete stop of the table.

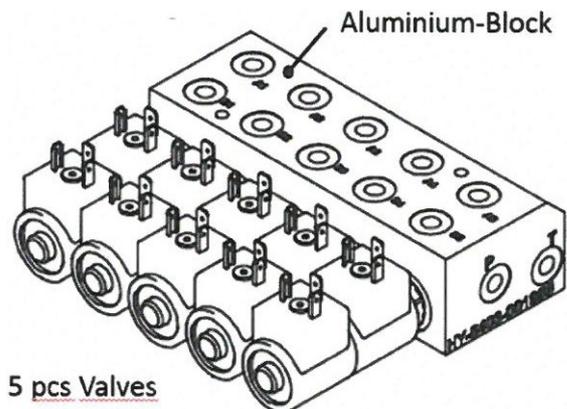


Figure 1: Large Valve Block arcus

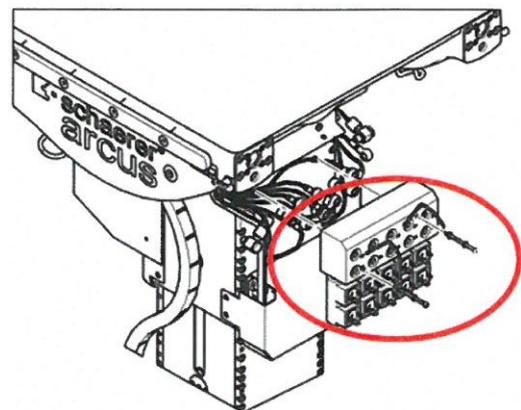


Figure 2: Position of Valveblock inside the table at the top end of the column

Description of the problem and possible cause

During routine quality control procedures of the large valve block at the supplier's factory, inaccurate, out of spec drill holes were discovered. The drill holes serve as positioner for the hydraulic valves, which control the flow of hydraulic oil through the hydraulic system and thus the movements of the components of the table, such as height column, lateral tilt, Trendelenburg, seat section and leg section.

The inaccurate drill holes may result in damage of the valves, which may result in malfunction of the table. Damaged valve sealing may result an uncontrolled flow of hydraulic oil which may result in a loss of pressure in the hydraulic tubes and subsequently the cylinders are not controlled correctly

anymore. This may result in a complete blocking of the surgical table in the current position, which may result in a critical situation for the patient. The patient would need to be taken off the surgical table and repositioned on a back up table.

Identification of the affected Schaerer arcus 501, 601 and 701 tables

Batch number tracking of the large valve block and serial number tracking of the Schaerer arcus surgical tables show that the following tables in the following countries are potentially equipped with a potentially faulty large valve block:

Country	Serial Nr.	Country	Serial Nr.
Brazil	AR-4815	Lebanon	AR-4838
	AR-4816	Mexico	AR-4831
	AR-4817		AR-4832
	AR-4818		AR-4833
	AR-4819		AR-4834
	AR-4820	Morocco	AR-4824
	AR-4829		AR-4825
	AR-4842		AR-4826
AR-4845	AR-4827		
Costa Rica	AR-4845	Netherlands	AR-4840
Egypt	AR-4801	Qatar	AR-4821
	AR-4802		AR-4822
	AR-4803		AR-4843
	AR-4804		AR-4844
	AR-4805	Switzerland	AR-4828
	AR-4806		AR-4839
	AR-4807		AR-4841
	AR-4808		AR-4846
	AR-4809		AR-4847
	AR-4810		AR-4848
	AR-4811	AR-4854	
	AR-4812	Taipei	AR-4030
	AR-4813	Thailand	AR-4835
Greece	AR-4795	Tunesia	AR-4836
India	AR-4800	UAE	AR-4797
Ireland	AR-4823	United Kingdoms	AR-4837
Korea	AR-4852		

Which measures are to be taken by the user and the authorized Schaerer distributor?

Our sales records show that one or more Schaerer arcus 501, 601 or 701 surgical table was shipped to your organization or customers in your country.

Every customer will be contacted by the Schaerer Medical Customer Service and the affected large valve bleeks will be replaced/ exchanged. Please keep this FSCA Information on file at least until the measures taken are fully completed.

Until now, no incident has been reported to Schaerer where a patient or user was threatened. No surgical procedure was negatively affected or had to be stopped so far. Schaerer therefore does not see a necessity to take the potentially affected tables out of service.

However, we strongly recommend to observe the movements of the table carefully and abnormally slow movements should be reported to the Schaerer Customer Service immediately.

Which measures have to be taken by authorized Schaerer distributors?

Please ensure that all customers and persons and functions within your organization who use the above mentioned arcus 501, 601 and 701 surgical tables receive and understand this field safety notice.

Schaerer Medical will provide replacement parts and instructions for the replacement. Please contact the customers according to the serial numbers and ensure the replacement of the large valve bleeks in due course.

If you have passed the product on to third parties, please forward a copy of this notice or inform Schaerer Medical contacts persons.

Please keep this notice at least until the corrective measure has been performed.

Contact Person

For further inquiries, please do not hesitate to contact Schaerer Medical AG or your local Schaerer representative.

For quality and regulatory inquiries, please contact Mr. Michael Meyer, mm@schaerermedical.ch

For service and logistic support, please contact Customer Service: service@schaerermedical.ch

This is a voluntary corrective action. The appropriate authorities have received a copy of this field safety notice.

We apologize for any inconvenience, however, safety comes first and therefore, consider this action as a preventive measure to increase the safety of our products.

Sincerely yours,

Schaerer Medical AG

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Michael Meyer
Head of Quality Management
and Regulatory Affairs