

Date: 29/09/2022

Urgent Field Safety Notice
Talk Pad 8, 10, 13

For Attention of*: All Talk Pad customers/Users

Contact details of local representative (name, e-mail, telephone, address etc.)
Stephen Hyde, Smartbox AT, email: steve.hyde@thinksmartbox.com , 0044 (0)1684 578868

Urgent Field Safety Notice (FSN)

Talk Pad 8, 10, 13

Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)* Talk Pad Communication Aid - Class 1 Medical device
1.	2. Commercial name(s) Talk Pad 8, 10, and 13
1.	3. Unique Device Identifier(s) (UDI-DI) 5060446901236, 5060446901243, 5060446901250
1.	4. Primary clinical purpose of device(s)* A communication aid comprising Apple iPad, Grid for iPad software and service package. It is supplied with documentation and accessories to support use.
1.	5. Device Model/Catalogue/part number(s)* TP08A, TP08B, TP10A, TP10B, TP13A, TP13B
1.	6. Software version N/A
1.	7. Affected serial, lot number range or date range All Talk Pad devices sold from October 2020 to Aug 2022
1.	8. Associated devices TP08, TP10, TP13 - Case only

2 Reason for Field Safety Corrective Action (FSCA)*	
2	1. Description of the product problem* There is a potential for the screws holding the stand to the Talk Pad case to come loose. The screws are small self-tapping screws so could be swallowed
2	2. Hazard giving rise to the FSCA* Potential choking hazard if screws become loose.
2	3. Probability of problem arising <1% of devices have reported this issue
2	4. Predicted risk to patient/users The risk of choking is defined as minimal based on the number of reported cases vs total sales. Users who have been identified as being at higher risk of choking are young children and those more likely to put things in their mouths.
2	5. Further information to help characterise the problem N/A
2	6. Background on Issue The issue was raised by a small number of Smartbox customers who had used their device over a period of time. A more recent case was reported to the MHRA who have followed up with Smartbox to discuss this Field Safety Notification.
2	7. Other information relevant to FSCA This field may only contain additional information that is deemed necessary by the manufacturer to supplement information relevant to the FSCA.

3. Type of Action to mitigate the risk*	
3. 1. Action To Be Taken by the User*	<p> <input checked="" type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input checked="" type="checkbox"/> Return Device** (see below) <input type="checkbox"/> Destroy Device </p> <p> <input type="checkbox"/> On-site device modification/inspection </p> <p> <input type="checkbox"/> Follow patient management recommendations </p> <p> <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) </p> <p> <input type="checkbox"/> Other <input type="checkbox"/> None </p> <p> **If you are concerned or have experienced this issue, please contact Smartbox to arrange a repair so we can collect your Talk Pad to update the hinge fixings. </p> <p> Repairs - thinksmartbox.com - no charge will apply </p>
3. 2. By when should the action be completed?	ASAP
3. Is follow-up of patients or review of patients' previous results recommended?	<p>Yes</p> <p>This issue can occur to Talk Pads over time, so a periodic review of the device to assess whether the screws have loosened is advised.</p>
3. 3. Is customer Reply Required? *	Yes
3. 4. Action Being Taken by the Manufacturer	<p> <input type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input type="checkbox"/> IFU or labelling change <input checked="" type="checkbox"/> Other <input type="checkbox"/> None </p> <p> Option for update to Talk Pad case via Smartbox repairs process. Repairs - thinksmartbox.com </p>

Update solution:



We will replace your existing screws with a domed nut and screw solution. The domed nut has a smooth finish acting as a protective barrier as well as concealing the screw threads. The screws will be countersunk to provide a flush finish on the underside of the hinge.

The repairs process will involve collection of your device by courier on a day to suit you, the update of the fixings, and the return of your device to you ASAP by courier. As part of our repairs process, we will provide you with all the information you need to prepare your device for repair however if you have any questions, please call us on 01684 578868.

3	5. By when should the action be completed?	Please review the need to update the hinge fixings ASAP	
3.	6. Is the FSN required to be communicated to the patient /lay user?	No	
3	7. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?		
	Yes	Not appended to this FSN	

4. General Information*		
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	3. For Updated FSN, key new information as follows: N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to: N/A	
4	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Smartbox Assistive Technology Ltd
	b. Address	Ysobel House, Enigma Commercial Centre Sandys Road, Malvern, WR14 1JJ,
	c. Website address	www.thinksmartbox.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Yes, MHRA	
4.	9. List of attachments/appendices:	N/A
4.	10. Name/Signature	Stephen Hyde Head of Product Quality
Transmission of this Field Safety Notice		
<p>This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.*</p>		

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.