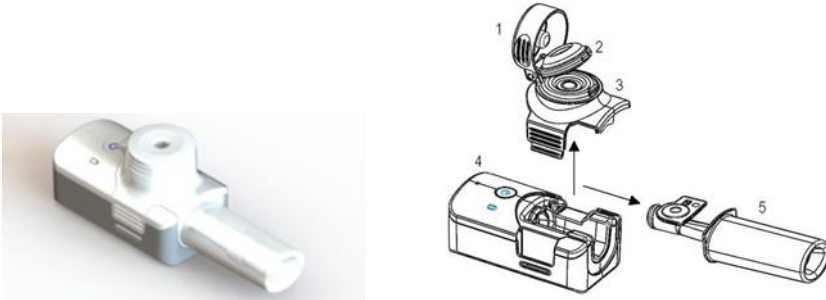






**Follow-up Field Safety Notice (FSN)**  
**Breelib™**  
**Resolution of previous report of inaccurate dosing**

<b>1. Information on Applicable Devices*</b>	
1	1. Device Type(s)*
.	<p>The device concerned is the Breelib™ Nebuliser Unit, which is part of the Breelib Inhalation System (Breelib™). Breelib™ is a small handheld nebuliser system. It consists of a Breelib Nebuliser Unit (1 = cap, 2 = dosing system and 3 = nebuliser body), a base unit (4) and a mouthpiece (5).</p> 
1	2. Commercial name(s)
.	Breelib™
1	3. Unique Device Identifier(s) (UDI-DI)
.	05056143201625 (Starter Pack, EU1); 05056143201632 (Monthly Pack EU); 05056143201663 (Starter Pack, EU2); 05056143201649 (Starter Pack, LAT1); 05056143201656 (Monthly Pack LAT1). GMDN 35457
1	4. Primary clinical purpose of device(s)*
.	<p>The Breelib™ Inhalation System is a breath activated vibrating mesh nebuliser with passive flow and active volume control. It is designed to be used for oral inhalation of VENTAVIS® nebuliser solution (iloprost) indicated for the treatment of adult patients with primary pulmonary hypertension, classified as NYHA functional class III, to improve exercise capacity and symptoms. The Breelib™ Inhalation System is intended to be used by adult, conscious, cooperative patients, who can control their breathing. The patient may use the device outside a professional healthcare facility (home use environment). It is intended for single patient use only.</p>
1	5. Device Model/Catalogue/part number(s)*
.	<p>The Breelib™ Nebuliser Unit is contained in the Breelib™ Starter Pack model numbers: 08CD1042 (EU1), 08CD1050 (EU2), 08CD1051 (TUR) and 08CD1046 (LATAM). The Breelib™ Nebuliser Unit is also contained within the Monthly Pack (see 1.8. for model numbers).</p>
1	6. Affected serial or lot number range
.	<p>Breelib™ Nebuliser Units with serial numbers greater than 333055419000041 (Starter Pack) and 333055577000193 (Monthly Pack) are NOT subject to the previously reported Field Safety Notice.</p>
1	7. Associated devices
.	<p>The Breelib™ Monthly Pack model numbers: 08CD1043 (EU1&amp;2), 08CD1052, 08CD1047.</p>

<b>2 Reason for Field Safety Corrective Action (FSCA)*</b>	
2	<b>1. Description of the product problem*</b>
.	All Breelib™ Nebuliser Units on the market have passed the current product release testing and comply with the manufacturers' product specifications which includes delivered dose. In January 2020 it was reported that during quality control testing the manufacturer identified a level of variability of the dose delivered by the Nebuliser Heads. The variability indicated potential for the device to deliver an occasional under-dose or overdose of the drug product VENTAVIS®. An investigation identified the root cause for this variability to be the doser component. A new improved tool for manufacture of the doser component is now in use.
2	<b>2. Hazard giving rise to the FSCA*</b>
.	The previously reported hazard has now been resolved.
2	<b>3. Probability of problem arising</b>
.	Not applicable – the problem has been resolved.
2	<b>4. Predicted risk to patient/users</b>
.	No increased safety risk has been identified. A review of safety data from launch in April 2017 to the middle of September 2020 has not identified any safety signal. There has been no increase in reporting since publication of the initial Field Safety Notice in January 2020.
2	<b>5. Further information to help characterise the problem</b>
.	Not applicable.
2	<b>6. Background on Issue</b>
.	Refer to original Field Safety Notice (FSN-VEC-001-2019).
2	<b>7. Other information relevant to FSCA</b>
.	Not applicable.

<b>3. Type of Action to mitigate the risk*</b>		
<b>3.</b>	<b>1. Action To Be Taken by the User*</b>  <input type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device  <input type="checkbox"/> On-site device modification/inspection  <input type="checkbox"/> Follow patient management recommendations  <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU)  <input type="checkbox"/> Other <input checked="" type="checkbox"/> None  <p>* There have been no incident reports involving potential overdose or under-dose due to the nebuliser (refer to section 2.4). Breelib™ Nebuliser Units with a Serial Number greater than 333055419000041 (Starter Pack) and 333055577000193 (Monthly Pack), are NOT subject to the previously reported Field Safety Notice (refer to Section 1.6). They will be available on the market from October 2020.</p> <p>According to standard recommendations, patients should seek medical advice if they experience any new side effects or experience side effects at an increased frequency or severity. Any adverse events associated with use of the Breelib™ Nebuliser Unit should be reported to the manufacturer.</p>	
3.	2. By when should the action be completed?	N/A
3.	3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
<b>3.</b>	<b>4. Action Being Taken by the Manufacturer</b>  <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>Breelib™ Nebuliser Units supplied with serial numbers greater than 333055419000041 (Starter Pack) and 333055577000193 (Monthly Pack) contain dosers from a new manufacturing tool and hence do not exhibit the previously reported dose variability.</p>	
3	5. By when should the action be completed?	October 2020
3.	6. Is the FSN required to be communicated to the patient /lay user?	N/A
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?  <p>Communication to patients will be via the Patient Support Providers and physicians at Pulmonary Hypertension Centres using the information provided in this follow-up FSN.</p>	
Choose an item.                      Choose an item.		

4. General Information*		
4.	1. FSN Type*	Update
4.	2. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Vectura Group plc
	b. Address	One Prospect West, Chippenham, SN14 6FH, United Kingdom
	c. Website address	www.vectura.com
4.	3. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	4. List of attachments/appendices:	Distributor reply form
4.	5. Name/Signature	
		

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>

## MEDICAL DEVICE FIELD SAFETY NOTICE RESPONSE

Breelib™ Nebuliser Unit – Resolution of previous report of inaccurate dosing

### Acknowledgement and Receipt Form

Response is Required by 30<sup>th</sup> November 2020

28 October 2020

## Section 1: Bayer AG

### Bayer AG Contact Information:

Form Completed by and Title:	
Contact Name and Title:	
Telephone Number:	
Email Address:	
Company Name:	
Street Address:	
City, Postcode	
Country	

### Please check applicable option(s) below:

- ☐ I certify that Bayer AG received, read and understood the Follow-up Field Safety Notice, FSN-VEC-001-2019.
- ☐ I confirm that the Follow-up FSN has been communicated to all Bayer Affiliates where the Breelib™ Inhalation System is on the market:
- |                                    |                                   |   |                                |
|------------------------------------|-----------------------------------|---|--------------------------------|
| <input type="checkbox"/> Austria   | <input type="checkbox"/> Germany  | <input type="checkbox"/> United Kingdom         | <input type="checkbox"/> Italy |
| <input type="checkbox"/> Poland    | <input type="checkbox"/> Portugal | <input type="checkbox"/> Other (please specify) |                                |
| <input type="checkbox"/> Argentina | <input type="checkbox"/> Chile    | <input type="checkbox"/> Other (please specify) |                                |

☐ I confirm that the Bayer Affiliates in these territories have been instructed to communicate the FSN to all distributors, Patient Support Programmes supporting use of Breelib™ in patients with pulmonary arterial hypertension (PAH) and all PAH treatment centres.

Signature:

Date:

Please return the completed and signed Acknowledgement and Receipt Form to: Sally Du Toit, Vectura Delivery Devices, Director Device Vigilance, mdi@vectura.com.  
If you experience difficulty in carrying out the instructions contained in this communication, contact mdi@vectura.com.

## Section 2: Bayer Affiliates

### Bayer Affiliate Contact Information:

Form Completed by and Title:	
Contact Name and Title:	
Telephone Number:	
Email Address:	
Affiliate Name:	
Street Address:	
City, Postcode	
Country	

### Please check applicable option(s) below:

- ☐ I certify that we received, read and understood the Follow-up Field Safety Notice, FSN-VEC-001-2019.
- ☐ I confirm that the Follow-up FSN has been communicated to all applicable distributors, Patient Support Programmes supporting use of Breelib™ in patients with pulmonary arterial hypertension and PAH treatment centres within our territory.

Signature:

Date:

Please return the completed and signed Acknowledgement and Receipt Form to: **<Reply form return details to be completed by Bayer>**.

If you experience difficulty in carrying out the instructions contained in this communication, contact your local **<Bayer>** representative: **<Bayer representative contact details to be completed by Bayer>**