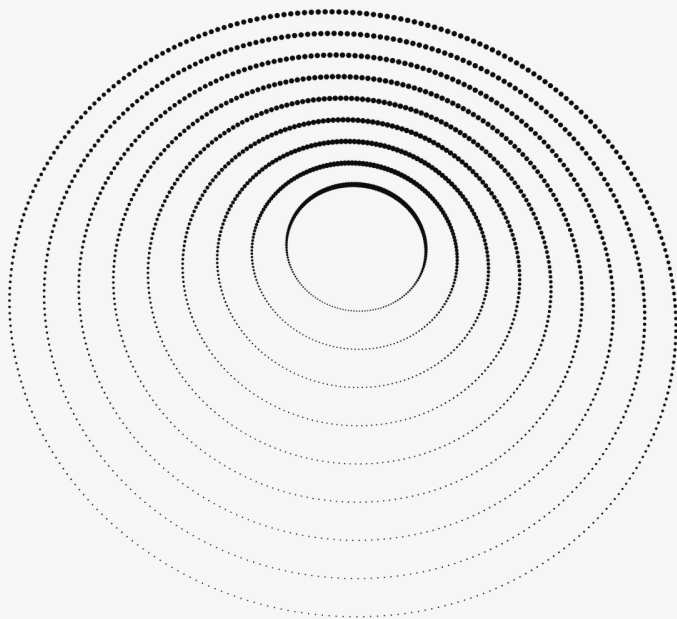




GUIDE 08 JOINT INSPECTION

The joint inspection

How to examine a device once, with every party present, in an agreed sequence that moves from looking to measuring to taking apart, and leaves one record that every party shares.



ABOUT

A failed device can be examined only once. Every step that follows power-on, disassembly, or a cut changes what the next step can find. The joint inspection is the way to take those steps in the right order, with every party watching, so the evidence is made once and shared by all.

This guide explains what a joint inspection protocol contains, how the examination is staged from non-destructive to destructive, what must be decided before the day, how the day runs, and the decisions that cannot be undone.

FOR

Legal counsel who must negotiate the protocol and know what to insist on.

Manufacturers — complaint, service, and engineering teams who attend the inspection and often bring the only service tool.

Hospitals — clinical engineering and risk management staff who hold the device and may host the examination.

NOTE

This guide is general technical information. It is not legal advice. The protocol for a specific device is written for that device, and the parties' agreement governs.

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SERIES This guide is one of fifteen practical guides from Alpha Devices. The full list is on the back cover; all are free at alphadevices.io/resources.html.

01

One device, one chance

An inspection protocol is a written, agreed sequence of steps. It exists because the parties do not agree on what happened, and because the examination will destroy some of the evidence of it. The protocol decides, in advance, what will be done, in what order, by whom, and how each step is recorded.

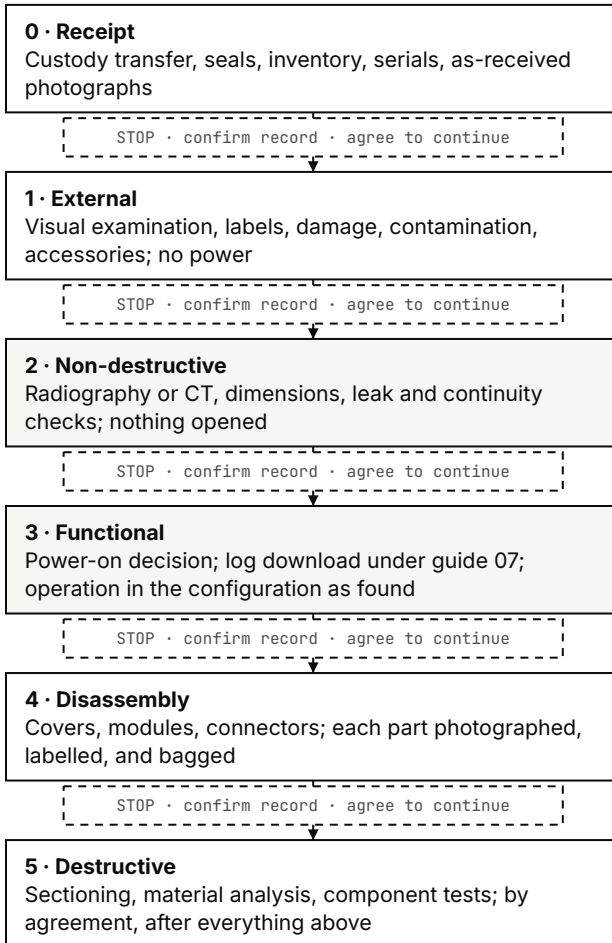
PURPOSE	To establish the condition of the device and record it, before any step that changes it. Not to decide the cause. Analysis follows the inspection, from the record it made.
PARTIES	Everyone with an interest: the facility, the manufacturer, the patient's representatives, and any component supplier the failure may reach. Each sends an engineer who can follow the steps and object to one.
PHASES	From the outside in: receipt, external examination, non-destructive tests, functional tests, disassembly, destructive examination. Each phase is complete and recorded before the next begins.
STOP POINTS	Agreed points at which the inspection pauses for every party to confirm the record and consent to the next phase. Any party may call an unscheduled stop. A dispute stops the work; it does not change the protocol on the day.
RECORD	Photographs, measurements, downloads, and a written log, all time-stamped, all copied to every party before anyone leaves. The record is the product of the inspection.

NOTE

Guides 01 and 07 cover the time before the inspection: preservation of the device and of its data. The protocol assumes both have been done, and begins by checking.

FIGURE

From the outside in



Reversible

Phases 0 to 2 change nothing. They can be repeated by anyone, later.

Changes the device

Power-on writes the log; disassembly breaks seals. From here the record is the only copy of the earlier state.

Irreversible

Often a separate session, under its own protocol, after the analysis of phases 0 to 4.

FIG 01

Each phase ends at a stop point. The order is not negotiable in principle, only in detail: nothing that changes the device is done before everything that does not has been recorded.

02 Writing the protocol

A protocol is a technical document agreed by lawyers. It is written by the engineers who will carry it out, and it answers the questions below in order.

01 Scope and objectives

Which device, accessories, consumables, and packaging; what the inspection is to establish; what it is not. Exemplar devices and the documents to have at hand: service manual, drawings, the log specification.

02 Place, equipment, people

The facility and its conditions; every instrument with its calibration; every attendee with a role. One person handles the device; the others observe and record.

03 The steps

Each step with its method, its instrument, the record it produces, and the person who performs it. Written so a stranger could repeat it. Nothing on the day that is not in the list.

04 Stop points and disputes

Where the inspection pauses; who confirms the record; what happens when a party objects. The rule is simple: an objection stops the step, the objection is recorded, and the work resumes only on agreement or reconvenes later.

05 What is not permitted

Service tools beyond read-only use; cleaning; repair; software update; removal of media; any step not listed. Stated, so that it does not have to be argued on the day.

06 Custody and copies

Who takes custody of the device and of every part removed; how parts are labelled and stored; how photographs, downloads, and logs are hashed and distributed before the session ends.

03

Before the day

01

The device, as it is

Confirm the preservation record (guide 01): where the device has been, who has touched it, whether it has been powered, cleaned, or serviced. If it was contaminated in use, the protocol decides whether and how it is decontaminated: cleaning removes evidence, and biological hazard is real.

02

Exemplars and references

An exemplar of the same model, software version, and configuration, for comparison and for any step too risky to try first on the evidence. The service manual, the drawings, and the log specification, so disassembly follows the designer's sequence.

03

Photography

A standard for every photograph: scale, serial or part label in frame, orientation stated, consistent lighting, a numbered sequence. Photographs are the record most relied on and most often inadequate.

04

The tools and who brings them

The manufacturer usually has the only service tool. The protocol names the tool, its version, the functions to be used, the functions excluded, and the observer who watches the screen.

- **CAUTION**

- A device returned to the manufacturer for "evaluation" before a protocol is agreed is examined once, by one party, under no protocol. The regulation requires the evaluation; it does not require that it happen alone.

04

On the day

The protocol is followed as written. The log is kept as it happens, by someone whose only job is the log.

01

Roll call and custody

Attendees recorded with roles; the device received against its custody record; seals and packaging photographed before they are opened.

02

Inventory as received

Every item, serial, label, and accessory listed and photographed before anything is moved. Discrepancies against the preservation record noted now.

03

Narrate and record

Each step announced before it is taken, its result stated aloud, both written in the log with the time. Photographs numbered against the log entry.

04

One pair of hands

One person handles the device for each step. Others observe, photograph, and ask for a step to be repeated or recorded differently.

05

Stops

At each stop point all parties review the log and photographs and agree the next phase. An unscheduled stop is called by saying so; work pauses until the objection is recorded.

06

Parts, data, and closing

Every part removed is labelled, photographed, bagged, and listed with its custodian. Every file is hashed and copied to each party. Then a final inventory against the opening one, signatures on the log, and the device resealed into custody.

05

What cannot be undone

Six decisions in an inspection change the device permanently. Each belongs in the protocol with its conditions, and none is taken on the day without the stop point before it.

POWER ON	Writes to the log, may run a self-test, may change state. Only after the external and non-destructive phases, with the log download planned (guide 07) and the screen recorded from the first frame.
CLEANING	Removes residues, deposits, and marks that show what the device was exposed to. Sampled and photographed first, or not done.
OPENING	Breaks seals, tamper labels, and the evidence of whether the device was opened before. Each seal photographed intact, then broken on camera.
CUTTING	Sectioning, pulling, and chemical analysis consume the part. On the exemplar first where possible; on the evidence only by agreement, at the end.
REPAIR	Any adjustment, replacement, or update, including by the manufacturer under a complaint investigation. Not part of an inspection; if it must happen, it happens after the record is complete.
RETURN	Sending the device back to the manufacturer or to service. After the inspection, under a custody record, with the parties' agreement on what may be done with it.

NOTE

After each of these, the earlier state exists only in the record. The record has to be good enough to stand in for the device.

06 Where inspections go wrong

These are the failures an engineering reviewer sees most often in inspection records, and in the inspections themselves.

01 **The manufacturer examined it first**
The device went back under the complaint process and was opened, tested, or repaired before any protocol existed. The complaint file is the only record.

02 **A step improvised**
Something was tried on the day because it seemed useful. It was not in the protocol, not agreed, and not reversible.

03 **Photographs without a reference**
No scale, no serial, no orientation. A picture of a part that cannot be shown to be that part.

04 **The tool did more than read**
A service tool used without an observer, with write functions available, and no record of which were used.

05

No exemplar

A destructive step taken on the evidence without first learning, on an identical device, what it would show.

06

Data on one laptop

Downloads and photographs copied later, from one party, with no hash recorded at the time.

07

A party absent

An inspection that proceeds without a party who was entitled to attend, and whose expert now disputes the record.

NOTE

A record with one of these gaps is still a record. The point is to know the gap before the other side points it out.

CHECKLIST

The joint inspection at a glance

- ☐ Preservation record reviewed: custody, power, cleaning, service since the event
- ☐ Protocol written by the engineers, agreed by every party, signed before the day
- ☐ Scope, device list, exemplar, and reference documents named
- ☐ Every step listed with method, instrument, record, and person
- ☐ Stop points before power-on, disassembly, and destructive steps
- ☐ Service tool named with version, permitted functions, and observer
- ☐ Decontamination decided in the protocol, with sampling first
- ☐ Photography standard: scale, serial, orientation, numbered sequence
- ☐ One handler per step; a dedicated log keeper; parts to a custodian as removed
- ☐ Files hashed and copied to every party; closing inventory and signatures

SOURCES

Sources and further reading

ASTM E860 — Standard Practice for Examining and Preparing Items That Are or May Become Involved in Criminal or Civil Litigation

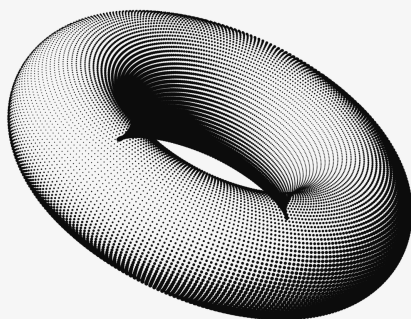
astm.org

ASTM E1188 — Standard Practice for Collection and Preservation of Information and Physical Items by a Technical Investigator; ASTM E1459 — Standard Guide for Physical Evidence Labeling and Related Documentation

astm.org

Alpha Devices — Guide 01, A device failed. What happens next?; Guide 07, What the device recorded

alphadevices.io



SERVICES

We write the protocol and run the inspection

We draft the protocol for the device in question, host or attend the inspection, handle the device, keep the log, and deliver the record to every party on the day.

01

Protocol

Written for the device, from its service documentation and our own examination of an exemplar, with the stop points and the excluded steps spelled out.

02

The examination

Radiography, measurement, functional testing, and controlled disassembly in our laboratory or on site, under the protocol, on camera.

03

The record

Numbered photographs, instrument data, downloads, and the log, hashed and distributed before the session closes.

TERMS

Terms used in this guide

Joint inspection

An examination of the evidence attended by every party, under one agreed protocol, with one shared record.

Protocol

The written, signed sequence of examination steps, with the method, instrument, record, and person for each, and the stop points between phases.

Non-destructive

A step that leaves the device as it was: looking, photographing, measuring, imaging. Can be repeated later by anyone.

Destructive

A step that consumes or permanently alters a part: sectioning, pulling, chemical analysis. The last phase of the inspection, taken by agreement.

Stop point

An agreed pause at which every party confirms the record so far and consents to the next phase.

Custody

Who holds the device or a part of it, recorded at every transfer, with seals where possible.

Exemplar

An identical device used for comparison and for any step too risky to perform first on the evidence.

Phase

One of the six stages of the inspection, from receipt to destructive examination, each closed by a stop point before the next begins.

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

WEB alphadevices.io

GUIDES

- | | | | |
|----|-------------------------------------|----|--------------------------------------|
| 01 | A device failed. What happens next? | 09 | How a device reaches the market |
| 02 | Searching MAUDE with purpose | 10 | Why the alarm did not help |
| 03 | Understanding waterfall design | 11 | When the software is the suspect |
| 04 | Reading an ISO 14971 risk analysis | 12 | Use error is a design question |
| 05 | The manufacturer's record | 13 | Complaints, MDRs and CAPA |
| 06 | Using LLMs to review case documents | 14 | Recalls, corrections and quiet fixes |
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