

**URGENT FIELD SAFETY NOTICE**

Olympus Flushing Pump (OFP-2) K10001143 & K10001144

FSCA Identifier: 158 (10 June 2013)

Manufacturer's Advice

Date: 10 June 2013

Dear Health Care Practitioner

**Description of the problem:**

The OFP-2 Flushing Pump is a peristaltic flushing pump intended for use in medical facilities under the direction of a trained physician. Olympus has recently received a small number of complaints associated with unlocked pump heads. If the pump head is in an unlocked position, this may, under certain circumstances cause the pump to stop and go into power stand-by mode. If the pump goes into stand-by mode, no water is delivered from the OFP-2 pump through the water tube connected to the Olympus flexible endoscope.

**Details on affected devices:**

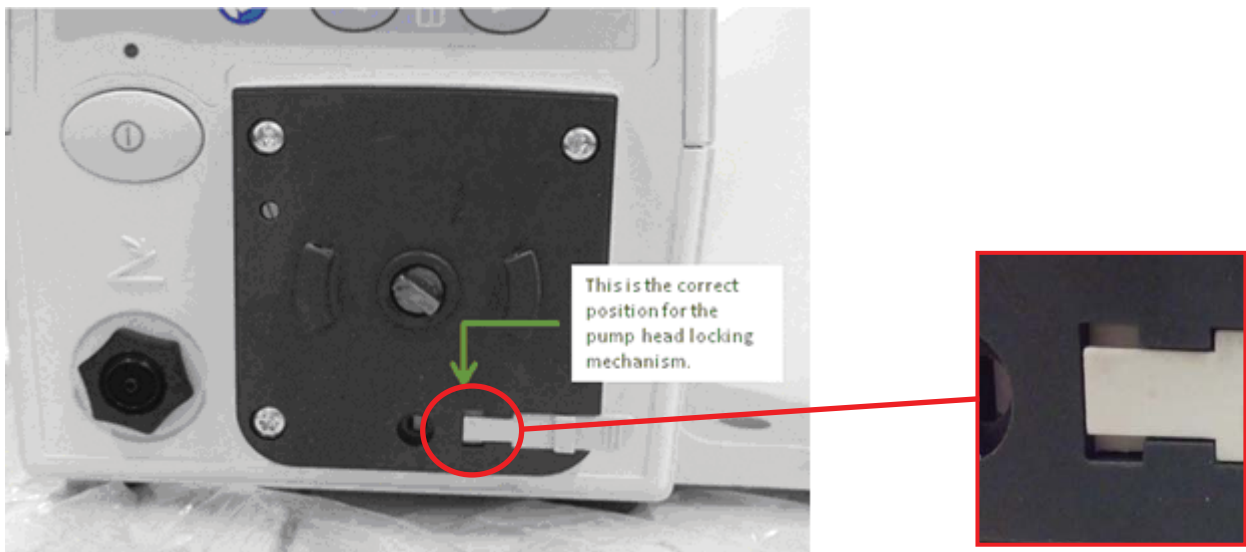
OFP-2 Flushing Pumps manufactured between December 2012 and May 2013 are potentially affected. The serial numbers of the potentially affected devices are identified below and the customers of those devices will receive a customer letter which will give detailed advice on the action to be taken.

21219998	21301653	21303753	21304099	21307019	21308633
21220351	21301654	21303754	21304100	21307020	21308634
21220352	21301655	21303755	21305825	21307021	21308635
21220353	21301656	21303641	21305826	21307022	21308636
21220354	21301657	21303756	21305827	21307325	21308638
21220355	21301663	21303757	21305828	21307326	21308956
21220356	21303025	21303758	21305829	21307327	21308957
21220525	21301658	21303759	21305830	21307328	21308958
21220526	21301659	21303760	21305831	21307329	21308959
21220527	21301660	21303761	21305832	21307330	21308960
21220528	21301661	21303762	21305833	21307331	21308961
21220529	21301662	21303645	21305834	21307691	21308962
21220530	21303026	21303646	21306019	21307692	21308963
21220531	21303027	21303642	21306020	21307693	21308964
21220532	21303028	21303643	21306021	21307694	21308965
21220533	21303029	21303644	21306022	21307695	21308966
21220534	21303030	21304004	21306023	21307696	21308967
21220535	21303031	21304005	21306024	21307697	21308626
21220536	21303032	21304006	21306025	21307698	21308637
21220537	21303033	21304007	21306026	21307699	21308639
21220538	21303034	21304008	21306027	21307332	21308640
21221127	21303035	21304009	21306028	21307333	21308641
21221128	21303036	21304010	21306942	21307334	21308642
21221129	21303037	21304011	21306943	21307700	21308643
21221130	21303041	21304012	21306944	21308624	21303043

21221131	21303042	21304095	21306945	21308625	21303262
21221132	21303038	21304096	21306946	21308627	21303723
21221133	21303039	21304013	21306947	21308628	21304511
21221134	21303040	21304014	21306948	21308629	21305591
21221135	21303263	21304015	21306949	21308630	21305592
21221136	21303751	21304097	21306950	21308631	21305593
21301652	21303752	21304098	21306951	21308632	

**Action taken by the user:**

Customers of the potentially affected OFP-2 Flushing Pumps are advised to ensure that the pump head locking mechanism is in the correct position, as shown below:



Instructions on how to remove the pump head from the device and re-install it, and how to correctly position the pump head locking mechanism are contained in the customer letter, additional guidance is provided in the IFU for the device. If users require assistance in performing this check, they should call their Olympus Service Center to request assistance

**Transmission of this Field Safety Notice:**

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. Please transfer this notice to other organisations on which this action has an impact. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

Contact reference person:

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