Safety notice reference: UA 20-001

date: 05 OCT 2020

URGENT FIELD SAFETY NOTICE

Product: CystoFlex™ UHD R

Issue: Serial number traceability

Dear customers,

Mauna Kea Technologies communicates this safety notice concerning the medical device confocal miniprobe™: **CystoFlex™ UHD R**.

This safety notice aims to inform you about the following points:

- Description of the issue
- Actions to be taken by the customer

Description of the issue

The CystoFlex™ UHD R Confocal Miniprobe is intended to allow imaging of anatomical tracts, i.e., urinary, including, but not limited to, urethra, bladder, and ureter, accessed through an endoscope or endoscopic accessories.

The internal memory of the CystoFlex™ UHD R Confocal Miniprobe™ is possibly misprogrammed. Once connected on the imaging system Cellvizio® 100 Series, the CystoFlex™ UHD R can communicate a wrong serial number different from the serial number affixed on the Confocal Miniprobe™.

There is no risk for the patient or the user to use the medical device.The customer can only identify a mismatch between serial number displayed on the screen of Cellvizio® 100 Series and serial number affixed on CystoFlex™ UHD R Confocal Miniprobe™.

Below are listed all serial numbers of **CystoFlex™ UHD R** which are affected by this safety notice:

CM-11489
CM-11490
CM-11491
CM-11492
CM-11493
CM-11694
CM-11695
CM-11696
CM-11697

Mauna Kea Technologies S.A.
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75010 Paris, France
Tel +33 1 48 24 03 45

www.maunakeatech.com

Mauna Kea Technologies, Inc.
24 Denby Road, Suite 140
Allston, MA 02134,
Tel +1 617 657 1550

Société Anonyme • RCS PARIS B 431 268 028 (2000B18081) • NAF 7219Z • SIRET: 431 268 028 00021

Actions to be taken by the customer
(1) You have to not use the affected medical devices anymore and quarantine device(s)
(2) Return affected devices to Mauna Kea Technologies
(3) Fill the enclosed Customer reply form and send it to Mauna Kea Technologies

This safety notice only concerns the serial numbers listed above. In case you have CystoFlex™ UHD R with others serial numbers, you can continue to use these devices.
Only concerned health facilities receive this safety notice.

Your national authority has been informed of this safety notice.

Do not hesitate to contact Mauna Kea Technologies for further questions:
- by phone: +33 1 70 08 09 67
- by mail: support@maunakeatech.com

Mauna Kea Technologies is committed to providing high quality products and attaches importance to your satisfaction with Mauna Kea Technologies products.

Sincerely,
Mauna Kea Technologies

Customer Reply

1. Field Safety Notice (FSN) information	
FSN Reference number*	*UA-20-001*
FSN Date*	*05 OCT 2020*
Product/ Device name*	*CystoFlex™ UHD R*
Product Code(s)	*MP-0013-HCYS / 211-0147*
Batch/Serial Number (s)	

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

Mauna Kea Technologies

3. Customer action undertaken on behalf of Healthcare Organisation				
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	*Customer to complete or enter N/A*		
☐	I performed all actions requested by the FSN.	*Customer to complete or enter N/A*		
☐	The information and required actions have been brought to the attention of all relevant users and executed.	*Customer to complete or enter N/A*		
☐	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:	
☐	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:	
		Qty:	Lot/Serial Number:	
		N/A	Comments:	
☐	No affected devices are available for return/ destruction.	*Customer to complete or enter N/A*		
☐	Other Action (Define):			
☐	I do not have any affected devices.	*Customer to complete or enter N/A*		

☐	I have a query please contact me (e.g. need for replacement of the product).	*Customer to enter contact details if different from above and brief description of query*
Print Name*		
Signature*		
Date*		

4. Return acknowledgement to sender	
Email	*support@maunakeatech.com*
Customer helpline	**+33 1 70 08 09 67**
Postal Adress	Mauna Kea Technologies 9 rue d'Enghien 75010 Paris FRANCE
Web Portal	www.maunakeatech.com
Fax	+33 1 48 24 12 18
Deadline for returning the customer reply form*	

Mandatory fields are marked with *

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

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

URGENT INFORMATION

Urgent Field Safety Notice (UA-20-001)

CystoFlex™ UHD R

Date /*Date* : 05 OCT 2020

DE / FROM :	**A / TO :**
Mauna Kea Technologies 9, rue d'Enghien 75010 Paris FRANCE Tel : +33 1 48 24 03 45 or +33 1 70 08 09 67 Fax : + 33 1 48 24 12 18 E-mail : support@maunakeatech.com	**Nom / Name :** **Adresse / Address :** **Code postal** / ***Zip code*:** **Ville** / ***City* :** **Pays** / ***Country*:**

Urgent Field Safety Notice (FSN)
CystoFlex™ UHD R
Serial number traceability

	1. Information on Affected Devices
	Device Type(s)* :
	Confocal Miniprobe™
	Commercial name(s) :
	CystoFlex™ UHD R
	Unique Device Identifier(s) (UDI-DI) :
	(01)03760187910147(11)180117(21)
	Primary clinical purpose of device(s)* :
	The CystoFlex™ UHD R Confocal Miniprobe™ is intended to allow imaging of anatomical tracts, i.e., urinary, including, but not limited to, urethra, bladder, and ureter, accessed through an endoscope or endoscopic accessories.
	Device Model/Catalogue/part number(s)* :
	MP-0013-HCYS / 211-0147
	Software version :
	NA

	Affected serial or lot number range :
	CystoFlex™ UHD R with the following serial numbers: ***CM-11489*** ***CM-11490*** ***CM-11491*** ***CM-11492*** ***CM-11493*** ***CM-11694*** ***CM-11695*** ***CM-11696*** ***CM-11697***
	Associated devices :
	Cellvizio® 100 Series

	2. Reason for Field Safety Corrective Action (FSCA)*
	Description of the product problem* :
	The internal memory of the CystoFlex™ UHD R Confocal Miniprobe™ is possibly misprogrammed. Once connected on the Cellvizio® 100 Series, the CystoFlex™ UHD R communicates a wrong serial number different from the serial number affixed on the Confocal Miniprobe™.
	Hazard giving rise to the FSCA* :
	There is no risk nor for the patient nor the user.
	Probability of problem arising :
	All serial numbers of CystoFlex™ UHD R Confocal Miniprobe™concerned by this issue have been identified.
	Predicted risk to patient/users :
	There is no risk nor for the patient nor user to use the medical device.The user can only identify a mismatch between serial number displayed on the screen of Cellvizio® 100 Series and serial number affixed on CystoFlex™ UHD R Confocal Miniprobe™.
	Further information to help characterise the problem :

	NA
	Background on Issue :
	The issue was detected by a user during technical inspection of CystoFlex™ UHD R Confocal Miniprobes™. The internal memory of the medical device is misprogrammed. Specific serial numbers of CystoFlex™ UHD R Confocal Miniprobes™are affected. Inspection by users and stock of manufacturer is performed .People responsible for the equipment is informed.
	Other information relevant to FSCA :
	The users can use CystoFlex™ UHD R Confocal Miniprobes™ not appearing in the list of serial numbers impacted by the FSCA.

	3. Type of Action to mitigate the risk*	
	Action To Be Taken by the User* : ☐ Identify Device ☒ Quarantine Device ☒ Return Device ☐ Destroy Device ☐ On-site device modification /inspection ☐ Follow patient management recommendations ☐ Take note of amendement/reinforcement of instructions For Use (IFU) ☐ None ☐ Other *The user have to not use the affected medical devices anymore and have to ship them to Mauna Kea Technologies.*	
	By when should the action be completed ? :	*Immediately*
	Particular considerations for : NA Is follow-up of patients or review of patients' previous results recommended? :	

	NA	
	Is customer Reply Required? * : (If yes, form attached specifying deadline for return)	Yes
	Action Being Taken by the Manufacturer : ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None *The internal memory of the CystoFlex™ UHD R Confocal Miniprobe™ concerned by this issue will be updated.*	
	By when should the action be completed ? :	*31 DEC 2020*
	Is the FSN required to be communicated to the patient /lay user ? :	*No*
	If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet ? :	
	NA	

	4. General Information*	
	FSN Type* :	New FSN, reference number UA-20-001
	For updated FSN, reference number and date of previous FSN :	NA
	For Updated FSN, key new information as follows:	
	NA	

	Further advice or information already expected in follow-up FSN? * :	Yes
	If follow-up FSN expected, what is the further advice expected to relate to :	
	Update of internal memory of CystoFlex™ UHD R Confocal Miniprobe™ concerned by the FSN	
	Anticipated timescale for follow- up FSN :	*31 DEC 2020*
	Manufacturer information : (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Mauna Kea Technologies
	b. Address	9 rue d'Enghien
	c. Website address	www.maunakeatech.com
	The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * :	
	List of attachments/appendices:	No
	Name:	Aline Criton, Regulatory and clinical affairs director

Transmission of this Field Safety Notice

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)

Please transfer this notice to other organisations on which this action has an impact. (As appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

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.*

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