



GUIDE 01 EVIDENCE PRESERVATION

A device failed. What happens next?

An evidence preservation checklist for counsel, risk managers, and clinical engineering.

AD

ABOUT

The first hours after a device-related incident decide what can be known later. A device that is reset, repaired, cleaned, or shipped away cannot tell its story twice.

This guide sets out the practical steps that keep the device, its data, and its records in a condition that an independent engineer can examine. It is written from the engineering perspective, for the people who must act first.

FOR

Legal counsel who must preserve evidence and plan an examination.

Risk managers who coordinate the response inside a facility.

Clinical engineering teams who hold the equipment and its records.

CONTENTS

01	Why the first hours matter	03
02	Six preservation steps	05
03	Reporting runs on its own clock	08
04	Common mistakes	09
	Checklist and sources	10
	How Alpha Devices helps	11

This guide is general technical information. It is not legal advice and does not replace your facility's policies, your reporting obligations, or the advice of counsel.

01

Why the first hours matter

A medical device keeps its evidence in fragile places. Settings live in memory. Event and alarm logs may hold a limited number of entries and overwrite the oldest first. Disposables and accessories leave the room with the waste. The device itself goes back into service, back to the manufacturer, or onto a repair bench.

None of this needs bad intent. It is the normal routine of a busy facility. But each normal step can remove information that later becomes the center of a dispute: what the device was set to do, what it actually did, and whether a part failed or was used outside its limits.

Three principles guide every step that follows.

RULE 1

Patient care comes first. Preservation starts only when the immediate situation is safe.

RULE 2

Preserve before you explain. Record what you see. Leave the explanation to the examination.

RULE 3

Document every transfer. Each time the device or its data changes hands, write down who, when, where, and why.

NOTE

A clear record made early is often worth more than a detailed test made late. Tests can be repeated. The original condition of the device cannot.

FIGURE

From event to examination

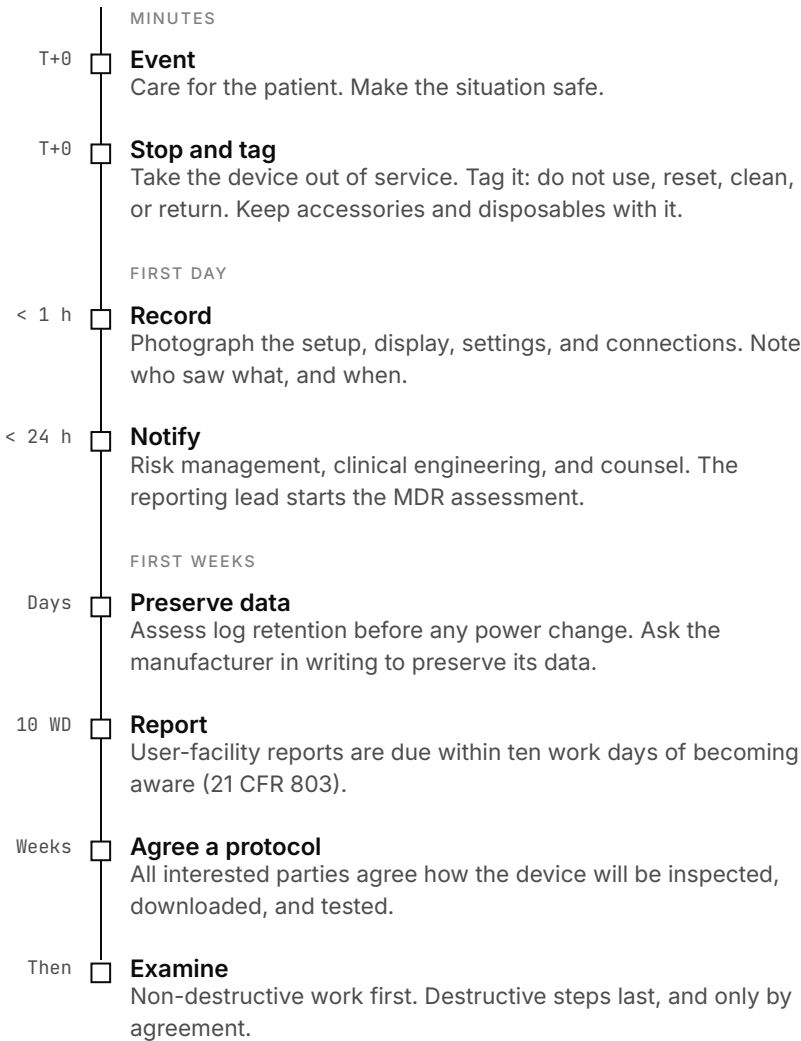


FIG 01 A typical sequence. Times are indicative; the reporting deadline is set by regulation and starts when the facility becomes aware of the event. WD = work days.

02

Six preservation steps

The six steps below follow the order in which the evidence is most at risk. Assign an owner to each step and record the date it was completed.

01

Secure the device

Identify and secure the device and everything used with it: accessories, disposables, tubing, cables, power supplies, and the packaging if it is still available. Record the model, serial number, lot number, software version, and the Unique Device Identifier (UDI) from the label.

Store the items in a locked area with a written log. Note the storage conditions. If the device was connected to a patient, record how it was disconnected and by whom.

02

Record its condition

Photograph the device before anyone touches it: the whole setup, each connection, the display, the settings, and any visible damage. Include a scale and the label in some photos. Do not change the settings to read them; photograph them as they are.

Interview the people who saw the event while their memory is fresh. Write down what they observed and when. Keep observations separate from explanations: "the alarm sounded" is an observation; "the sensor failed" is an explanation.

03

Preserve device data

Many devices store event logs, alarm histories, and therapy data. Some keep this data only while powered, and some overwrite the oldest entries. Before anyone powers the device down, plugs it in, resets it, or updates its software, have a qualified person assess how the data is kept.

When data is extracted, keep the original export files unchanged and work only on copies. Record the extraction method, the tool and version used, the device clock, its offset from local time, the time zone, and any change the extraction caused.

04

Request manufacturer data

The manufacturer may hold data that the facility does not: service records, remote-monitoring and cloud logs, complaint files, and its own analysis of returned units. Through the appropriate contact, ask in writing for this data to be preserved.

Ask three questions: what data exists, how long it is kept, and in what format it can be exported. Record the answers and the date of each request.

■ CAUTION

- A manufacturer may ask for the device to be returned for its
- own analysis. Before anything is shipped, agree in writing who
- will examine it, how, and in whose presence. A returned device
- may be opened, repaired, or tested to destruction.

05

Gather related records

Secure the records that place the device in context:

- maintenance, service, and preventive-maintenance records;
- alarm histories and nurse-call or central-station logs;
- relevant clinical records and the incident report;
- the instructions for use and any service manual in use at the time;
- prior complaints, work orders, and recalls for the same unit or model.

Match every record to the correct device, by serial number, and to the correct time period.

06

Plan the examination

Agree on a written protocol before any repair, return, disposal, or destructive work. The protocol should state what will be documented, how data will be collected, which tests will be run, who will attend, and how results will be shared.

Some steps change the evidence but cannot be avoided, such as decontamination of a device exposed to body fluids. Record what was done, why, and its likely effect on the evidence.

FORM

Chain-of-custody log

One line for every transfer of the device, its accessories, or its data.

DATE / TIME	FROM	TO	PURPOSE	SIGNATURE

03

Reporting runs on its own clock

Preservation and regulatory reporting are separate duties. Both start at the same time, and neither should wait for the other.

Under FDA's Medical Device Reporting rules (21 CFR Part 803), a device user facility, such as a hospital, must report a death that a device may have caused or contributed to, to both FDA and the manufacturer. It must report a serious injury to the manufacturer, or to FDA if the manufacturer is not known. These reports are due within ten work days after the facility becomes aware of the event. Facilities also submit an annual summary of their reports.

Manufacturers and importers have their own, separate reporting duties. Voluntary reports can also be made through FDA's MedWatch program.

ACTION

Involve the facility's MDR reporting lead promptly, and keep the reporting file with the incident record.

KEY POINT

A preservation request should name the device, the relevant dates, the data sources, and the people responsible for each one.

04

Common mistakes

Most lost evidence is lost by routine. These are the steps we see most often between the event and the first independent examination.

01

Resetting or updating the device

A reset, a battery change, or a software update can clear logs and settings.

02

Returning it to service

Another patient's use writes over the history of the event.

03

Discarding disposables

Circuits, sets, filters, and cassettes are often where the failure is.

04

Shipping it without a protocol

Once a unit is opened or repaired, its condition cannot be restored.

05

Photographing only the screen

Connections, accessories, and the surroundings are part of the evidence.

06

Mixing clocks and time zones

Device, network, and clinical clocks seldom agree. Record each offset.

07

Writing conclusions early

An incident report that names a cause before the examination can mislead everyone after it.

CHECKLIST

Preservation at a glance

- ☐ Device out of service and tagged
- ☐ Accessories, disposables, and packaging kept with it
- ☐ Model, serial, lot, software version, and UDI recorded
- ☐ Setup, display, settings, and damage photographed
- ☐ Witness observations written down with times
- ☐ Data retention assessed before any power change
- ☐ Original data exports kept; copies used for work
- ☐ Manufacturer asked in writing to preserve its data
- ☐ Maintenance, alarm, and clinical records secured
- ☐ Reporting lead informed; MDR assessment started
- ☐ Chain-of-custody log opened and kept current
- ☐ Examination protocol agreed before any change

SOURCES

FDA — Medical Device Reporting (MDR): How to Report Medical Device Problems

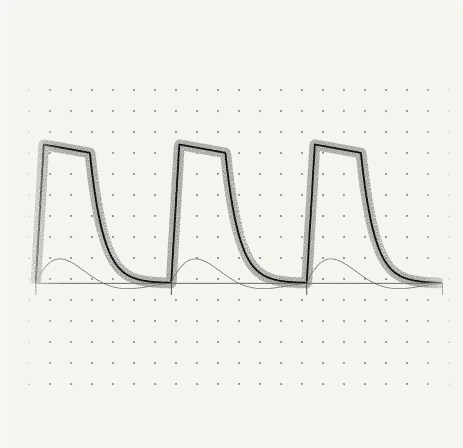
<https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>

eCFR — 21 CFR Part 803, Medical Device Reporting

<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-803>

NIST SP 800-86 — Guide to Integrating Forensic Techniques into Incident Response

<https://csrc.nist.gov/pubs/sp/800/86/final>



SERVICES

An independent examination, planned from the first day

We work with counsel, manufacturers, and health systems from the first call. Early involvement means the right evidence is kept and the examination answers the real question.

01

Preservation and protocol

We help define what to keep, draft the examination protocol, and attend joint inspections.

02

Inspection and data extraction

We document the device, extract and decode its logs, and reconstruct the event timeline.

03

Testing and analysis

We design tests that answer the questions the records leave open, and report the findings clearly.

CONTACT

Tell us about the device.

Send a short description of the device, the event, and any deadlines. We will tell you what to preserve now and recommend the next steps.

EMAIL info@alphadevices.io

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GUIDES

- 01 **A device failed. What happens next?**
- 02 Searching MAUDE with purpose
- 03 Understanding waterfall design

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