

Pressura eSTAR Readiness Review

Executive report

PTC-200 | Expanded fictional case ESTAR-TC-005B | Revision 3 | October 14 2026

Prepared by Panabistics Corp for device sponsors and submission owners evaluating the scope of a mock review.

Not ready for submission based on the expanded fictional evidence package.

Six Major findings and three Minor findings require a controlled response. The device is sufficiently defined to assess the internal evidence, but its release verification, pressure performance, alarm availability, usability, reuse support and operating range claims remain unresolved.

Expanded fictional demonstration authored for this sample. All device identities, specifications, document records, participants, test data and findings are invented. This is a source based editorial example, not an actual FDA filing, test laboratory record or output of the deployed automated reviewer.

The companion source book contains the fourteen invented D-series records used in this review. Source codes identify those records and their numbered sections. Public FDA references provide context; they do not authenticate the fictional evidence or turn this sample into an actual submission.

Decision and exposure

The PTC-200 case has a defined adult professional use, a controlled device and accessory configuration, risk controls, formal software records and several favorable test results. The readiness problem is concentrated in release verification, two adverse system observations, usability performance, reuse validation and the breadth of the accuracy claim. A complete looking set of report titles does not overcome these evidence conflicts.

Six Major and three Minor findings are supported by specified source sections. The Major findings require evidence or design and labeling decisions before package release. The Minor findings correct traceability and reporting defects; resolving them alone would not change the readiness conclusion. The same finding IDs, severity, evidence and closure rules appear in both reports.

Decision area	Required sponsor decision	Linked findings
Released software	Retain 3.2 only with an approved change impact assessment and justified verification coverage; select regression and any further formal tests from the actual change impact.	M01; informs M03 and M04 retesting
Cuff XL configuration	Investigate and correct the demonstrated failure, then verify the permitted family, or formally narrow the marketed family and reconcile every affected source.	M02; labeling and risk controls
Accuracy claim	Generate representative operating boundary evidence or narrow the claim and operating envelope with a justified impact assessment.	M06; independent from correcting XL
Alarm information and usability	Resolve the electromagnetic interruption and low battery response failure; update controls and validate the final user interface.	M03 and M04; integrate with M01 baseline
Reuse process and service life	Choose the final supported cleaning process and service life, then provide evidence matched to that process and life.	M05; instructions and material compatibility
Controlled package	Correct charging instructions, timer calculation and electrical report revision; perform a final consistency pass.	m01 to m03; after technical changes

Submission release should be held while any Major finding remains unclosed. Document corrections must accompany accepted technical evidence and a consistent final baseline. No financial return, clinical safety conclusion or regulatory outcome is inferred from this sample.

Device and evidence baseline

The PTC-200 is a single channel reusable pneumatic tourniquet controller for trained perioperative professionals treating adults. HW B and firmware 3.2 are the proposed baseline. The controller has an integral pump, valves, transducer, independent cutoff, display, alarms, timer and backup battery. It is used with H-200 Rev B and the C-200 M, L and XL Rev A single use cuff family. There is no home use, automatic pressure selection, pediatric use, wireless link or companion app. [D01.01-D01.04]

The cuff has intact skin contact for the defined exposure; the controller and hose have no patient contact. The controller and hose are reused, while cuffs are discarded after one patient. Biological evaluation addresses the cuff contact materials and exposure; cleaning assessment addresses the reusable controller process and life. [D01.04, D10, D11]

Evidence area	What is supported	Practical limit
Device definition	One model, hardware, firmware, accessory family, intended users and contact boundary are identified.	D01.01 to D01.05
Normal room condition regulation	M and L cuffs meet stated room condition limits on the tested power configurations.	D07; limited to tested conditions
Timer performance	All three reported signed errors are within plus or minus 2 seconds; the reporting statistic needs correction.	D07; m02
Risk controls	Pressure cutoff, transducer fault response and timing controls have a defined requirement and evidence structure.	D04 to D07; release bridge still open
Biological scope	Contact materials, exposure and the cuff family coverage rationale are described.	D10; full report access remains a boundary
Security boundary	No network or user data interface is present; internal service programming is explicitly assessed.	D13; no blanket cybersecurity exclusion

Findings requiring action

ID	Rating	Finding	Evidence sections
M01	Major	Released firmware 3.2 lacks formal verification coverage	D04.03, D05.04, D05.05, D06.01, D06.02, D06.03, D07.01
M02	Major	XL cuff under pressure result fails its acceptance criterion	D04.02, D04.03, D05.02, D07.01, D07.02, D07.03
M03	Major	EMC alarm information interruption exceeds the protocol limit	D04.02, D04.03, D05.01, D08.01, D08.02, D08.03, D08.04
M04	Major	Low battery critical task failures are counted as successful use	D02.03, D04.02, D04.03, D05.03, D09.01, D09.02, D09.03, D09.04, D09.05
M05	Major	Labeled cleaning process and reuse life lack matching validation	D02.02, D03.05, D04.02, D10.01, D10.04, D11.01, D11.02, D11.03, D11.04
M06	Major	Full operating range accuracy claim exceeds bench evidence	D05.02, D07.01, D07.02, D07.03, D07.04
m01	Minor	Referenced charging instructions are absent	D03.03, D03.04, D09.01, D09.04, D09.05
m02	Minor	Timer summary misstates maximum absolute error	D05.02, D07.06
m03	Minor	Electrical evidence declaration points to an absent revision	D14.02, D14.03, D08.01, D08.05

Major means a failure, unresolved assurance issue or evidence gap that can materially affect the proposed safety or performance argument. Minor means a reporting, instruction or traceability defect requiring correction without a separately demonstrated fundamental failure. These are Panabistics editorial ratings for this demonstration, not FDA deficiency categories, a probability score or a prediction of clearance.

The six Major findings are separate closure units. Shared test planning can address their dependencies, but none is counted again merely because the same defect appears in labeling, risk management or another report. The three Minor findings remain visible in the same register. Scope boundaries are not counted as deficiencies.

What must change in the evidence

M01 Released firmware 3.2 lacks formal verification coverage

SV-PTC-2026-01 Rev A reports 21 of 21 defined formal checks passing on 3.1 HW B. The submitted baseline and bench record identify 3.2 HW B. CHG-032 changes input debounce and battery-estimate filtering, but no approved impact analysis, 3.2 formal regression or evidence bridge is supplied.

Closure criterion: Close when the controlled evidence chain supports the released functions, explains retained results and documents the residual-issue and release disposition. A renamed report or repeated PASS assertion does not close the gap.

M02 XL cuff under pressure result fails its acceptance criterion

One U03 XL challenge on 3.2 HW B at 350 mmHg with a controlled 30 mL/min leak records 341, 342 and 340 mmHg after stabilization. Acceptance is 345 to 355 mmHg. Zero of three observations pass; signed errors are minus 9, minus 8 and minus 10 mmHg. The report nevertheless states all configurations passed.

Closure criterion: Close when the specific nonconformance has an approved technical disposition, final claims and configuration records agree, and confirmation evidence supports the retained criterion. Removing the row or averaging it with M/L passes is insufficient.

M03 EMC alarm information interruption exceeds the protocol limit

IMM-07 in the 3.2 HW B report records six seconds of display blanking during an electrostatic disturbance. Pressure regulation continues, but active alarm information is unavailable. The protocol permits no loss longer than two seconds. Nine other sequences meet their criteria; the summary says PASS and the deviation log provides no assessment.

Closure criterion: Close when the event, investigation, final functional criterion and executed confirmation agree, and the release/risk records adopt the supported disposition. Repeating a favorable sequence without addressing the original observation is insufficient.

M04 Low battery critical task failures are counted as successful use

HF-PTC-2026-01 Rev A evaluated 15 participants on firmware 3.2 HW B. In T06, N04, N09 and T03 mistook the low-battery icon for charging and continued without acknowledgement or mains connection. They completed only after task-solving prompts. Independent success is 12/15; assisted completion is 3/15, or 20 percent. The sponsor nevertheless reports 15/15 success, contrary to its independence rule.

Closure criterion: Provide traceable root-cause and corrective records, configuration identity, user-group rationale, independent task outcomes and a justified residual-risk disposition addressing the three original observations.

M05 Labeled cleaning process and reuse life lack matching validation

IFU Rev C specifies a 0.5 percent sodium hypochlorite wipe with 3 minutes wet contact. Its five-year life at 100 processing cycles annually represents 500 cycles. RV-PTC-2026-01 Rev A instead used 0.1 percent for 1 minute over 100 cycles, with passing appearance/function checks. No cleaning effectiveness study or bridge to the labeled process and life is supplied.

Closure criterion: The final claim must identify a supported process, controller configuration and lifetime, with clear distinction between cleaning/processing effectiveness and appearance/function compatibility endpoints.

M06 Full operating range accuracy claim exceeds bench evidence

The accuracy claim covers operation from 10 to 40 degrees C. The supplied nominal regulation subset is recorded at 23 degrees C on mains and initially full batteries; no 10- or 40-degree accuracy run or aged/near-depleted battery accuracy evidence is supplied. Three full-charge duration runs of 68, 66 and 64 minutes address a different endpoint.

Closure criterion: Close when the retained operating-range accuracy claim is supported by a traceable coverage argument and the necessary executed evidence, with exceptions resolved and final records aligned.

m01 Referenced charging instructions are absent

IFU-PTC-200 Rev C section 9 directs the operator to recharge according to section 12 before returning the controller to service. The submitted file contains no section 12 or equivalent controlled insert. Charging steps, charging-state explanation and readiness indication are therefore not supplied at the referenced location. The same IFU revision accompanied the human factors configuration.

Closure criterion: Provide the revised IFU and controlled location, with verification that the charging information is present, consistent with the baseline and available in the delivered instruction set.

m02 Timer summary misstates maximum absolute error

At 120 minutes, U01, U02 and U03 show signed timer errors +0.4, minus 0.8 and +1.2 seconds. The absolute values are 0.4, 0.8 and 1.2 seconds. Mean absolute error is $2.4/3 = 0.8$ seconds; maximum absolute error is 1.2 seconds. The submitted summary incorrectly labels 0.8 seconds as the maximum.

Closure criterion: Close when the corrected controlled record and any repeated statistics consistently reproduce the three observations and the two correct aggregate values, with the 3/3 passing disposition preserved.

m03 Electrical evidence declaration points to an absent revision

The declaration in D14.03 identifies ES-PTC-2026-220 Rev B. The controlled index in D14.02 and the supplied report identity in D08.01 instead identify Rev A, executed on firmware 3.2 hardware B. D08.05 confirms that only Rev A is supplied. No contents of an additional Rev B report are established.

Closure criterion: Provide a reconciled declaration and index with matching report code, revision, tested firmware and hardware. Any replacement report must be reviewed for its actual changes and its disposition of relevant anomalies before reliance.

Response sequence and release gate

1 Freeze the remediation baseline

Identify final HW, FW, cuffs, use claims and cleaning instructions. Keep a signed decision log of retained and narrowed claims. Owner: Regulatory lead with engineering and quality. Deliverable: Approved configuration and affected document list.

2 Resolve technical causes

Assess firmware change; investigate XL result and alarm interruption; analyze battery task failures and reuse mismatch. Document hypotheses and evidence, not a premature pass. Owner: Software, systems and human factors leads. Deliverable: Root cause and change assessments with risk updates.

3 Approve evidence plans

Select tests, boundary configurations and HF retest scope from the actual changes. Define acceptance before execution and identify dependencies. Owner: Verification lead with quality. Deliverable: Controlled protocols and rationale.

4 Execute and adjudicate

Run on final baseline, retain failures and deviations, link raw records and evaluate results against acceptance. A summary marked pass is insufficient. Owner: Test owners and independent reviewer. Deliverable: Executed reports with deviation disposition.

5 Reconcile labeling and assembly

Update claims, charging and cleaning instructions, risk links and revision index. Reconcile m01 to m03 and all linked sections. Owner: Regulatory and document control. Deliverable: Consistent controlled package.

6 Make the readiness decision

Evaluate every closure rule and remaining limitation. Obtain actual device specific classification, predicate and standards determinations outside this fictional demonstration. Owner: Accountable submission owner. Deliverable: Evidence backed release decision; no automatic readiness upgrade.

The response sequence is a dependency plan, not a promised completion date or a quotation for remediation. Duration depends on the root causes, test scope, laboratory and user study availability, and the sponsor decisions. This mock review identifies actions; it does not execute product redesign, testing or submission preparation.

Acceptance and scope boundaries

An action plan is not closure. Each finding needs a controlled response, updated evidence and an independent check of the stated closure criterion.

A new firmware number is not evidence of corrected behavior. Record build identity and the impact on every reused test and usability result.

A narrowed claim is a design and labeling decision with consequences. Update the device profile, risk analysis, comparison, validation scope and all affected instructions together.

A pass summary cannot override an out of limit observation or assisted completion. Retain the original result, investigate it and identify the superseding evidence.

Biological evidence is assessed for the defined intact skin cuff materials and exposure. A networked security scenario is not invented for this standalone device; internal service programming still has controls to assess. The comparison dossier is a fictional reasoning exercise. Real comparator identity, classification, actual standards applicability and current recognized versions must be established for a real submission. These boundaries are distinct from the nine findings. [D10, D12-D14]

The comprehensive report contains the full domain assessments, source cited findings, claim and configuration matrices, risk links, sponsor questions and closure checks. The source book makes the underlying invented evidence available for inspection. This executive report summarizes the same case and decision.