CooperSurgical
Healthy women, babies, and families™

August 19, 2019

URGENT FIELD SAFETY NOTICE

COOPERSURGICAL EMBRYOLOGY HEATED PLATE WITHIN THE RI WITNESS™

Dear Valued CooperSurgical Customer,

CooperSurgical has issued a Field Safety Notice for 606 serial numbers of its Embryology Heated Plate within the RI Witness™ [CooperSurgical part numbers 6-70-807, 6-70-807-A, & 6-70-807-B]. The RI Witness uses Radio Frequency Identification (RFID) to detect and monitor all activity in the IVF laboratory. RFID helps mitigate the risk of human error every time samples are moved from one dish or tube to another and safeguards every step of the IVF cycle. The heated plates comprise a heated composite surface with window for a light source and either sit on top of existing bench-tops or can be integrated to be flush fitted within workstations.

CooperSurgical is issuing this Notice because the touchpad may not work properly after cleaning. The touchpad 'Change Setpoint' LED may flash (either continuously or intermittently) followed by the Green 'ready to use' status indicator switching off or appearing non-responsive. Or, the alarm may sound and the Green 'ready to use' status indicator may switch off. The nonconformity was detected during complaint investigations and a corrective action has been initiated to prevent future recurrence. **Please be aware that there is no inherent risk to the embryo or embryologist due to this failure because the temperature controller continues to maintain temperature and adequate time remains for the embryologist to complete the procedure.** No adverse events have been reported to CooperSurgical due to this potential issue.

This Notice affects 606 serial numbers manufactured between March 25, 2016 and October 5, 2018 and our records indicate that you have purchased the affected product from CooperSurgical. Please see Figure 1 for a reference where the serial number can be found on your unit. If the affected product at your facility is displaying any of the above characteristics, please complete the attached **Acknowledgement and Receipt Form** to arrange for an onsite field service call at CooperSurgical's expense. Otherwise, this issue will be addressed at your next onsite routine service at no expense for the correction. Please be advised that we are expecting the EHO Flush to be approximately an extra 2 hours and the EHP Sit on Top to require approximately an extra 20 minutes during this service.

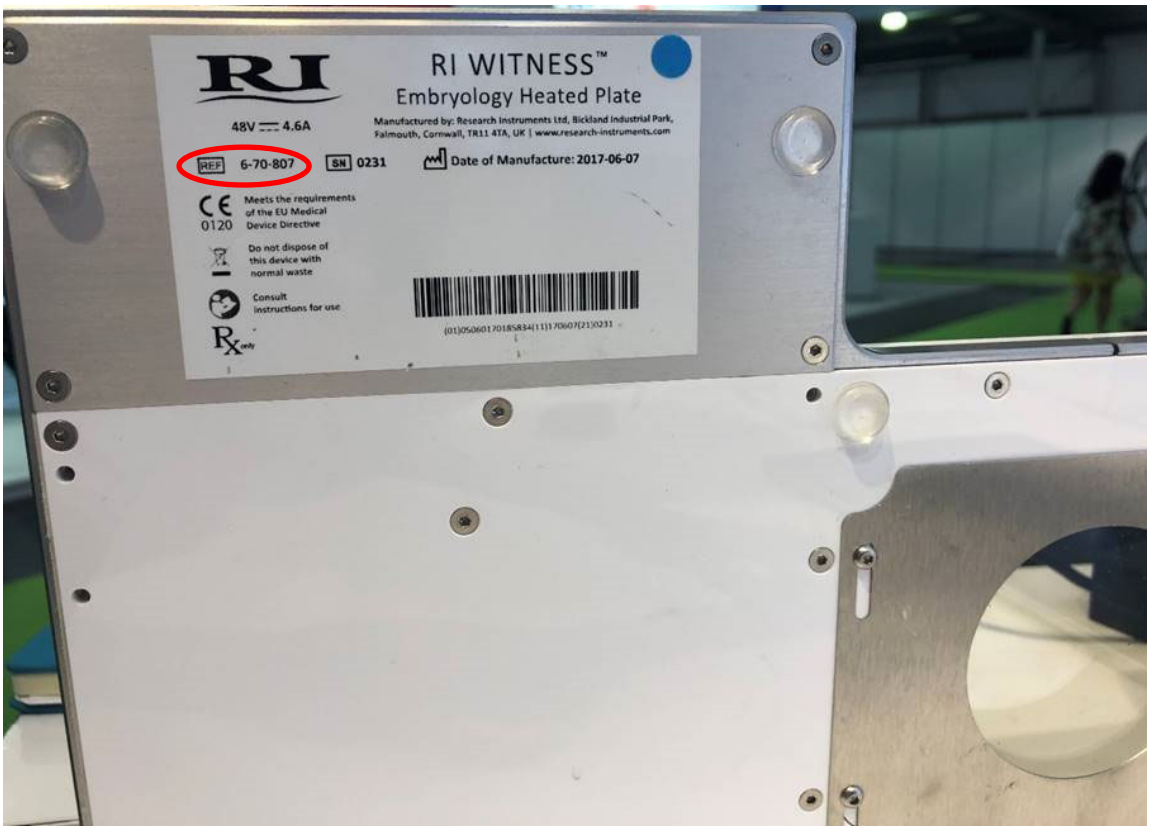

Figure 1

The relevant regulatory authorities have been notified of this field safety notice.
We sincerely apologize for any inconvenience caused by this Field Safety Notice.
CooperSurgical is committed to high quality, safe and effective products. Please feel free to reach us at +001.203.601.5200 ext. 3300 with any questions regarding this notice.

Sincerely,

[redacted]

COOPERSURGICAL EMBRYOLOGY HEATED PLATE WITHIN THE RI WITNESS™

Affected Serial Numbers

0006	0051	0097	0146	0192	0244	0292	0354	0420	0487	0617	0672	0732	0783
0007	0052	0098	0147	0193	0245	0293	0356	0421	0489	0618	0673	0733	0784
0008	0053	0100	0148	0194	0246	0294	0357	0424	0490	0619	0674	0734	0785
0009	0054	0101	0149	0195	0247	0297	0358	0426	0491	0622	0675	0735	0786
0010	0055	0102	0150	0196	0248	0298	0359	0428	0492	0628	0676	0736	0787
0011	0056	0103	0151	0197	0249	0299	0360	0429	0493	0630	0677	0738	0788
0012	0057	0104	0152	0198	0250	0300	0361	0430	0494	0631	0678	0739	0789
0013	0058	0105	0153	0199	0251	0302	0362	0431	0495	0632	0679	0740	0790
0014	0060	0106	0154	0200	0252	0303	0364	0432	0496	0633	0680	0741	0791
0015	0061	0107	0155	0201	0253	0304	0366	0433	0497	0634	0681	0742	0792
0016	0062	0108	0156	0203	0254	0306	0367	0434	0498	0635	0682	0743	0793
0017	0063	0109	0157	0204	0255	0307	0368	0435	0499	0636	0683	0744	0794
0018	0064	0110	0158	0205	0256	0308	0369	0438	0501	0637	0684	0745	0795
0019	0065	0111	0159	0206	0257	0309	0370	0440	0502	0638	0685	0747	0796
0020	0066	0112	0160	0207	0258	0311	0371	0441	0503	0639	0686	0748	0797
0021	0067	0113	0161	0208	0259	0312	0372	0442	0504	0641	0687	0749	0798
0022	0068	0114	0162	0209	0260	0313	0373	0443	0505	0642	0688	0752	0799
0023	0069	0115	0163	0210	0261	0314	0374	0444	0508	0643	0689	0753	0800
0024	0070	0116	0164	0211	0263	0315	0375	0445	0509	0644	0690	0754	0801
0025	0071	0117	0165	0212	0264	0316	0378	0446	0511	0645	0691	0755	0802
0026	0072	0118	0166	0213	0265	0317	0380	0447	0512	0646	0703	0756	0803
0027	0073	0119	0167	0214	0266	0318	0381	0449	0513	0647	0704	0757	
0028	0074	0120	0168	0215	0267	0319	0383	0450	0514	0648	0705	0758	
0029	0075	0121	0169	0216	0268	0320	0386	0453	0515	0649	0707	0759	
0030	0076	0122	0170	0217	0269	0321	0388	0455	0516	0650	0708	0760	
0031	0077	0123	0171	0218	0270	0322	0389	0456	0520	0651	0709	0761	
0032	0078	0124	0173	0219	0271	0323	0390	0457	0528	0653	0710	0762	
0033	0079	0125	0174	0220	0272	0324	0393	0458	0530	0654	0712	0763	
0034	0080	0126	0175	0221	0273	0325	0394	0459	0600	0655	0713	0764	
0035	0081	0127	0176	0224	0275	0326	0395	0460	0601	0656	0714	0765	
0036	0082	0128	0177	0225	0276	0327	0396	0462	0602	0657	0716	0766	
0037	0083	0129	0178	0227	0277	0328	0399	0463	0603	0658	0717	0767	
0038	0084	0130	0179	0228	0278	0329	0400	0464	0604	0659	0718	0768	
0039	0085	0131	0180	0229	0279	0330	0403	0466	0605	0660	0719	0769	
0040	0086	0132	0181	0230	0280	0331	0405	0468	0606	0661	0720	0770	
0041	0087	0133	0182	0231	0281	0332	0406	0475	0607	0662	0721	0771	
0042	0088	0134	0183	0232	0282	0333	0408	0476	0608	0663	0722	0774	
0043	0089	0136	0184	0235	0283	0334	0411	0477	0609	0664	0723	0775	
0044	0090	0137	0185	0237	0284	0335	0412	0479	0610	0665	0724	0776	
0045	0091	0140	0186	0238	0285	0336	0413	0480	0611	0666	0725	0777	
0046	0092	0141	0187	0239	0286	0337	0414	0481	0612	0667	0726	0778	
0047	0093	0142	0188	0240	0287	0342	0415	0482	0613	0668	0727	0779	
0048	0094	0143	0189	0241	0288	0348	0416	0483	0614	0669	0728	0780	
0049	0095	0144	0190	0242	0290	0349	0417	0484	0615	0670	0729	0781	
0050	0096	0145	0191	0243	0291	0350	0419	0485	0616	0671	0730	0782	

Acknowledgement and Receipt Form: Response is required

Please complete this form and return it via email: recall@coopersurgical.com or fax to
+001.203.601.9870 ATTN: Product Surveillance.
CooperSurgical will arrange for a product field service at your facility after this form has been received.

Customer Account #: _____ Account Name: _____

Street Address: _____ Town, State, Zip Code:_____

Contact Name: _____ Phone Number: _____

Email address: _____

I have read and understand the Notice instructions provided in the August 19, 2019 letter. Yes __ No___

Any adverse events associated with product subject to this Notice? Yes __ No____

If yes, please explain: _____

Please check the appropriate boxes below and complete the table if applicable.

☐ We have no inventory within the scope of this Notice.

☐ We have the following affected product at our facility. We have identified the affected product and will need the following serial numbers serviced onsite.

Serial Number	Quantity to be Serviced

If you have additional questions, please contact a CooperSurgical Product Surveillance representative at **+001.203.601.5200 ext. 3300** or email us at **recall@coopersurgical.com**. Adverse reactions or quality problems experienced with the use of this product may be reported to the respective Competent Authority's Adverse Event Reporting program either online, by regular mail or by fax.

Acknowledgement and Receipt Form: Response is required

Please complete this form and return it via email: recall@coopersurgical.com or fax to
+**001.203.601.9870 ATTN: Product Surveillance.**
CooperSurgical will arrange for a product field service at your facility after this form has been received.

FOR DISTRIBUTORS ONLY:

Customer Account #: _____ Account Name: _____

Contact Name/Title: _____ Phone Number: _____

Email address: _____

Please complete the appropriate information below if applicable.

I have read and understand the Notice instructions provided in the August 19, 2019 letter. Yes __ No__

I have checked my stock and have quarantined inventory consisting of _____units

Serial Number shipped to Customer : _____ Quantity Shipped:_____

I have identified and notified my customers that were shipped or may have been shipped this product by _____(Specify date and method of notification)

Or

Please notify the attached is a list of customers who received/may have received this product.

Signature of Receipt: _____

PLEASE E-MAIL COMPLETED RESPONSE FORM TO recall@coopersurgical.com
OR FAX +**001.203.601.9870 ATTN: Product Surveillance**