



COMPANY PRESENTATION · CAPABILITIES

Medical device failure analysis.

Independent engineering for counsel, manufacturers, and healthcare organizations.

What this presentation covers

Twenty minutes

Audience: counsel, quality and engineering teams, clinical engineering and risk management

The same content is on alphadevices.io

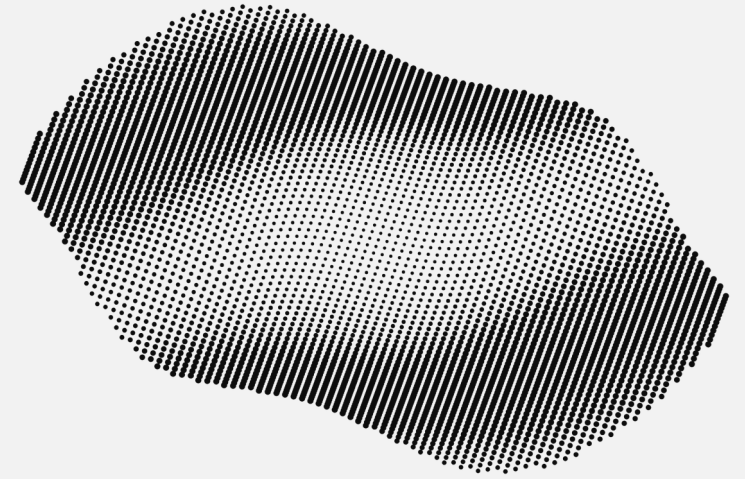
- 01 The firm
- 02 Capabilities
- 03 Who we work with
- 04 Device experience
- 05 How we work
- 06 Resources and tools
- 07 Contact

01

SECTION 01

The firm

An independent engineering consultancy focused on medical devices, based in Philadelphia.



A medical device is a system of interacting parts. Understanding an incident takes more than examining a single component.

alphadevices.io/about

Independent

We serve plaintiff and defense counsel, manufacturers, hospitals, and medical examiners. Opinions follow the evidence, whichever side retains us.

Understanding the complete system

We examine mechanics, electronics, fluid flow, heat transfer, sensors, and software to understand how the device behaved.

- Inspections and controlled experiments test the proposed explanations.

Design and quality records show how requirements and risks were addressed.

- MAUDE reports and other FDA records put the device's history beside the incident evidence.

We work with clients from the initial technical assessment through reporting and expert testimony.

- An engagement may involve a specific test, a documentation review, or a broader investigation.

Independent analysis in major litigation

\$1.1B

PHILIPS RESPIRONICS LITIGATION

Device analysis and expert-witness support in the Philips Respironics litigation, which reached a \$1.1 billion U.S. personal-injury and medical-monitoring settlement. The recall covered 15 million devices worldwide (FDA).

\$50M

OTHER LITIGATION SUPPORTED

Nearly \$50 million in combined verdicts and settlements across other matters supported by Alpha Devices.

8

DEVICE CATEGORIES

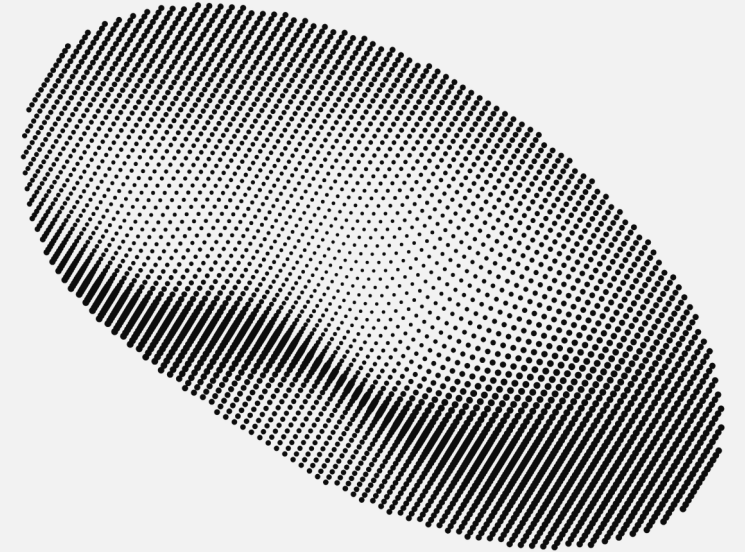
From cardiac and respiratory systems to infusion, temperature management, and patient support. See section 04.

02

SECTION 02

Capabilities

Six ways to answer the technical question. Testing, software analysis, documentation review, and FDA research each contribute to the answer.



Six capabilities, one question at a time

TABLE 01

The six capabilities on alphadevices.io/capabilities. The next three slides give the work behind each.

CAPABILITY	WHAT IT ANSWERS	WHAT YOU RECEIVE
01 Failure analysis & reconstruction	Determine what failed, how it happened, and which explanations the evidence supports.	A documented assessment of the failure mechanisms, the alternatives, and the limits of the evidence
02 Custom testing & measurement	Design experiments that answer the questions the records leave open.	A focused test program with methods, measurements, results, and limitations
03 Software, firmware & device data	Connect logged events with the physical behavior of the device.	An account of system behavior and event timing, with missing or conflicting data identified
04 Design & quality documentation	Review the QMS, DHF, risk file, and traceability matrix against real-world performance.	Design decisions and risk controls assessed against test results and field experience
05 MAUDE & FDA database analysis	Place an incident in context with adverse-event reports, recalls, and regulatory history.	A history of related reports and regulatory events, with search criteria and data limits
06 Expert reports & testimony	Explain the engineering clearly in reports, demonstratives, deposition, and trial.	Expert reports, technical demonstratives, and testimony grounded in the investigation

Failure analysis & reconstruction · Custom testing & measurement

01 FAILURE ANALYSIS & RECONSTRUCTION

Determine what failed, how it happened, and which explanations the evidence supports.

- Mechanical, electrical, thermal, and fluid-system analysis
- Device condition, accessories, and maintenance history
- Incident reconstruction and comparative evaluation
- Assessment of both malfunction and normal operation

You receive: A documented assessment of the failure mechanisms, the alternative explanations, and the limits of the available evidence.

02 CUSTOM TESTING & MEASUREMENT

Design experiments that answer the questions the records leave open.

- Custom fixtures and instrumented test environments
- Sample-device and comparative testing
- Pressure, flow, temperature, and particle measurements
- Repeatable experiments built around the technical question

You receive: A focused test program with recorded methods, measurements, results, and limitations.

Software, firmware & device data · Design & quality documentation

03 SOFTWARE, FIRMWARE & DEVICE DATA

Connect logged events with the physical behavior of the device.

- Code and firmware evaluation
- Event logs, waveforms, and time alignment
- Alarm, sensor, and control-logic analysis
- Correlation of recorded events with bench testing

You receive: A documented account of system behavior and event timing, with missing or conflicting information identified.

04 DESIGN & QUALITY DOCUMENTATION

Review the QMS, DHF, risk file, and traceability matrix against real-world performance.

- Verification and validation protocols, results, and deviations
- Complaint investigations and corrective and preventive action (CAPA)
- Warnings, instructions, design changes, and foreseeable use
- Analysis against the standards and requirements that applied at the time

You receive: An assessment of design decisions and risk controls against test results and field experience, with supporting records and open questions identified.

MAUDE & FDA database analysis · Expert reports & testimony

05 MAUDE & FDA DATABASE ANALYSIS

Place an incident in context with adverse-event reports, recalls, and regulatory history.

- Targeted searches by device, manufacturer, product code, and event type
- Review of event narratives, report patterns, and relevant dates
- Cross-checking related records and identifying potential duplicates
- Comparison with device testing, complaints, and design records

You receive: A history of relevant reports and regulatory events, supported by source records, search criteria, and a clear statement of the data's limitations.

06 EXPERT REPORTS & TESTIMONY

Explain the engineering clearly in reports, demonstratives, deposition, and trial.

- Early case assessment and evidence priorities
- Independent opinions and technical responses
- Discovery and deposition preparation
- Expert testimony and demonstrative development

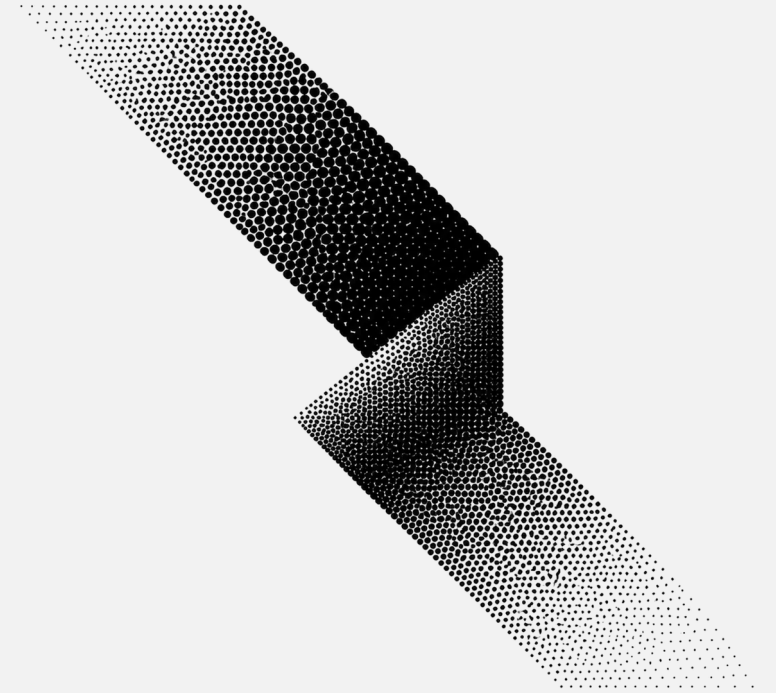
You receive: Clear expert reports, technical demonstratives, and testimony grounded in the investigation.

03

SECTION 03

Who we work with

Legal counsel, manufacturers, hospitals and health systems, and medical examiners. The question differs; the method is the same.



Four kinds of client, four kinds of question

TABLE 02

Counsel on either side of a matter, engineering and quality teams, clinical engineering and risk management, and death investigators.

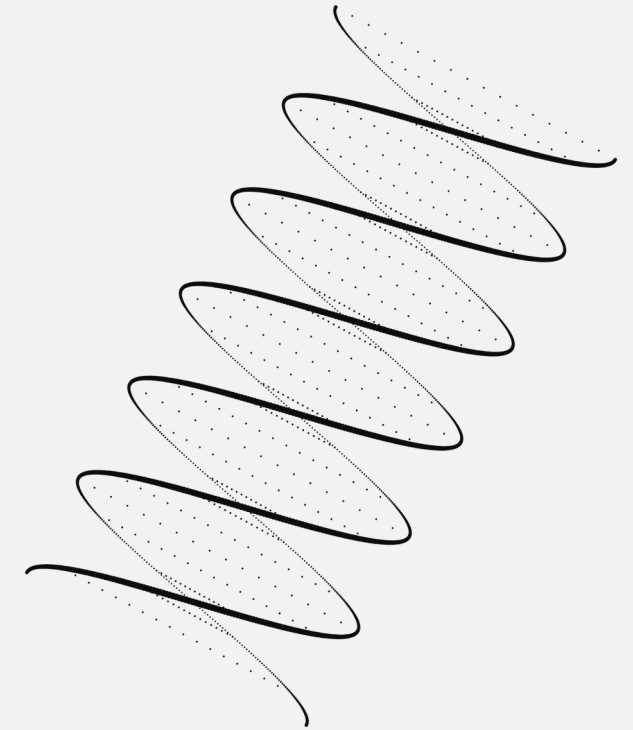
CLIENT	THE QUESTION	WHAT WE DO	WHAT YOU RECEIVE
Legal counsel	Understand the engineering behind the case.	– Identify inspection priorities, key design records, and evidence gaps – Reconstruct device behavior and evaluate causation theories – Connect MAUDE reports and recall history with the incident evidence	Independent analysis from early case assessment through reports, deposition, and trial.
Manufacturers	Find the cause of a device complaint.	– Investigate performance complaints and disputed failures – Review QMS records, the DHF, risk files, and requirements traceability – Evaluate complaint and recall patterns alongside test evidence	Focused testing and documented findings for engineering, quality, risk, and legal teams.
Hospitals & health systems	Establish the device’s role in an incident.	– Inspect equipment and review configuration and maintenance records – Connect device logs, alarms, and operating conditions – Identify evidence gaps and recommend further testing	An independent technical assessment to inform incident review, equipment decisions, and the response to a claim.
Coroners & medical examiners	Determine what the device did.	– Examine and document the device and its accessories – Extract and interpret device logs, alarms, and settings – Identify what the device evidence can and cannot establish	An independent engineering account of the device’s condition and recorded behavior, to inform the death investigation.

04

SECTION 04

Device experience

Experience across clinical and home-care device systems. The same grounding in mechanics, electronics, software, heat transfer, and fluid flow carries across the categories.



Device categories and the questions that guide the work

TABLE 03

Eight categories on alphadevices.io/devices. Each investigation starts from the question, not the category.

CATEGORY	DEVICES	ENGINEERING QUESTIONS
Cardiac & circulatory support	Heart-lung systems, perfusion pumps, and extracorporeal circuits.	Flow delivery, pressure, temperature, control behavior, and the interaction between pumps, sensors, and circuits.
Respiratory & sleep therapy	Ventilators, CPAP and BiPAP systems, and breathing circuits.	Pressure and flow, triggering, therapy delivery, alarm response, and materials in the breathing-gas pathway.
Surgical & procedural equipment	Powered surgical tools, energy-delivery systems, and operating-room equipment.	Mechanical performance, power and thermal behavior, accessories, protective functions, and use conditions.
Home care & portable devices	Home respiratory therapy, portable treatment, and patient-support equipment.	Settings, power interruptions, alarms, maintenance, and operation outside a controlled clinical environment.
Transplant & organ preservation	Organ transport, preservation, and perfusion systems.	How pressure, flow, temperature, and monitoring interact to maintain the intended operating conditions.
Infusion & fluid delivery	Infusion systems, syringe pumps, and fluid-management equipment.	Delivery accuracy, occlusion response, air detection, flow control, and the relationship between alarms and physical performance.
Warming & temperature management	Forced-air warming, heater-cooler systems, and circulating-fluid devices.	Heat transfer, airflow, particle transport, temperature regulation, and protective controls.
Patient support & monitoring	Hospital beds, positioning equipment, sensors, and alarm systems.	Mechanical movement, sensor behavior, alarm timing, operating configuration, and interactions with connected equipment.

05

SECTION 05

How we work

Four steps in every engagement, and three commitments that hold throughout.



From the first question to the last answer

01

Define the question

Clarify the technical question, review the available evidence, and agree on priorities and deadlines.

02

Follow the evidence

Inspect the device, review the records, and design tests that can distinguish between competing explanations.

03

Explain the findings

Present the methods, results, and limitations in a clear report for counsel and technical teams.

04

Support what comes next

Answer follow-up questions, evaluate opposing opinions, and present the findings in deposition and at trial.

Three commitments, and the requirements that applied at the time

THREE COMMITMENTS

Opinions follow the evidence.

- Possible causes of failure and evidence of normal operation get the same weight. We say what is established, what is uncertain, and what more could help.

Test what the records cannot answer.

- Where the documents leave a question open, we design experiments that distinguish between explanations, and report the limitations with the results.

Explain it clearly.

- Methods and results in terms counsel, clients, and juries can follow: reports, demonstratives, deposition, trial.

STANDARDS AND REGULATORY CONTEXT

The requirements that applied at the relevant time.

- IEC 60601, ISO 14971, IEC 62304, IEC 62366, and the device-specific standards, in the editions then in force.
- QMSR (21 CFR 820, incorporating ISO 13485:2016) since February 2, 2026; the former sections for earlier records.

Clearance, approval, and compliance answer different questions.

- None of them alone establishes the cause of an incident.

Practical guides and Claude skills, free on alphadevices.io

FIFTEEN PRACTICAL GUIDES

- 01 A device failed. What happens next?
- 02 Searching MAUDE with purpose
- 03 Understanding waterfall design
- 04 Reading an ISO 14971 risk analysis
- 05 The manufacturer's record
- 06 Using LLMs to review case documents
- 07 What the device recorded
- 08 The joint inspection
- 09 How a device reaches the market
- 10 How medical alarms work, and what the records show
- 11 When the software is the suspect
- 12 Use error and device design
- 13 Complaints, MDRs and CAPA
- 14 Recalls, corrections and other field actions
- 15 Building the device timeline

SIX CLAUDE SKILLS FOR CASE DOCUMENT SETS

- 01 Case brief
 - 02 Deposition summary
 - 03 Deposition compare
 - 04 Device timeline
 - 05 Complaint reader
 - 06 openFDA search
- Written instructions Claude follows on a case folder: index, extract, cite, verify. Every statement in the output can be opened and checked.
 - alphadevices.io/ai



Tell us about the device.

Share a brief overview of the device, the question you need answered, and any deadlines. We explain how we can help and recommend the next steps.

CONTACT

Alpha Devices Corporation

Independent medical device engineering

info@alphadevices.io

alphadevices.io