

14842-DOC APM, Urgent Field Safety Notice Customer

1. Purpose of the Documents

The purpose of this document is to inform all users of the RoboticScope about a potential patient risk.

2. Potential Patient Risk

It has been shown that the combination of a high patient position (situs approx. 110 cm above floor level) and extremely flat viewing angles of the camera head potentially increases the risk of touching the patient with the elbow of the robotic arm. Distinct caution must be taken when using the ArcView with Initial Positions 1, 2 or 7.



Warning: If not handled carefully, there is a potential risk of touching the patient with the elbow of the robotic arm (see Figure 1 and Figure 2).

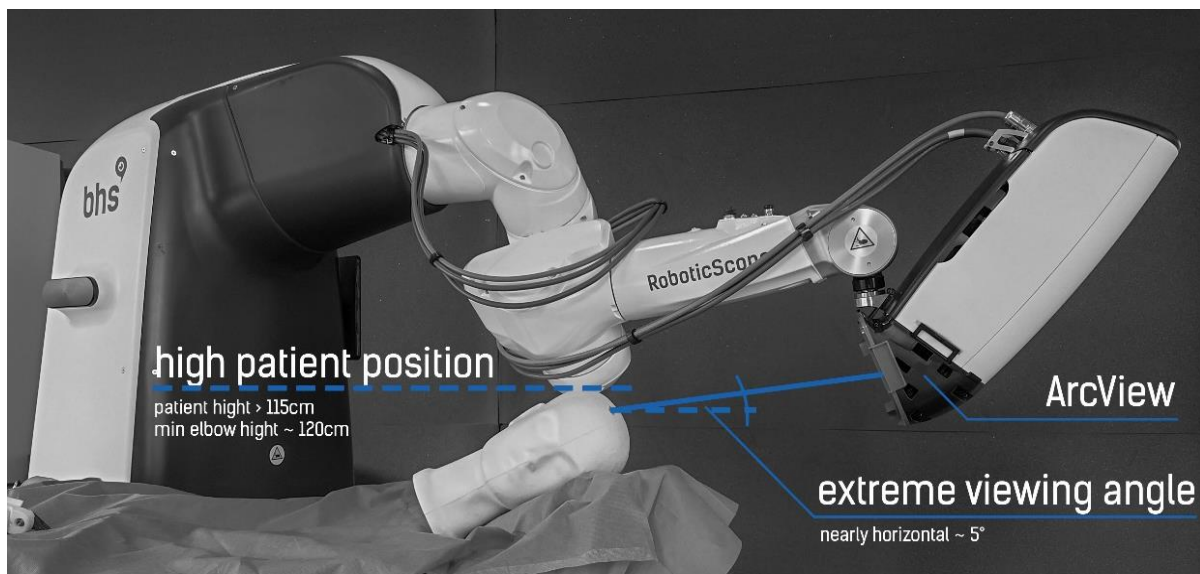


Figure 1 - Elbow extremely close to patient head (Initial Position 2)



Figure 2 - Front view - Elbow extremely close to patient head (Initial Position 2)

3. How to avoid this situation

The risk of touching the patient with the elbow of the robotic arm can be minimized by a patient positioning below 110 cm.



Note/Tip: The handlebars of the RoboticScope® are approx. 100 cm above ground. Use them as a reference for adjusting the height of the patient (see Figure 3).

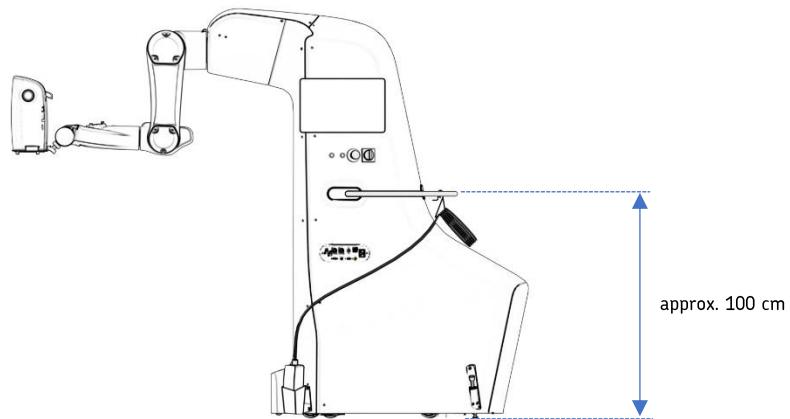


Figure 3 - RoboticScope handlebars for height reference

In cases where the combination of flat angles (with or without ArcView) and a high patient position is indispensable we highly recommend using Initial Position 5 and avoid Initial Positions 1, 2 and 7. As described in the 12863-DOC IFU, RoboticScope Instructions for Use in Section 4.2.1 it is always mandatory to “Make sure that there is enough space around the device when the robotic arm is moving. The robotic arm must not be moved while you are performing surgical activities.”

4. Customer Reply and Confirmation

Fields with an * are required.

4.1. Customer Details

Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

4.2. Customer action undertaken on behalf of Healthcare Organisation

<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A		
<input type="checkbox"/>	I performed all actions requested by the FSN.	Customer to complete or enter N/A		
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A		
<input type="checkbox"/>	I have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		N/A	Comments:	
<input type="checkbox"/>	I have destroyed affected devices - enter number destroyed and date complete.	Qty:	Lot/Serial Number:	
		Qty	Lot/Serial Number:	
		N/A	Comments:	
<input type="checkbox"/>	No affected devices are available for return/ destruction	Customer to complete or enter N/A		
<input type="checkbox"/>	Other Action (Define):			
<input type="checkbox"/>	I do not have any affected devices.	Customer to complete or enter N/A		
<input type="checkbox"/>	I have a query please contact me (e.g. need for replacement of the product).			
Print Name*				
Signature*				
Date*				

4.3. Return acknowledgement to sender

Email	support@bhs-technologies.com
Address	BHS Technologies GmbH Langer Weg 11 6020 Innsbruck, Austria
Web	bhs-technologies.com
Deadline for returning the customer reply form	31.01.2022

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

14873-DOC APM, Urgent Field Safety Notice Distributor

1. Purpose of the Documents

The purpose of this document is to inform all users of the RoboticScope about a potential patient risk.

2. Potential Patient Risk

It has been shown that the combination of a high patient position (situated approx. 110 cm above floor level) and extremely flat viewing angles of the camera head potentially increases the risk of touching the patient with the elbow of the robotic arm. Distinct caution must be taken when using the ArcView with Initial Positions 1, 2 or 7.



Warning: If not handled carefully, there is a potential risk of touching the patient with the elbow of the robotic arm (see Figure 1 and Figure 2).

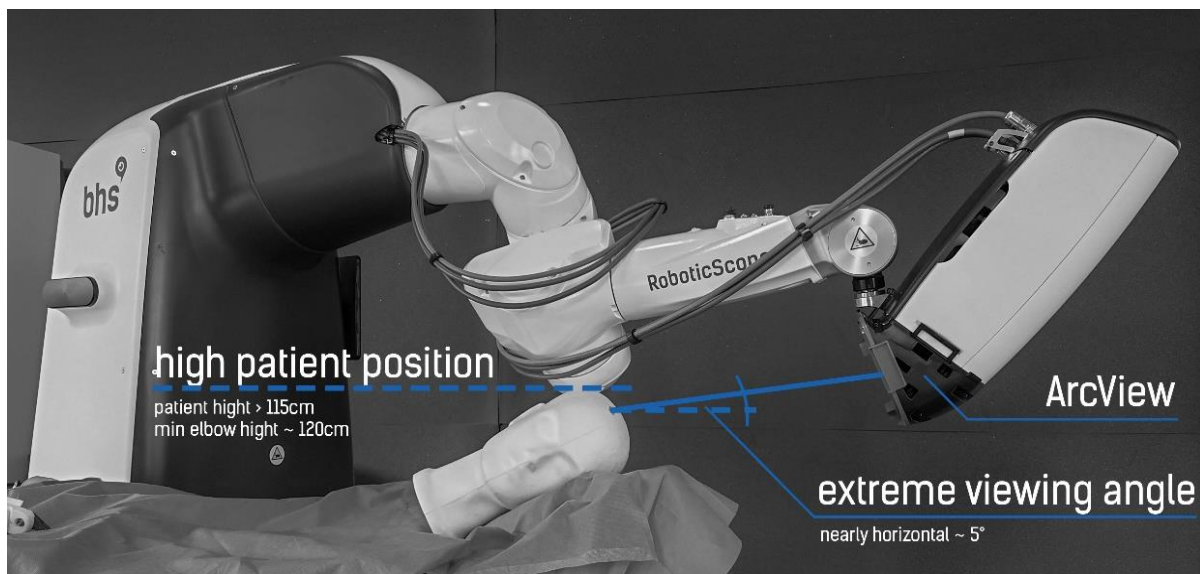


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Note/Tip: The handlebars of the RoboticScope® are approx. 100 cm above ground. Use them as a reference for adjusting the height of the patient (see Figure 3).

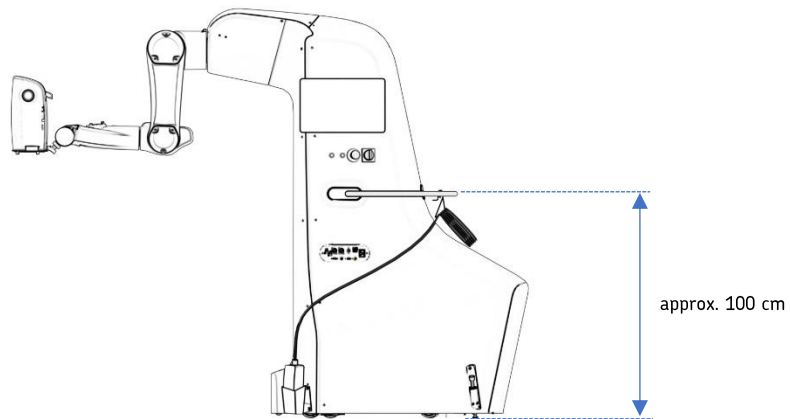


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4. Distributor Reply and Confirmation

Fields with an * are required.

4.1. Distributor Details

Company Name*	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

4.2. Distributors/Importers (tick all that apply)

Fields with an * are required.

<input type="checkbox"/>	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	Distributor/Importer to complete or enter N/A		
<input type="checkbox"/>	I have checked my stock and quarantined inventory	Distributor/Importer to enter quantity and date		
<input type="checkbox"/>	I have identified customers that received or may have received this device			
<input type="checkbox"/>	I have attached customer list			
<input type="checkbox"/>	I have informed the identified customers of this FSN	Date of communication:		
<input type="checkbox"/>	I have received confirmation of reply from all identified customers			
<input type="checkbox"/>	I have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		N/A	Comments:	
<input type="checkbox"/>	I have destroyed affected devices - enter number destroyed and date complete.	Qty:	Lot/Serial Number:	
		Qty:	Lot/Serial Number:	
		N/A	Comments:	
<input type="checkbox"/>	Neither I nor any of my customers has any affected devices in inventory			
Print Name*				
Signature*				
Date *				

4.3. Return acknowledgement to sender

Email	support@bhs-technologies.com
Address	BHS Technologies GmbH Langer Weg 11 6020 Innsbruck, Austria
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