

Urgent Medical Device Correction - Immediate Action Required
iLab™ Polaris Systems

September 18, 2019

Dear Physician or Health Care Professional,

Boston Scientific (BSC) is initiating a voluntary correction of certain iLab Polaris Systems which were upgraded with a previous Polaris 2.10 software version (disk batch 629774). This letter provides instructions and recommendations to the user until a software upgrade (disk batch 636991) is completed.

A BSC representative will be in contact with you directly to schedule a software upgrade at your facility.

The iLab Polaris Systems can continue to be used during this time following the recommendations and instructions within this letter.

Description and Clinical Implications

iLab Polaris Systems with the previous Polaris 2.10 software version (disk batch 629774) installed are intended per labelling to archive Diastolic Hyperemia-Free Ratio™ (DFR) data in three available formats:

1. Multi-Frame UltraSound (US)
2. Secondary Capture (SC) Image Storage
3. True Color SC

BSC has determined that due to a bug in the software disk batch 629774, **only the True Color SC format will archive DFR data as intended**. If either Multi-Frame US or SC Image Storage formats are used, the DFR data **will not be archived and the user will not be notified of this unexpected behavior**.

No adverse effects are anticipated to occur due to the inability to archive DFR data. BSC has received no reports of patient harm as a result of this issue.

Cath Lab Manager or Cath Lab Head Nurse Actions

1. Distribute this letter to iLab Polaris System operators within your facility.
2. Immediately post a copy of **Attachment 2** Instructions to Archive DFR Data on or in a visible location near each system at your facility.

Recommendations

If you possess a system with a serial number listed in **Attachment 1** please note that:

1. After case closure and archiving the DFR data will be stored for only six (6) months on the iLab Polaris System. After this timeframe the case will be automatically deleted from the system and cannot be retrieved.
2. The DFR data can be archived on CD/DVD, removable hard drive, or hospital network only by using the True Color SC format. You can ensure your data is archived using the True Color SC format following the instructions in **Attachment 2**.
3. **Ensure that all cases are archived (per the instructions in Attachment 2) to prevent data loss. Note that archived cases will be automatically deleted after six (6) months.**

BSC is notifying regulatory authorities of this action as required. BSC regrets any inconvenience this may cause and appreciates your understanding as we take the necessary steps to ensure this is resolved in an expedient and satisfactory matter. BSC is committed to continuing to offer products that meet the expected high quality standards.

Sincerely,



Brendan Smith
Boston Scientific Quality Systems
763-494-1133
BSCFieldActionCenter@bsci.com

Encl: Acknowledgement Form

Health care professionals and consumers may report serious adverse events (side effects) or product quality problems with the use of this product to Boston Scientific by calling 1-866-868-4004 and to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, fax or phone.

Online: www.fda.gov/MedWatch/report.htm

Regular Mail: use postage-paid FDA form 3500 available at www.fda.gov/MedWatch/getforms.htm and mail to MedWatch, 5600 Fishers Lane, Rockville, MD, 20852-9787

Fax: (800) FDA-0178

Phone: (800) FDA-1088

Urgent Medical Device Correction - Instructions

The Acknowledgement Form enclosed with this letter must be completed and returned **even if you do not have any affected units.**

1. **Immediately post this information in a visible location near the product to ensure this information is easily accessible to all users of the device.**
2. **Complete and return the Acknowledgement Form.**
Complete the enclosed Acknowledgement Form (even if you do not have any affected products).
3. Return the form to:

Email: BSCFieldActionCenter@bsci.com

or

Fax to: 1-866-213-1806

Please email or fax your completed form immediately.

Attachment 1 – Affected Product Listing

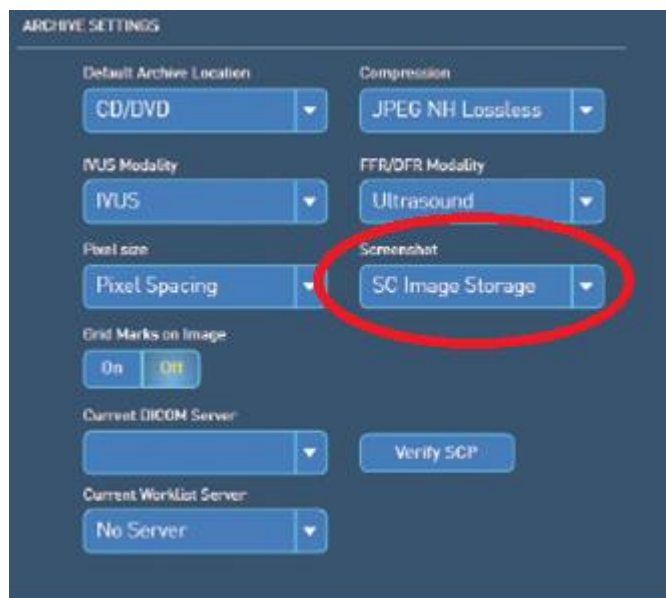
iLab™ Polaris Systems

UPN	GTIN	Serial Numbers				
H74939322100CZ0	08714729974918	200204	200209	200217	200308	200310
		200448	200450	200456	200457	200458
		200461	200480	200481		
H74939322100IZ0	08714729974925	200103	200145			
H74939322240C0	08714729946205	200044	200118	200360	200498	
H74939322240I0	08714729946236	200170				
H749ILAB100C270	08714729842521	8361	10312	10443		
H749ILAB100C27H0	08714729845096	10548				
H749ILAB100C27Z0	08714729845119	7402	8397	8497	8498	8508
		8516	8522	8523	8530	10044
		10053	10275	10278	10362	10365
		10496	10500	10565	10566	10604
		10651	10667	10694	10753	10770
		10867	10872	10873	10875	10876
		10952	8475		10292	
H749ILAB100CART0	08714729761235	6582	7023	7857		
H749ILAB100CARTH0	08714729845072	5637	5716	6650	6894	4031
		5003	5043	5060	5109	5232
		5239	5393	5465	5651	5678
		5860				
H749ILAB100CARTZ0	N/A	6193	6350	8264	6819	6921
		6934	7332	7341	7362	7733
		7828	7858	7933	7934	8011
		8155	8290	6383		8098
H749ILAB100INS0	08714729119593	5182	5219	5296	5398	8157
H749ILAB100INSZ0	N/A	6760	7723			
H749ILAB100N270	08714729842514	10108				
H749ILAB100N27Z0	08714729845133	8365	8367	10504		
H749ILAB240C270	08714729848950	10657				
H749ILAB240C27R0	08714729848981	10501				
H749ILAB240CART0	08714729777694	4274	8046	8048	5892	7818
		4773	5585	8113	5165	4402
		6468	6319	5313	7511	4952
		6010				
H749ILAB240CARTZ0	08714729810162	5277	5457	4116	5403	5078
H749ILAB240INS0	08714729765127	5664	5666	6327	6733	6994
		6136	6206	6172	7604	7602
		7353	6273	6993		
H749ILAB240INSZ0	N/A	4045			5508	
H749ILAB240N270	08714729848882	10221	10261	8540		

Attachment 2

iLab Polaris System Notice Instructions to Archive DFR Data

1. Select “**System Utilities**” from the “**Polaris**” drop down menu on top left of the screen.
2. As a User, in the “**Global Profile**” screen you can change the default archiving settings.
3. The “**Screenshot**” Field in “**ARCHIVE SETTINGS**” section is the one impacted by the issue described above.
4. Make sure to select the option “**True Color SC**”



5. BSC Technical Service will be available to guide you if you require assistance.