Advisory Note

Urgent Field Safety Notice

Title / Subject:	Field Safety Notice: BWS-L Yoke 2019
Document ID:	FSN-002
Target Audience:	Customers of BWS-L (including integrated with other systems)
Date of Issue:	29 July 2019
Commercial name of the affected product:	Body-Weight Support Light (BWS-L)
FSCA ID:	FSCA-002
Type of action:	- Halt usage of the medical device for specific type of patients until correction has been completed.
Approval:	Approval by Motek Executive Management Board.

Arno Stienen, Director

1 Purpose

The safety of your patients and staff is most important to us. We are contacting you today to maintain the high safety status of your medical device. We are asking for your support in the implementation of this Field Safety Notice, which concerns the use of the Body-Weight Support Light (BWS-L) that is part of your setup with either the C-Mill, N-Mill, the GRAIL or M-Gait.

This Field Safety Notice (FSN-002) invalidates and replaces an earlier Field Safety Notice (FSN-001) you might have received regarding the BWS-L.

! Please pay special attention if you use the BWS-L with patients with cranial fractures, with patients after recent craniotomy/craniectomy or comparable surgery, or with patients whose skull has a lower than normal structural stability for any other reason (from here on defined as 'patients with cranial deficiencies'). For these patients, *stop* using the BWS-L immediately --- *even if your system has been recently cleared after the visual inspection process of the earlier Field Safety Notice (FSN-001)* --- and follow the steps described below.

2 Description Medical Device and model designation

Body-Weight Support Light (BWS-L). The BWS-L can be used stand-alone, or can be provided together with another medical product, such as the C-Mill, N-Mill, the GRAIL or M-Gait.

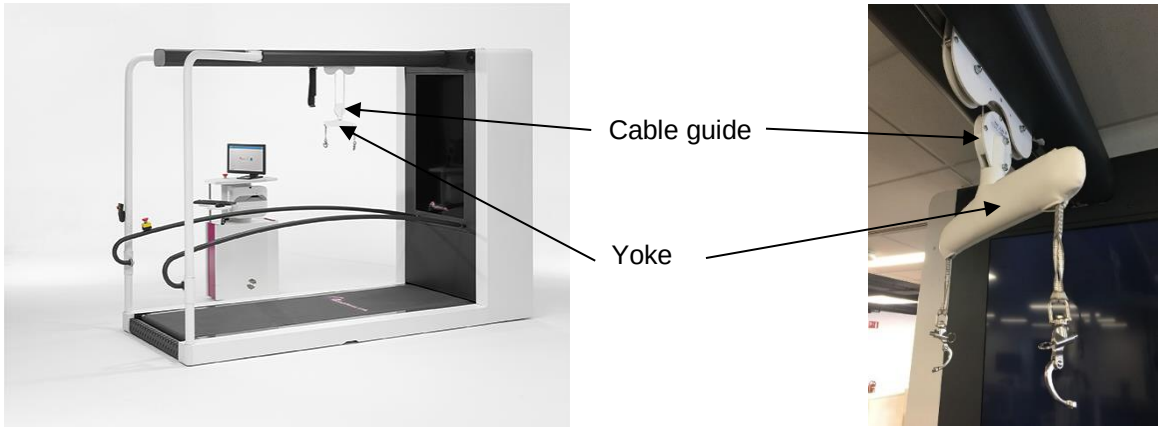
2.1 Serial Numbers or other identification of devices concerned

We identified that your setup is potentially affected from this issue. You can identify the affected system by the serial number. The Serial Number of the medical device can be found on the device label.

Please see the appendix for an overview of all potentially affected devices.

3 Reason for issuing Field Safety Notice

We have discovered a potential manufacturing deviation of the yoke of the BWS-L that in rare occasions may result in the yoke detaching from the cable guide.



3.1 Description of Potential Hazardous Situation

In our risk-analysis, we have determined that if the padded yoke detaches during treatment, the patient will be caught in the safety harness that is connected to the system via a separate safety belt. In such a situation, the padded yoke may make contact with the head of patient and can potentially cause significant discomfort. However, please pay special attention if you use the BWS-L with patients with cranial deficiencies.

If you are treating patients with cranial deficiencies, stop using the BWS-L for these patients immediately, as the hazardous situation of the detachment of the yoke might result in serious or even deadly harm.

Based on our risk-analysis, you can keep on using the systems for patients other than those with cranial deficiencies.

4 Action to be taken

4.1 Dissemination of this Field Safety Notice

You will have to share this notice with all those within your organisation who need to be aware.

4.2 Confirmation

In your country, this field safety action is being coordinated with the respective national competent authority, and we are therefore required, without exception, to demonstrate the receipt of this information. We therefore ask you to confirm your receipt of this Field Safety Notice.

Please reply by email to *support@motekforcelink.com* and attach a completed and signed copy of the Advisory Notice Confirmation (last page of this notice) within 10 business days of receipt of this notice. Please allow us to follow up with you should we not receive your confirmation.

4.3 Corrective and/or Preventive Action

In all cases, if you are treating patients with cranial deficiencies, stop using the BWS-L for these patients immediately.

There are three possible options for the next step. *Please select one* that is most appropriate for your institute and send us this information via the Advisory Notice Confirmation.

A. You request a Yoke Replacement Kit to be send to you directly, such that a skilled person from your institute can do the replacement under our remote supervision. The replacement consists of removing two easily accessible bolts, replacing the affected components, and reinserting two new bolts. Verification will require you to take two pictures of the reinserted bolts, and confirmation by Motek Medical BV is needed before you can use the system again for patients with cranial deficiencies. Detailed instructions will be provided. The difficulty level of this replacement is low (similar to assembling IKEA furniture) and the entire procedure should only take 15 minutes using basic tools.

B. Or, you *do not* treat patients with cranial deficiencies and you *do not* want to order a Yoke Replacement Kit. If so, you can continue using the BWS-L as normal and can consider this Field Safety Notice to be *not applicable* for your usage (even though we still need you to send in the Advisory Notice Confirmation). In the next service visit, we will replace the yoke to further minimize any risk.

C. Or, you *do* treat patients with cranial deficiencies, but you *do not* want to order a Yoke Replacement Kit. In this case, you can keep on using the system for patients other than those with cranial deficiencies. Before treatment of patients with cranial deficiencies can

recommence, the yoke will need to be replaced first in the next scheduled service visit. Unfortunately, due to the limited availability of service engineers, this options is likely to take longer than option A above.

4.4 Contact reference person

In case of any questions with respect to this Field Safety Notice you are advised to contact Motek Medical BV (support@motekforcelink.com) or your local representative.

Please send a completed and signed copy of the Advisory Notice Confirmation on this page via email to support@motekforcelink.com within 5 business days of receipt of this notice.

Advisory Notice Confirmation

Customer acknowledges that:

☐ Information, notices and directives in this notice has been understood, and communicated and implemented in Customer's Organization.

Of the options given in section 4.3 (“Corrective and/or Preventive Action”), Customer selects:

☐ A) Stop using the BWS-L and the Yoke Replacement Kit that can be installed by a skilled employee of Customer.

☐ B) Customer *does not* treat patients with cranial fractures, with patients after recent craniotomy/craniectomy or comparable surgery, or with patients whose skull has a lower than normal structural stability for any other reason. Customer can continue to use the BWS-L as normal. The Yoke will be replaced at the next service visit.

☐ C) Customer *does* treat patients with cranial fractures, with patients after recent craniotomy/craniectomy or comparable surgery, or with patients whose skull has a lower than normal structural stability for any other reason. *Customer stops usage of the BWS-L for these patients with reduced structural stability of the skull*, but Customer can continue to use the BWS-L under normal instructions for other types of patients. The Yoke will be replaced at the next service visit.

Customer

Name institute:

Address:

City: **Postal code:**

Country:

Phone: **E-mail:**

Contact person: **Function:**

Signature : **Date:**

Device Name (please encircle): **C-Mill | N-Mill | GRAIL | M-Gait | BWS-L**

Device S/N (see label on device):

5 Appendix – Serial number overview

Since the BWS-L can be used stand-alone, or can be provided together with another medical product, such as the C-Mill, N-Mill, the GRAIL or M-Gait, your device may have multiple serial numbers. Please find an overview of the potential affected devices in the tables below.

BWS serial numbers				
RB011-0091	RB011-0073	RB011-0054	RB011-0033	RB011-00-0016
RB011-0088	RB011-0072	RB011-0053	RB011-0032	RB011-00-0015
RB011-0084	RB011-0071	RB011-0051	RB011-0031	RB011-00-0011
RB011-0083	RB011-0068	RB011-0050	RB011-0029	RB011-00-0010
RB011-0082	RB011-0067	RB011-0049	RB011-0028	RB011-00-0007
RB011-0080	RB011-0066	RB011-0048	RB011-0027	RB011-00-0006
RB011-0070	RB011-0065	RB011-0047	RB011-0026	RB011-00-0005
RB011-0079	RB011-0060	RB011-0046	RB011-0024	RB011-00-0003
RB011-0078	RB011-0059	RB011-0041	RB011-0023	RB011-00-0001
RB011-0076	RB011-0058	RB011-0036	RB011-0022	AS9924-00-0001
RB011-0075	RB011-0057	RB011-0035	RB011-00-0021	AS9924-03-0002
RB011-0074	RB011-0056	RB011-0034	RB011-00-0017	

C-Mill, N-Mill, the GRAIL or M-Gait serial numbers				
SY011-0009	SY012-0062	SY012-0045	SY012-0023	TM003-0116
SY012-0080	SY012-0061	SY012-0044	SY012-0022	TM014-0070
SY012-0076	SY012-0060	SY012-0042	SY012-0020	TM014-0072
SY012-0072	SY012-0059	SY012-0041	SY012-0018	TM014-05-0056
SY012-0071	SY012-0058	SY012-0040	SY012-0014	TM9903-00-0059
SY012-0070	SY012-0055	SY012-0039	SY020-0008	TM9914-04-0028
SY012-0068	SY012-0054	SY012-0038	SY020-0012	14-05-0055
SY012-0067	SY012-0050	SY012-0036	SY020-0014	
SY012-0066	SY012-0048	SY012-0029	TM001-0022	
SY012-0065	SY012-0047	SY012-0026	TM003-00-0087	
SY012-0063	SY012-0046	SY012-0025	TM003-00-0110	