How to Manage Your End-of-Support Imaging Equipment

BY : TRISH PAYNE

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Discovering the Possibilities

INTRO

Trish Payne

Block Imaging, Director of Compliance

- Worked for Block for almost 15 years.
- My primary focus is on regulatory, FDA, and understanding the OEM obligation to 3rd parties and our customers.
- Co-Chair the Medical Device Servicing Community (MDSC)

  Born out of the 2018 FDA meeting concerning Medica Device Servicing and Remanufacturing Activities.

MDSC https://www.mdsc.online/

We are a community of people who want to advance the safety, effectiveness and quality of medical device servicing in the U.S., together.

Comprised of OEM's, ISO's, HDO 's, Professional Org's, End Users

IMDRF International Medical Device Regulators Forum

https://www.fda.gov/medical-devices/cdrh-international-affairs/international-medical-device-regulators-forum-imdrf

- IMDRF is a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices (GHTF) and aims to accelerate international medical device regulatory harmonization and convergence.

- Established in October 2011

- Australia, Brazil, Canada, China, EU, Japan, Singapore, South Korea, United Kingdom, US.

TODAY'S TOPIC

HOW TO MANAGE YOUR END OF SUPPORT IMAGING EQUIPMENT

EOL EXAMPLE

HOLOGIC®

January 2015

PRODUCT DISCONTINUATION NOTIFICATION: (End of Service life)

Product: Fluoroscan InSight (version 1):

Dear Fluoroscan Customer,

As a valued Hologic customer, you have our commitment to provide you with the highest quality customer service, product support and technologically advanced products. We pride ourselves in being the leading manufacturer of Mini C-arms, a goal that could not be achieved without customers like you. Unfortunately, the increasing scarcity of replacement parts for older Mini C-arm systems makes it difficult for us to support some older models.

Our records indicate that your facility purchased a **Fluoroscan *InSight (version 1)* Mini C-arm.** This system is now a discontinued model (SN beginning with 08); last manufactured over seven years ago. After careful consideration, it is necessary to declare **End of Life on this product**. Therefore **after January 31, 2015**, we will no longer offer full service agreements but will continue to provide phone support, time and materials service and service agreements based ***ONLY*** on the availability of replacement parts.

Hologic wants to continue its relationship with you into the future. We remain committed to providing our customers with the highest quality products and service. We regret any inconvenience that this may cause, however we believe you will find our new product offerings very attractive. If there are any questions, please contact the Customer Service department at 1-800-321-4659.

> **For customers looking to upgrade to the latest Flat Detector Mini C-arm technology:** Hologic will be offering a special upgrade for facilities receiving this notification. This limited time offer combines special system pricing and trade-in offer incentives for customers upgrading their older Hologic Mini C-arm system to the latest **InSight-FD** technology. Please contact a Hologic representative to discuss this offer by going to the following site.
> http://www.fluoroscan.com/contact-sales-representative

For the latest updates and product information, please register you contact information via this link:
http://www.fluoroscan.com/.

Sincerely,

Roger D. Mills
Vice President
Service and Support

END OF LIFE

What does End of Life mean?

IMDRF International medical device regulators defines End of Life as

“Life cycle stage of a product starting when the manufacturer no longer sells the product beyond its useful life as defined by the manufacturer and the product has gone through a formal EOL process including notification to users”. (Draft Document April/May 2022, 3.16)

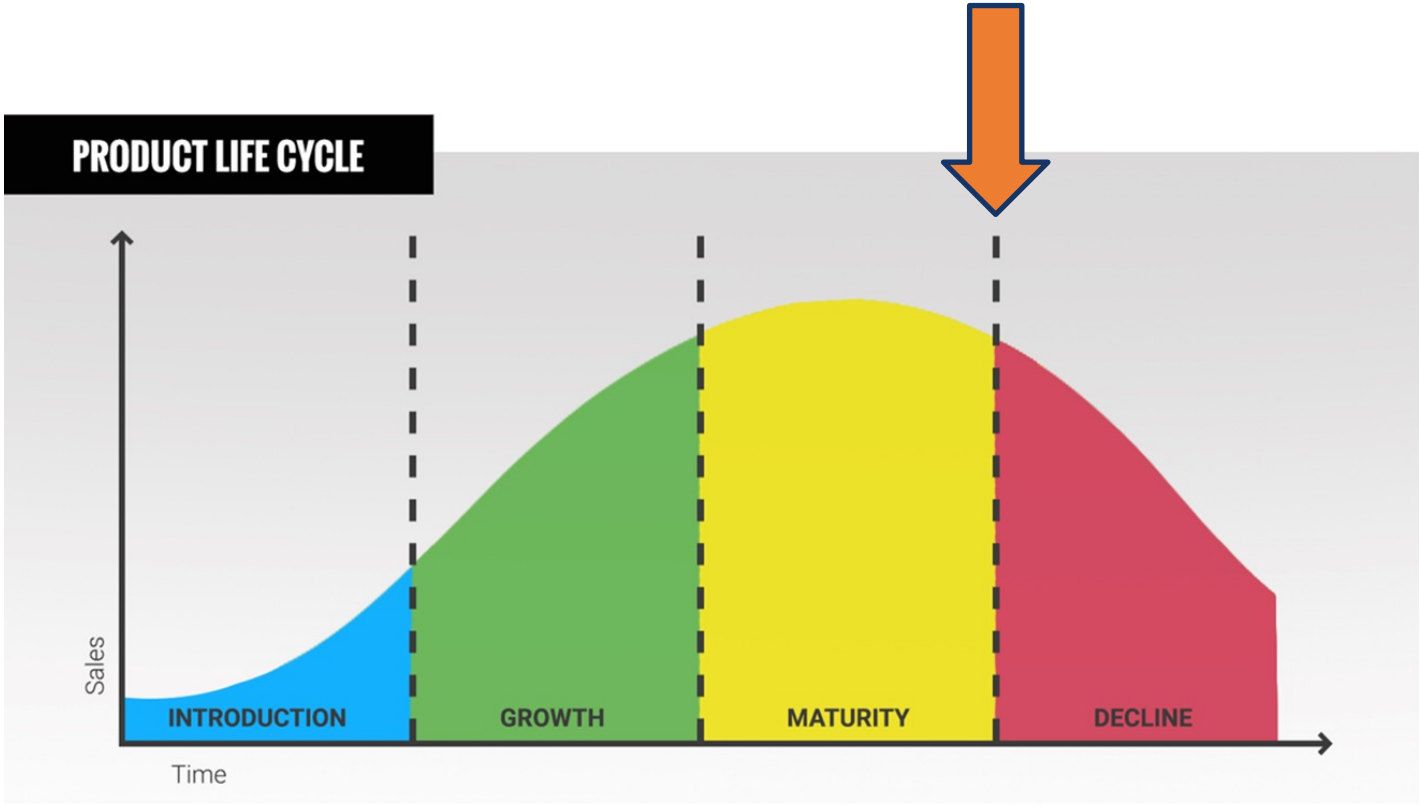
USEFUL LIFE

FDA

SUBCHAPTER H - MEDICAL DEVICES
PART 821 -- MEDICAL DEVICE TRACKING REQUIREMENTS
Subpart D - Records and Inspections

Sec. 821.60 Retention of records.

Persons required to maintain records under this part shall maintain such records for the useful life of each tracked device they manufacture or distribute. The useful life of a device is the time a device is in use or in distribution for use. For example, a record may be retired if the person maintaining the record becomes aware of the fact that the device is no longer in use, has been explanted, returned to the manufacturer, or the patient has died.

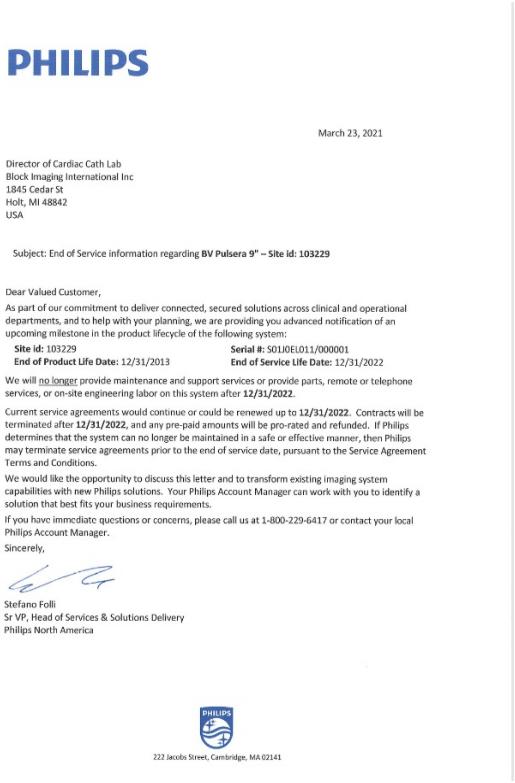

PRODUCT LIFE CYCLE
Sales
Time
INTRODUCTION
GROWTH
MATURITY
DECLINE

You can start planning now

You've received a letter that says your device is "End of Life".

- You know your equipment will be EOS in the next 2-5 years most likely.
- You can start the planning process earlier.

EOS EXAMPLE



PHILIPS

March 23, 2021

Director of Cardiac Cath Lab
Block Imaging International Inc
1845 Cedar St
Holt, MI 48842
USA

Subject: End of Service information regarding **BV Pulsera 9" – Site id: 103229**

Dear Valued Customer,

As part of our commitment to deliver connected, secured solutions across clinical and operational departments, and to help with your planning, we are providing you advanced notification of an upcoming milestone in the product lifecycle of the following system:

Site id: 103229 **Serial #:** S01J0EL011/000001
End of Product Life Date: 12/31/2013 **End of Service Life Date:** 12/31/2022

We will no longer provide maintenance and support services or provide parts, remote or telephone services, or on-site engineering labor on this system after **12/31/2022**.

Current service agreements would continue or could be renewed up to **12/31/2022**. Contracts will be terminated after **12/31/2022**, and any pre-paid amounts will be pro-rated and refunded. If Philips determines that the system can no longer be maintained in a safe or effective manner, then Philips may terminate service agreements prior to the end of service date, pursuant to the Service Agreement Terms and Conditions.

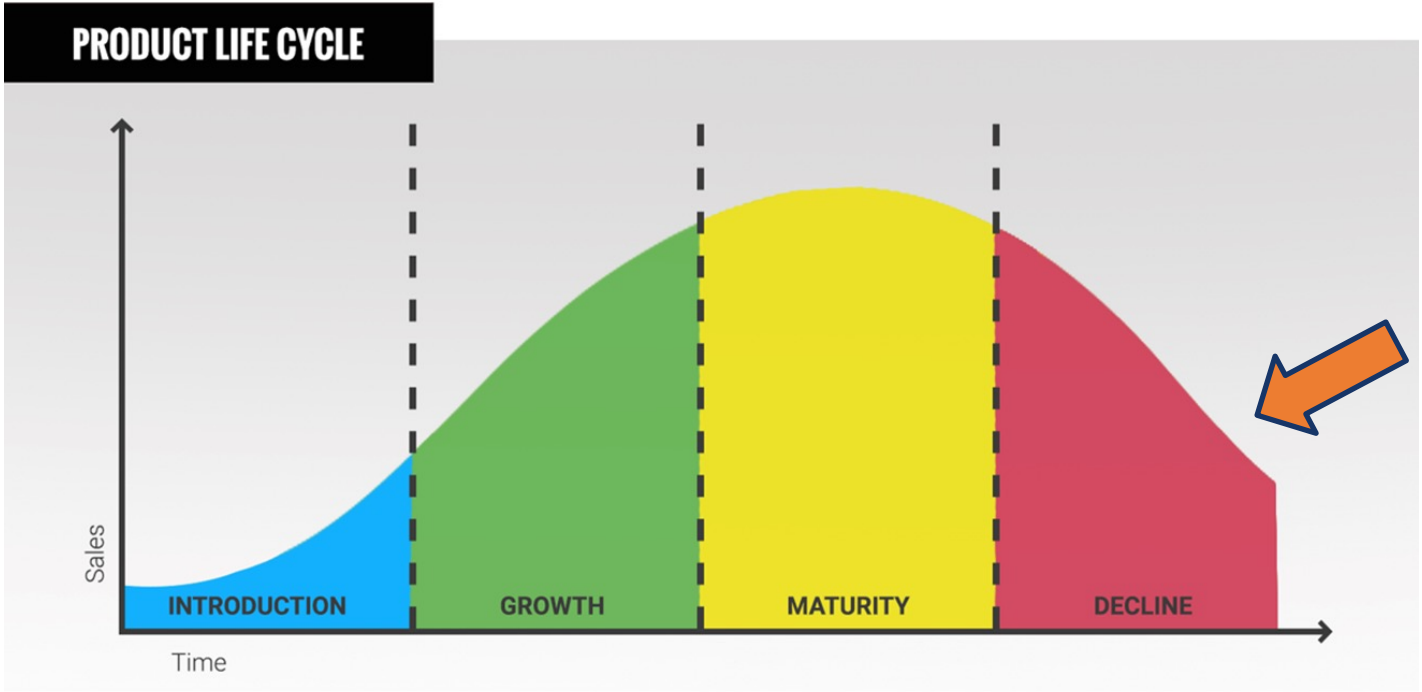
We would like the opportunity to discuss this letter and to transform existing imaging system capabilities with new Philips solutions. Your Philips Account Manager can work with you to identify a solution that best fits your business requirements.

If you have immediate questions or concerns, please call us at 1-800-229-6417 or contact your local Philips Account Manager.

Sincerely,

Stefano Folli
Sr VP, Head of Services & Solutions Delivery
Philips North America

PHILIPS
222 Jacobs Street, Cambridge, MA 02141


PRODUCT LIFE CYCLE
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OVERVIEW BREAKDOWN

You've received a letter that says your device is "End of Support".
What now?

Let's break this down.

1) What does End of Support mean?
2) Could there be more devices approaching EOS that we don't know about?
3) What options do you have?

END OF SUPPORT

What does End of Support mean?

IMDRF International medical device regulators defines End of Support as

"Life cycle stage of a product starting when the manufacturer terminates all service support activities and service support does not extend beyond a certain date." (Draft Document April/May 2022, 3.16)

WHAT DOES THIS MEAN EXACTLY?

- OEMs are running low on parts for the devices
- OEMs no longer have FSEs focused on these devices.
- Support will continue until the specified date with best efforts usually T&M type contract.
- No guaranteed uptime.
- No remote service.
- Won’t extend service on an EOS product especially if determined that the product is not safe.

LEGACY MEDICAL DEVICE

Sometimes an OEM will deem a device not safe if it falls into two categories

- Not physically safe
- Cybersecurity threat

These are referred to as Legacy Medical Devices

“Medical devices that cannot be reasonably protected against current cybersecurity threats”
(3.22 Legacy Medical Device syn. Legacy Device)

LEGACY CONT.

The MDS2 provides a list of vulnerabilities so that you can monitor them closely.

Meet with your IT team to devise a plan moving forward.

March 2023: HSCC Health Sector Council – Supplement to Health Industry Cybersecurity- Managing Legacy Technology Security (HIC-MaLTS)

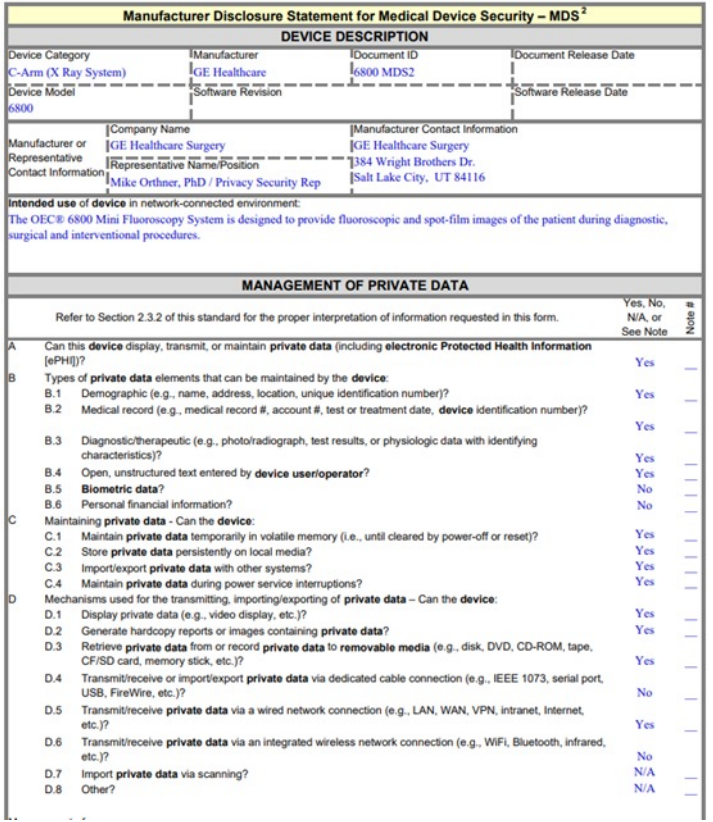
https://healthsectorcouncil.org/wp-content/uploads/2023/07/HIC-MaLTS-Quick-Reference-Guide.pdf

Principles and Practices for the Cybersecurity of Legacy Medical Devices- IMDRF

https://www.imdrf.org/documents/principles-and-practices-cybersecurity-legacy-medical-devices

Cybersecurity in Medical Devices: Quality System Considerations and content of Premarket Submissions

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cybersecurity-medical-devices-quality-system-considerations-and-content-premarket-submissions



Manufacturer Disclosure Statement for Medical Device Security – MDS²

DEVICE DESCRIPTION

Device Category	Manufacturer	Document ID	Document Release Date
C-Arm (X Ray System)	GE Healthcare	6800 MDS2	
Device Model	**Software Revision**		**Software Release Date**
6800			

Manufacturer or Representative Contact Information	Company Name	Manufacturer Contact Information
	GE Healthcare Surgery	GE Healthcare Surgery
	Representative Name/Position	384 Wright Brothers Dr.
	Mike Orthner, PhD / Privacy Security Rep	Salt Lake City, UT 84116

Intended use of device in network-connected environment:

The OEC® 6800 Mini Fluoroscopy System is designed to provide fluoroscopic and spot-film images of the patient during diagnostic, surgical and interventional procedures.

MANAGEMENT OF PRIVATE DATA

	Refer to Section 2.3.2 of this standard for the proper interpretation of information requested in this form.	Yes, No, N/A, or See Note	Note #
A	Can this **device** display, transmit, or maintain **private data** (including **electronic Protected Health Information** [ePHI])?	Yes	
B	Types of **private data** elements that can be maintained by the **device**:		
B.1	Demographic (e.g., name, address, location, unique identification number)?	Yes	
B.2	Medical record (e.g., medical record #, account #, test or treatment date, **device** identification number)?	Yes	
B.3	Diagnostic/therapeutic (e.g., photo/radiograph, test results, or physiologic data with identifying characteristics)?	Yes	
B.4	Open, unstructured text entered by **device user/operator**?	Yes	
B.5	**Biometric data**?	No	
B.6	Personal financial information?	No	
C	Maintaining **private data** - Can the **device**:		
C.1	Maintain **private data** temporarily in volatile memory (i.e., until cleared by power-off or reset)?	Yes	
C.2	Store **private data** persistently on local media?	Yes	
C.3	Import/export **private data** with other systems?	Yes	
C.4	Maintain **private data** during power service interruptions?	Yes	
D	Mechanisms used for the transmitting, importing/exporting of **private data** – Can the **device**:		
D.1	Display private data (e.g., video display, etc.)?	Yes	
D.2	Generate hardcopy reports or images containing **private data**?	Yes	
D.3	Retrieve **private data** from or record **private data** to **removable media** (e.g., disk, DVD, CD-ROM, tape, CF/SD card, memory stick, etc.)?	Yes	
D.4	Transmit/receive or import/export **private data** via dedicated cable connection (e.g., IEEE 1073, serial port, USB, FireWire, etc.)?	No	
D.5	Transmit/receive **private data** via a wired network connection (e.g., LAN, WAN, VPN, intranet, Internet, etc.)?	Yes	
D.6	Transmit/receive **private data** via an integrated wireless network connection (e.g., WiFi, Bluetooth, infrared, etc.)?	No	
D.7	Import **private data** via scanning?	N/A	
D.8	Other?	N/A	

MDS2 FORM

What is an MDS2 Form?

The Manufacturer Disclosure Statement for Medical Device Security, generally abbreviated MDS2 (or MDS^2), is manufacturer-completed and provided upon request.

Answers questions like:

- How can the device be patched?
- Does it require physical access, or can updates be provided remotely?
- Can the operator install patches on their own, or does everything have to go through the vendor?
- Does the device store or transmit Protected Health Information (PHI)?
- Does the device have anti-malware software?

COULD THERE BE MORE DEVICES APPROACHING EOS?

Tracking your equipment internally and with the OEM is vital.

Different ways to do this:

- Site ID and Serial Numbers tracking
- ECRI- recalls
- Inventory management company or internal role

Do you know about everything you have?

YOUR EQUIPMENT IS EOS: WHAT SHOULD YOU DO NEXT?

Don’t procrastinate.

Customers are usually told about EOS anywhere from 12-24 months prior to EOS. Don’t put the letter aside get started!

OEMs know at least 2 years before EOS. Ask!

If you pre-paid have the contracted pro-rated and refunded – go ahead and start getting that refund.

INTERNAL EVALUATION

QUESTIONS TO ASK:

- Where are we with Preventative Maintenance?
- Is the system still meeting our expectations and requirements?
- What do we want to be doing in a couple of years that you can’t do now?
- Current Budget? Future Budget? Cuts?

3RD PARTY EVALUATION

THIRD PARTY EVALUATION

Having a trusted 3rd party company evaluate the parts and service availability left for your system can potentially help your budget. On average you can save you 30-40% of what you were spending.

3RD PARTY EVAL CONT.

THIRD PARTY EVALUATION

An evaluation will shed light on:

• If the equipment is dead? (Some equipment is so old that used parts vendors have abandoned the last few bits and pieces based on space constraints).

• Are there parts on the market to support it?

• Is there service to support it?

• How much longer do we have?

QUESTION:

Do you know how many EOL & EOS pieces of equipment you have right now in inventory?

REAL LIFE EXAMPLE

- Hospital receives EOS letter on XYZ Cath Lab
- Entire system cost: $1,000,000
- Used for Years
- Received a letter
- Assumed upgrading to the latest and greatest was the only option
- Quote from OEM offered a very low trade in value and a very expensive piece of equipment
- They called a third party to sell the system told them about the EOS letter
- They expressed that they loved their system worked great
- The third party was able to provide an evaluation of parts and service and offer a service contract for the system
- They saved tons of money and was able to keep using the system they loved for several more years.

QUESTIONS?