

Pressura eSTAR Evidence Source Book

Expanded fictional submission records

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

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.

This source book is the input evidence for the companion executive and comprehensive mock review reports. It contains both favorable observations and deliberate deficiencies. A test summary saying pass must be compared with the actual numbers and protocol criteria. The review reports show that analysis and distinguish a failed result, an untested claim and a reporting error.

Each D-series record is an authored extract with section identifiers. Read together they define the complete evidence boundary for this demonstration. They are not a completed eSTAR PDF, authentic laboratory reports, actual approved quality records or a substitute for device specific evidence. No sample value is a clinical treatment recommendation.

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Navigation uses PDF bookmarks and linked chapter names. Evidence references such as D07.03 identify numbered sections in the companion source book. Finding IDs M01 to M06 and m01 to m03 are identical across both reports.

D01 Device profile and configuration baseline

DP-PTC-200 | Revision C | Authored fictional record

D01 01 Device identity and clinical function

The Pressura Digital Tourniquet Controller PTC-200 is a reusable, nonsterile, single channel pneumatic pressure controller proposed for temporary control of limb blood flow during adult surgical procedures. Example Clinical Systems Inc is the fictional manufacturer. This demonstration configuration is hardware B with released firmware 3.2. There are no alternate controller models, software options or connected accessories in the package.

The trained healthcare professional selects pressure and monitors application duration for the particular procedure. The device does not select a patient specific pressure, determine limb occlusion pressure, measure blood flow or recommend treatment duration. Numerical engineering limits in this source book describe the invented device. They are not clinical instructions for use on a patient.

The pump supplies air through the H-200 hose to a permitted cuff. The controller compares measured pneumatic pressure with the selected setpoint and operates inlet and exhaust valves to regulate pressure. The independent cutoff switch provides an additional hardware limit. Pressure display, audible and visual alarms, a procedure timer and battery indication support the user's monitoring tasks. None substitutes for the professional's observation of the patient and procedure.

D01 02 Submitted configuration and physical interfaces

The controller enclosure measures 230 by 180 by 160 mm and has a mass of 2.8 kg. It accepts 100 to 240 V AC at 50/60 Hz and includes a rechargeable backup battery. The pneumatic channel comprises an integral pump, controlled inlet and exhaust valves, an internal pressure transducer and an independent cutoff switch. One processor performs sensing, control, display, alarms and timer functions. The controlled hardware baseline is B.

The user accessible interfaces are the mains inlet, pneumatic port, front panel display, pressure selection controls, start and stop controls, alarm acknowledgement and timer controls. There is no user accessible data or firmware port. Authorized service can open the enclosure and use an internal programming connector with a controlled service fixture. This service path is a separate lifecycle boundary described in D13.

The supplied hose H-200 Rev B is the only permitted hose. The proposed cuff family is C-200 M, C-200 L and C-200 XL, each Rev A. These are single patient, single use, nonsterile cuffs supplied under the same fictional manufacturer's configuration control. M, L and XL are accessory configurations of the one controller, not additional controller variants. The cuff family has common patient contact materials and processing; its pneumatic loads differ and require configuration coverage in the bench evidence.

Item	Configuration	Role and boundary
Controller	PTC-200 HW B and FW 3.2	Reusable nonsterile pressure regulation unit
Hose	H-200 Rev B	Reusable pneumatic connection with no patient contact
Cuff M	C-200 M Rev A	Single use intact skin accessory; smaller family load

Item	Configuration	Role and boundary
Cuff L	C-200 L Rev A	Single use intact skin accessory; intermediate family load
Cuff XL	C-200 XL Rev A	Single use intact skin accessory; largest family load
Service fixture	Controlled internal programming fixture	Authorized service only; not a clinical accessory

D01 03 Design limits and labeled claims

The submitted design baseline defines the numerical limits below. These values allow the reader to judge the invented results against an explicit criterion. A result inside the pressure range is not, by itself, proof that regulation accuracy, alarm behavior, usability and reuse claims are all supported. Each claim has its own evidence and configuration boundary.

The proposed accuracy statement is within plus or minus 5 mmHg after 10 seconds stabilization over the full labeled operating range. It is stated for all three permitted cuffs and mains or battery operation. The source package does not restrict this claim to room temperature, full battery or a reduced cuff family. The timer accuracy claim applies over a 120 minute timer interval. Neither the timer interval nor the pressure range prescribes a clinical treatment setting.

Characteristic	Invented specification	Evidence implication
Pressure selection	100 to 350 mmHg in 5 mmHg steps	Test endpoints, intermediate settings and permitted loads
Pressure regulation	Within plus or minus 5 mmHg after 10 seconds stabilization	Claim includes operating environment and permitted power states
Independent pressure cutoff	400 mmHg	Verify limit behavior separately from normal regulation
High pressure alarm	Setpoint plus 20 mmHg sustained for 2 seconds	Assess detection, annunciation and user response
Low pressure alarm	Setpoint minus 20 mmHg sustained for 5 seconds	Assess loss of pressure and meaningful annunciation
Timer	Within plus or minus 2 seconds over 120 minutes	Report maximum absolute error, not only an average
Battery	At least 60 minutes from full charge; alarm at 15 minutes estimated remaining	Support runtime, estimation and actionable user response
Operating environment	10 to 40 degrees C; 30 to 75 percent RH noncondensing	Claims require coverage or justified bounds
Storage	Minus 10 to 50 degrees C	Storage conditioning requires separate rationale
Service life	Five years at 100 cleaning cycles per year	Reuse claim covers 500 cycles and labeled cleaning process

D01 04 Users patients and component contact

The proposed patient population is adults aged 18 years and older undergoing surgery. The intended users are trained surgeons, circulating nurses and other licensed perioperative healthcare professionals in operating rooms and ambulatory surgical centers. Home operation, self use, use by untrained people, pediatric or neonatal use and automatic limb occlusion pressure determination are outside the proposed scope.

The cuff's outer woven polyester and edge binding directly contact intact skin for no more than 120 minutes per procedure in this invented use definition. The silicone bladder is enclosed by the textile; seam thread and hook and loop fastener are described in the material declaration. The controller and hose do not contact the patient. This contact map supports a specific biological evaluation scope rather than an empty applicability statement. D10 documents its reasoning and remaining access to full test reports.

The controller and hose are reused between patients; the cuffs are discarded after one patient's use. No device component is claimed sterile or intended to enter the sterile surgical field. The controller exterior is cleaned and disinfected between patients under the proposed IFU. The case does not authorize sterilization, immersion or cuff reprocessing. Those boundaries are part of the evaluation, not options left for the reader to guess.

D01 05 Version and evidence configuration map

The released baseline is firmware 3.2 on hardware B. The formal software verification report executed firmware 3.1 on hardware B. Change CHG-032 alters input debounce and battery estimate filtering. The provided change record describes implementation but contains no approved impact assessment, regression selection or evidence bridge. Later system and usability observations on 3.2 do not identify which 3.1 software requirements remain covered after this change.

System bench report PT-PTC-2026-01 Rev B, human factors report HF-PTC-2026-01 Rev A and electrical and EMC report ES-PTC-2026-220 Rev A identify firmware 3.2 on hardware B. The declaration index references ES Rev B, which is absent. Software revision coverage and the electrical document revision pointer are separate issues: the first affects release assurance; the second concerns retrieval and accuracy of the assembled evidence.

Record	Firmware and hardware	Configuration assurance boundary
D01 released baseline	3.2 and B	Defines proposed device
D06 formal software verification	3.1 and B	No approved bridge to 3.2
D07 system bench	3.2 and B	M and L room condition results; XL failure and range gaps
D08 electrical and EMC	3.2 and B	IMM-07 recorded interruption exceeds criterion
D09 human factors	3.2 and B	15 nurses and technologists; battery task needs correction
D11 reuse validation	Controller exterior study	100 cycles using a different concentration and contact time

D01 06 Package status and demonstration boundary

The fourteen D-series records in this source book are the entire authored evidence set for the expanded demonstration ESTAR-TC-005B. They provide controlled narrative and table records for a mock readiness assessment. They do not include actual instrument files, photographs, biological laboratory reports, signed quality approvals or a completed eSTAR PDF. Apparent report codes and revisions are invented identifiers, not representations of performed laboratory work.

This expanded case is a standalone authored demonstration. Its specified failures and inconsistencies illustrate evidence assessment and response planning. These records do not describe a real device, sponsor, patient or test program.

No actual device classification, FDA product code, predicate clearance, standards conformity, clinical safety, market authorization or regulatory outcome is established. A real submission must supply genuine controlled evidence and current device specific regulatory determinations. The review's evidence conclusions are limited to the authored package and the explicitly defined fictional device.

D02 Intended use and clinical workflow

IU-PTC-200 | Revision B | Authored fictional record

D02 01 Indication patient population and clinical users

The Pressura Digital Tourniquet Controller, model PTC-200, is intended to provide temporary control of limb blood flow during adult surgical procedures through a compatible pneumatic tourniquet cuff. The clinician selects pressure and application duration for the particular patient and procedure. The controller maintains and displays the selected engineering setpoint; it does not determine a clinically appropriate pressure, select a treatment duration or measure an automatic limb occlusion pressure. The design specifications in the technical record are operating limits and performance criteria, not a treatment algorithm.

The intended patient population is adults aged 18 years and older. Pediatric and neonatal use are outside the proposed indication. Intended operators are trained surgeons, circulating nurses and other licensed perioperative healthcare professionals working in hospital operating rooms or ambulatory surgical centers. The professional responsible for the procedure retains responsibility for the clinical prescription and interpretation of device information. A circulating nurse may prepare the equipment and monitor it within the facility's allocation of professional responsibilities; the device does not itself allocate those responsibilities.

Home use, patient self use and use by an untrained person are excluded. The controller is nonsterile and remains outside the sterile surgical field. Its interface is intended to be viewed and operated by clinical staff near the controller. No remote display, remote alarm receiver, companion application or network connection forms part of the intended workflow.

D02 02 Marketed system and patient contact boundary

The submitted system contains one reusable PTC-200 controller, hardware B with firmware 3.2, and reusable hose H-200 Rev B. Permitted cuffs are the manufacturer's C-200 M, C-200 L and C-200 XL, all Rev A. These are single patient, single use, nonsterile cuffs. They are not returned to the controller's between-patient cleaning process. The controller has one pneumatic channel; the evidence does not describe simultaneous operation of two cuffs or a multi-channel configuration.

Only the cuff's outer textile and edge binding contact intact patient skin during the proposed use, for no more than 120 minutes per procedure. The controller and hose have no patient contact in the defined use. The component boundary in the contact map distinguishes cuff disposal from reusable-controller cleaning.

The professional must use a permitted cuff configuration and establish a pneumatic connection before initiating regulation. Cuff selection involves the permitted device configuration and the patient's procedure; this record supplies no patient-specific cuff application technique or clinical pressure recommendation. The 120-minute exposure boundary is not a statement that every selected pressure or continuous application for that duration is clinically safe.

D02 03 Interaction sequence and interruption management

The assessed interaction sequence begins with confirmation of model and configuration, inspection of the available equipment, connection of the permitted cuff circuit, selection and confirmation of the prescribed pressure, and initiation of regulation. During use the operator monitors displayed pressure, timer and alarm information. The operator must interpret an alarm as a request for assessment of the

patient, equipment and continuing procedure; an audible signal alone does not identify the appropriate clinical response. Pressure changes and application duration remain under professional control.

The six human factors task groups in D09 represent configuration identification, circuit connection, pressure selection and monitoring, high-pressure alarm response, timer setting and acknowledgement, and low-battery interruption response. They sample important interactions in the defined workflow rather than constituting a complete clinical operating procedure.

Mains and internal battery operation are intended to support the same local control functions. A low-battery indication at an estimated 15 minutes of remaining operation requires the operator to recognize the state, acknowledge it and arrange continued power or a controlled clinical response. Connecting mains is an available equipment response in the simulated task. Continuing without recognizing the warning can allow an avoidable interruption while a procedure is in progress. The risk analysis treats that scenario separately from a pressure accuracy failure; continued regulation at the time of the warning does not remove the need to understand it.

D03 Proposed labeling and claims

IFU-PTC-200 | Revision C | Authored fictional record

D03 01 Proposed label scope and configuration

The proposed IFU identifies Example Clinical Systems Inc as manufacturer and Pressura PTC-200 as the single controller model. The submitted configuration is hardware B with firmware 3.2 and hose H-200 Rev B. It lists cuffs C-200 M, L and XL Rev A as permitted, single patient, single use accessories. The professional must confirm that the cuff and hose belong to this permitted configuration before use. Substitution of an unlisted cuff is not represented by this IFU or by the submitted bench record.

The intended-use section describes temporary control of limb blood flow in adults aged at least 18 years during surgical procedures. Trained surgeons, circulating nurses and other licensed perioperative healthcare professionals are the intended users. Use is confined to operating rooms and ambulatory surgical centers; home use, self use, pediatric and neonatal use, automatic limb occlusion pressure determination and use in a sterile surgical field are excluded. Clinical pressure and time are selected by the treating professional rather than by a device recommendation.

D03 02 Numerical operating and performance statements

The specification panel provides the engineering setpoint range, stabilized pressure regulation claim, cutoff and alarm conditions. It makes the regulation claim for all three permitted cuff configurations across the stated operating environment and mains or battery power. The IFU does not restrict that accuracy statement to the medium and large cuffs or to a room-temperature, fully charged battery condition. Those scope statements determine the configuration and environmental coverage that the bench evidence must support.

The controller is described as 230 by 180 by 160 mm, with a mass of 2.8 kg and a 100 to 240 V AC, 50/60 Hz supply. Operating conditions are 10 to 40 degrees C and 30 to 75 percent relative humidity, noncondensing; storage is minus 10 to 50 degrees C. The internal battery claim is at least 60 minutes of operation from full charge.

Label statement	Proposed value or rule	Interpretive boundary
Selectable pressure	100 to 350 mmHg in 5 mmHg steps	Equipment selection range; no clinical setting is prescribed.
Pressure regulation	Within plus or minus 5 mmHg after 10 seconds of stabilization	Claim applies to M, L and XL cuffs over the labeled operating conditions.
Independent cutoff	400 mmHg	Engineering protective limit, not a therapeutic target.
High-pressure alarm	Setpoint plus 20 mmHg for 2 seconds	A sustained deviation condition rather than any momentary display excursion.
Low-pressure alarm	Setpoint minus 20 mmHg for 5 seconds	A distinct delay and threshold from the high-pressure alarm.
Timer display	Accuracy within plus or minus 2 seconds over 120 minutes	Display performance criterion; not a safe treatment-duration recommendation.

Label statement	Proposed value or rule	Interpretive boundary
Low-battery alarm	15 minutes estimated remaining operation	An estimate requiring operator attention, not a guarantee of remaining treatment time.
Battery duration	At least 60 minutes from full charge	Does not replace the missing charging instructions referenced by section 9.

D03 03 Alarm information and low battery response

The front panel presents pressure, timer and alarm state using the display and audible buzzer. Section 9 instructs the operator to attend to a low-battery warning, acknowledge it and connect mains or manage an orderly interruption according to the clinical situation. It distinguishes acknowledgement of the warning from restoration of an adequate power supply. A device that continues regulating immediately after the warning has not thereby demonstrated sufficient battery capacity for the rest of a procedure.

The battery-state graphic used in the proposed IFU and on the validation configuration is the interface assessed in D09. The IFU text describes the warning, but it supplies no independent evidence that users distinguish that warning graphic from a charging indication. Human factors observations must therefore be reconciled with the intended instruction. A facilitator's explanation during validation is not part of the on-device interface and cannot be substituted for a successful independent response.

D03 04 Charging cross reference in the submitted IFU

Section 9 contains the sentence: Recharge the backup battery according to the instructions in section 12 before returning the controller to service. The submitted Rev C file ends without section 12. Its contents list and body provide no charging section, charging display explanation, readiness indication or charging steps. The record does not supply an alternative controlled page or separate charging insert that fulfills this reference.

The document-completion record identifies no alternative instruction for establishing the charged state before the next use. The missing content must be reconciled with the controlled display and power behavior before the IFU is finalized; no new charging duration or performance claim is entered in this submitted section.

D03 05 Between patient processing and stated service life

The proposed between-patient instruction specifies wiping the controller exterior with 0.5 percent sodium hypochlorite and maintaining a wet contact period of 3 minutes, while avoiding fluid entry into the ports. The reusable controller remains outside the sterile field; no sterilization cycle is specified. The hose and single use cuffs must remain distinct in the system boundary so that controller exterior evidence is not presented as evidence for every connected component or for reuse of a cuff.

The five-year controller life at 100 processing cycles per year represents 500 cycles. Validation must cover the labeled chemical concentration, wet contact time and cumulative exposure. Appearance or function checks under a different process do not alone establish cleaning effectiveness or compatibility throughout that life; compare the claim with RV-PTC-2026-01 Rev A.

D04 Risk management and control traceability

RM-PTC-2026-01 | Revision B | Authored fictional record

D04 01 Scope and fictional risk method

This authored risk record covers the single-channel PTC-200 controller, hardware B and submitted firmware 3.2, used with hose H-200 Rev B and permitted C-200 M, L and XL Rev A cuffs. It considers operation by trained perioperative professionals for adult procedures. Pressure and application duration remain clinical selections; the numerical engineering limits in this dossier are not recommended treatment settings. The record contains invented scenarios and judgments, not reports of injury or estimates of real clinical event rates.

The fictional sponsor method describes a hazardous situation, the intended control and the evidence needed to support that control. Potential serious harm is considered for sustained excessive pressure, unrecognized loss of pressure, interruption or delayed release during a procedure, and cross-patient contamination. No numerical probability is assigned because this example contains no clinical exposure denominator. A control is recorded as supported only for its stated configuration and tested condition. A passing result from another firmware revision or an isolated nominal condition does not automatically establish the current release or the complete labeled range.

D04 02 Hazard and control register

The following register identifies the principal scenarios used in this sample. Each control is a fictional design measure rather than an assertion of real-world risk reduction. The independent pressure cutoff acts separately from normal firmware regulation, while the alarm and display remain necessary for the operator to understand device state. The low-pressure alarm is not treated as proof that an under-pressure regulation result is acceptable: the performance criterion and the alarm threshold answer different questions.

The battery-interruption scenario includes correct recognition and response to the low-battery state. Its acceptance cannot be reduced to whether a buzzer sounded. Contamination is associated with repeated controller handling between patients and with the defined accessory boundary. Single-use cuffs are not assigned a cleaning cycle. The cleaning-control claim is evaluated in D11 against the process actually described by IFU Rev C, rather than inferred from a generic statement that the controller is reusable.

Control	Hazardous situation	Intended measure	Evidence connection
RC-01	Sustained excessive cuff pressure	Firmware pressure limit plus independent cutoff at 400 mmHg	D05.02; D07.05
RC-02	Unrecognized loss of pressure or regulation outside the claimed band	Closed-loop regulation and high/low pressure alarms	D07.02 to D07.04
RC-03	Prolonged inflation or delayed response to elapsed time	Timer display and timeout information selected by the professional	D07.06
RC-04	Electronics fault or lost essential alarm information	Safe-state behavior, supervisor checks and interpretable alarm presentation	D05.01; D08.02 to D08.04

Control	Hazardous situation	Intended measure	Evidence connection
RC-05	Interruption following depleted battery	Low-battery warning at 15 minutes estimated remaining operation and response instructions	D05.03; D09.04
RC-06	Cross-patient contamination or deterioration during reuse	Defined between-patient cleaning and component-specific reuse boundaries	D03.05; D10; D11

D04 03 Evidence status and unresolved control coverage

For the submitted 3.2 build, nominal M and L regulation runs and the timer observations provide positive system evidence. They do not erase the XL challenge result. All three XL readings at a 350 mmHg setpoint with a controlled 30 mL/min leak are below the 345 mmHg lower acceptance boundary. The summary statement that all configurations passed is inconsistent with that recorded condition. RC-02 therefore requires a configuration-specific disposition, not another unqualified PASS label.

For alarm presentation, D08 records one of ten immunity sequences with six seconds of lost display information against a two-second limit. Continued pressure regulation is a useful observation, but it addresses a different functional channel from the unavailable active alarm information. RC-04 cannot be accepted through a claim that the processor continued controlling pressure. Similarly, the three of fifteen participants who continued without the required low-battery response in D09 are not independent successes after facilitator prompting. Their result remains relevant to RC-05.

The formal software evidence in D06 covers 3.1, while CHG-032 changes debounce and battery-estimate filtering before the 3.2 release. No approved change-impact assessment or bridge establishes which prior results remain applicable. This is a separate release-evidence gap even where a 3.2 system result is positive. The complete control-to-test disposition must therefore connect build identity, accessory configuration, observed data and the release decision.

Evidence question	Current disposition	Finding connection
3.2 formal software applicability	Not established by passing 3.1 verification	M01
XL regulation at 350 mmHg with controlled leak	0 of 3 observations within 345 to 355 mmHg	M02
Complete 10 to 40 degrees C accuracy claim	Nominal ambient evidence only	M06
Immunity alarm-information availability	IMM-07 exceeds two-second limit	M03
Low-battery user response	3 of 15 require facilitator intervention	M04
Labeled reuse process and five-year life	Different process and insufficient cycle coverage	M05

D04 04 Residual risk and release disposition

The fictional draft residual-risk worksheet labels the principal controls acceptable for intended professional use but does not incorporate the newly visible XL failure, the IMM-07 interruption or the unassisted low-battery task failures. That statement is retained as a sponsor position requiring revision, not adopted as an independent conclusion. There is no approval signature or completed release authorization in this authored record. The appropriate disposition is open pending reconciliation of the evidence.

Closure requires the owner of each affected control to record what changed, what remains supported and what evidence answers the unresolved condition. Restricting a claim or accessory scope may be considered only through controlled design, labeling and submission decisions; a reviewer cannot silently remove the XL row or the operating extremes to make the existing results pass. Any retained limitation must be visible in the risk analysis, instructions and comparison rationale. The final review must also check that new responses do not create contradictory firmware or report revisions elsewhere in the package.

D05 Software architecture requirements and change record

SD-PTC-2026-01 | Revision B | Authored fictional record

D05 01 Architecture and control boundary

Submitted firmware 3.2 executes on the controller's single processor. The sensing function reads the internal pressure transducer; the regulation function commands the integral pump and inlet/exhaust valves for the selected setpoint. The alarm function evaluates pressure and device-state conditions and drives the display and buzzer. The timer provides elapsed-time presentation. A supervisor monitors execution and fault transitions. This is an authored functional architecture, not source code or a measured proof of hardware independence.

The independent cutoff switch is a separate protective element with a 400 mmHg engineering threshold. The display-information path is observed separately from the pressure-control path.

User connections are mains and the pneumatic port only. There is no network, radio, USB, removable media, app or remote operation. Authorized service programming uses an internal connector with the enclosure open and a controlled fixture; D13 defines that boundary.

D05 02 Quantitative requirement baseline

These fictional engineering limits define the baseline used by labeling and the bench protocols; they are not clinical treatment settings. They are supplied explicitly in this expanded case.

Regulation within plus or minus 5 mmHg is distinct from the low-pressure alarm at setpoint minus 20 mmHg. A smaller deviation can fail accuracy without crossing the alarm threshold.

Requirement	Defined behavior	Scope
SW-01	Display acquired cuff-circuit pressure	HWB controller and permitted pneumatic configuration
SW-02	Setpoint 100 to 350 mmHg in 5 mmHg steps; regulation within plus or minus 5 mmHg after 10 seconds	Full claimed operating environment
SW-03	High alarm at setpoint +20 mmHg persisting 2 seconds; low alarm at setpoint minus 20 mmHg persisting 5 seconds	Audible/visual presentation
SW-04	Independent cutoff at 400 mmHg	Separate protective element
SW-05	Timer display accuracy plus or minus 2 seconds over 120 minutes	Displayed interval measurement
SW-06	Low-battery alarm at 15 minutes estimated remaining operation	Battery estimate and recognizable warning
SW-07	Present setpoint, pressure, timer and alarm state; support defined fault transitions	Front-panel interface and supervisor
PWR-01	At least 60 minutes operation from full charge	Claimed battery duration
ENV-01	Operation 10 to 40 degrees C and 30 to 75 percent RH noncondensing; storage minus 10 to 50 degrees C	Engineering environmental claims

D05 03 Alarm presentation and battery interface

The interface presents pressure, selected setpoint, elapsed time and alarm state on one display, with a buzzer for warning presentation. The fictional battery display includes a low-battery symbol alongside charge-related status information. The implementation intent is to distinguish a warning requiring action from an indication that charging is occurring. The supplied usability evidence shows that this distinction was not consistently understood: three of fifteen participants continued without acknowledgment or mains connection until prompted.

No redesigned interface or independent retest is included. Display correctness does not establish successful unassisted user response. The battery remaining-operation estimate is filtered in software; aged-battery accuracy is not characterized by this record.

D05 04 CHG 032 and missing release assessment

CHG-032 changes front-panel input debounce behavior and battery-estimate filtering between firmware 3.1 and 3.2 on unchanged HW B. The change record identifies those two functions and assigns the new release number. It does not include an approved impact analysis, a regression-selection rationale, completed 3.2 formal verification or a documented equivalence bridge to the 3.1 verification record. No fictional approval signature is inserted to close that absence.

The source does not establish that CHG-032 caused the low-battery use failures or the immunity interruption. Impact, retained-result justification and regression selection remain undocumented.

D05 05 Release trace and evidence limitations

The current configuration baseline is firmware 3.2 on HW B. Formal verification SV-PTC-2026-01 Rev A identifies 3.1; system bench PT-PTC-2026-01 Rev B identifies 3.2; human factors HF-PTC-2026-01 Rev A and electrical/EMC ES-PTC-2026-220 Rev A identify 3.2. These are separate evidence objects with different purposes. A common model number does not erase the software difference, while a common software number does not make a human-factors study an immunity test.

A configuration ledger should identify build, hardware, accessory condition, purpose and disposition. Source-code hashes, compiler configuration and production logs are outside this excerpt; their omission is not used to create additional findings.

D06 Formal software verification record

SV-PTC-2026-01 | Revision A | Authored fictional record

D06 01 Record identity and executed configuration

This fictional verification summary identifies firmware 3.1 on hardware B. It reports unit, integration and software-system verification against the seven functional requirement groups defined in the software baseline. The executed configuration is not firmware 3.2. The record is authored evidence for a demonstration and is not a real laboratory record, a certification or a claim that an actual commercial controller was tested.

The illustrative execution register contains twenty-one planned checks, three in each requirement group. Each check is reported executed once with a passing disposition. The denominator is therefore twenty-one checks on the 3.1 configuration, not twenty-one devices, twenty-one clinical uses or a reliability sample. No failures are reported within that defined formal register. The detailed procedures, source-code instrumentation and machine logs are not supplied; the summary must not be promoted into independent verification of those underlying artifacts.

D06 02 Formal check register

Each group contains three illustrative functional checks, each executed once on 3.1. A group pass is not a pass for every conceivable fault or environmental condition. Detailed procedures and logs are not supplied.

Group	Illustrative checks	Executed / passing	Configuration
SW-01 sensing	Input scaling; display update; invalid sensor handling	3 / 3	3.1 HW B
SW-02 regulation	Setpoint bounds; closed-loop command logic; stabilization handling	3 / 3	3.1 HW B
SW-03 alarms	High persistence; low persistence; audible/visual state linkage	3 / 3	3.1 HW B
SW-04 limits	Command clamp; independent-cutoff input handling; recovery lockout logic	3 / 3	3.1 HW B
SW-05 timing	Elapsed count; interval display; timeout transition	3 / 3	3.1 HW B
SW-06 battery	Estimate input; warning transition; display-state selection	3 / 3	3.1 HW B
SW-07 interface/fault	Input acceptance; supervisor transition; fault-state information	3 / 3	3.1 HW B
Total	Twenty-one checks, not a patient or device denominator	21 / 21	3.1 HW B only

D06 03 Unresolved 3 2 applicability

The verification record contains no executed 3.2 formal checks and no approved bridge. CHG-032's debounce and battery-filter changes are not linked to a signed impact assessment, selected regression

set or a disposition showing why particular 3.1 results remain valid. The omission is explicit; it cannot be repaired by changing the version printed on the summary.

The 3.2 bench and usability records supply complementary evidence but do not contain unit or integration regression coverage of the changed paths. No approved retained-evidence decision is supplied.

D06 04 Acceptance and reporting boundary

The record supports one positive statement and one unresolved decision: all twenty-one defined formal checks are reported passing on 3.1, and applicability to release 3.2 is not demonstrated. The report must retain both statements. Calling all software testing absent would discard positive evidence; calling the submitted release verified would add a conclusion the record does not supply.

D07 System bench protocol and results

PT-PTC-2026-01 | Revision B | Authored fictional record

D07 01 Protocol configuration and observation rules

The authored system bench record uses three fictional controller units U01, U02 and U03, each HW B with firmware 3.2, supplied hose H-200 Rev B and C-200 M, L or XL Rev A cuffs on a nonpatient pneumatic fixture. Nominal ambient is logged as 23 degrees C and 45 percent RH. Pressure observations use a fictional reference channel checked at zero and the upper test setting; the check record accepts agreement within 0.5 mmHg. These are invented protocol details, not traceable calibration certificates.

Regulation observations begin after the specified ten-second stabilization interval. For nominal M and L runs, three stable observations are recorded at 30, 60 and 90 seconds after command start. Setpoints are engineering challenge values of 100, 200 and 350 mmHg, not suggested clinical settings. Two power states are included: mains operation and a battery beginning fully charged. Each of three units receives both cuff sizes, all three setpoints and both power states, giving thirty-six run records and 108 stable observations.

The XL leak challenge is one additional run with three observations, not three independent devices. The supplied tables are invented executed data for this demonstration.

D07 02 Nominal M and L regulation results

All 108 M/L nominal stable observations fall within the applicable setpoint band. Each cell below summarizes nine runs and twenty-seven observations for one cuff/power combination. The three setpoints and three units are represented within each combination. Signed error is measured pressure minus selected setpoint. A negative value indicates under-pressure; it is not automatically a failed result unless it exceeds the permitted band.

Cuff and power	Runs / observations	Lowest signed error	Highest signed error	Within plus or minus 5 mmHg
M, mains	9 / 27	minus 2.4 mmHg	+2.1 mmHg	27 / 27
M, full battery	9 / 27	minus 2.7 mmHg	+2.4 mmHg	27 / 27
L, mains	9 / 27	minus 3.2 mmHg	+2.6 mmHg	27 / 27
L, full battery	9 / 27	minus 3.4 mmHg	+3.0 mmHg	27 / 27
Combined nominal subset	36 / 108	minus 3.4 mmHg	+3.0 mmHg	108 / 108

D07 03 XL controlled leak result and summary contradiction

The additional XL run uses U03 on mains at a 350 mmHg engineering setpoint with a controlled 30 mL/min leak. After stabilization, measured values are 341, 342 and 340 mmHg. The acceptance band is 345 to 355 mmHg. All three observations are below its lower boundary; none satisfies the regulation requirement. The mean measured pressure is 341 mmHg and the mean signed error is minus 9 mmHg. The largest absolute deviation is 10 mmHg.

The report's conclusion nevertheless states that all configurations passed. No approved deviation assessment, corrected table, root-cause evidence or repeat test is attached. A possible measurement

issue, fixture issue or product mechanism cannot be selected by assumption. The raw recorded values remain the source for the finding. The 0.5 mmHg fictional reference check does not make a reading of 342 mmHg reach the 345 mmHg boundary.

The combined inventory is thirty-seven runs and 111 stable readings: 108 nominal M/L readings pass and three XL challenge readings fail. These are bench counts, not clinical outcomes.

Run	Stable observation	Measured	Acceptance	Signed error	Disposition
XL-LEAK-01, U03	30 seconds	341 mmHg	345 to 355 mmHg	minus 9 mmHg	Fail
Same run and unit	60 seconds	342 mmHg	345 to 355 mmHg	minus 8 mmHg	Fail
Same run and unit	90 seconds	340 mmHg	345 to 355 mmHg	minus 10 mmHg	Fail

D07 04 Operating range coverage and battery duration

The proposed accuracy claim covers operation from 10 to 40 degrees C and 30 to 75 percent RH noncondensing. No accuracy run at 10 or 40 degrees C is supplied. The nominal battery runs start fully charged; no regulation evidence identifies aged or near-depleted battery conditions. Consequently, a full operating-range accuracy conclusion cannot be derived from the nominal subset, even after the XL failure is resolved.

Separate nominal battery-duration observations are U01 68 minutes, U02 66 minutes and U03 64 minutes from full charge to the protocol's defined end-of-operation indication at 23 degrees C. All three meet the at-least-sixty-minute claim in those recorded conditions. The denominator is three units with one duration run each. These observations do not characterize battery aging, warning interpretation or regulation at every charge state. They must not be used as a surrogate for the missing accuracy-corner coverage.

Condition	Accuracy evidence supplied	Review boundary
23 degrees C, M/L, mains	108-reading nominal subset includes mains runs	Supports tested subset only
23 degrees C, M/L, initially full battery	Nominal subset includes full-battery runs	Not aged or near-depleted coverage
10 degrees C and 40 degrees C	None	Operating temperature corners unresolved
Aged / near-depleted battery accuracy	None	Battery-state accuracy unresolved
Full-charge duration at nominal ambient	3 units: 68, 66, 64 minutes	All meet 60 minutes; not full life characterization

D07 05 Safety function observations

The protocol includes engineering checks of the separate cutoff, pressure-alarm persistence and simulated fault presentation. For the three units, the independent cutoff check records activation at 400 mmHg on the fictional reference channel. Pressure alarms are observed using the defined high and low offset conditions: setpoint plus twenty mmHg sustained two seconds, and setpoint minus twenty mmHg sustained five seconds. All three units show the expected audible and visual transition for each challenge. These checks do not convert the XL regulation error into an acceptable accuracy result.

The fault challenge uses a simulated transducer-fault input and records a safe-state/alarm response on all three units. It is a defined system observation, not evidence for every possible electronics failure. The protocol does not provide a complete fault-injection matrix. Any broader assertion about all supervisor or watchdog failures must be supported through the formal software and risk-control evidence rather than inferred from this single challenge.

D07 06 Timer data and arithmetic correction

Timer display errors are signed differences from the reference interval at 120 minutes. U01 is +0.4 seconds, U02 is minus 0.8 seconds and U03 is +1.2 seconds. Absolute errors are therefore 0.4, 0.8 and 1.2 seconds. Their sum is 2.4 seconds; dividing by three gives mean absolute error 0.8 seconds. The maximum absolute error is 1.2 seconds. Every observation is within the plus or minus 2-second criterion.

The summary incorrectly calls 0.8 seconds the maximum absolute error. This is a reporting-statistic error; all three timing results remain passing. The corrected record must preserve the signed observations, units, interval and denominator.

Unit	Interval	Signed error	Absolute error	Criterion	Result
U01	120 minutes	+0.4 seconds	0.4 seconds	at most 2 seconds absolute	Pass
U02	120 minutes	minus 0.8 seconds	0.8 seconds	at most 2 seconds absolute	Pass
U03	120 minutes	+1.2 seconds	1.2 seconds	at most 2 seconds absolute	Pass
Correct aggregate	3 units	Not used as maximum	Mean 0.8; maximum 1.2 seconds	All 3 within criterion	3 / 3 pass
Submitted summary	120 minutes	not applicable	States maximum 0.8 seconds	Arithmetic label incorrect	Minor m02

D08 Electrical and electromagnetic evidence

ES-PTC-2026-220 | Revision A | Authored fictional record

D08 01 Report identity and submitted configuration

This fictional report is ES-PTC-2026-220 Rev A for the PTC-200 controller on HW B with firmware 3.2. The described configuration includes hose H-200 Rev B and a representative C-200 L Rev A cuff circuit on a nonpatient fixture. Both mains and battery operation are included in the functional observation setup. Only Rev A is supplied. A declaration pointer to Rev B elsewhere is an inventory discrepancy, not evidence that a newer passing report exists.

The report describes fictional power and functional observations without asserting certification, conformity to any real standard, official test levels or laboratory accreditation.

The ten-sequence immunity log below is an authored engineering record. Its purpose is to make the functional acceptance decision auditable, especially the separation between continued regulation and lost alarm information. Counts refer to defined sequences in one fictional report, not ten devices, ten patients or a demonstrated probability of safe performance.

D08 02 Functional acceptance criteria and observation method

Before each sequence the controller is set to the protocol's engineering operating state, with pressure regulation active and a visible alarm message deliberately present for observation. A synchronized display capture and event log are used to compare the disturbance interval with pressure control and alarm-information availability. These are invented methods for this case and are not represented as an accredited test procedure.

The protocol permits no loss of essential alarm information longer than two seconds. Regulation, display availability and recovery are recorded separately. Recovery without intervention does not erase a duration exceedance.

The fictional electrical inspection and post-sequence functional checks identify no other open defect in the described setup. This is limited to the record and is not a standards-conformity claim.

Observed function	Protocol decision rule	Interpretation
Essential alarm information	No unavailability longer than 2 seconds	Independent of continued pressure regulation
Pressure regulation	Continue the commanded functional state through the sequence	Record separately from display visibility
Recovery	Record restoration and any operator intervention	Recovery does not erase an exceeded interruption limit
Post-sequence function	Complete the defined display/alarm/control check	No certification or real-standard conformity conclusion

D08 03 Ten sequence executed immunity log

The log contains ten sequences with one execution each. Nine meet the protocol's stated functional criteria. During IMM-07, an electrostatic disturbance is associated with display blanking for six seconds. Regulation continues, but the active alarm information is unavailable during that interval. The value is three times the two-second allowed duration and exceeds it by four seconds.

Internal challenge labels below do not assert official test levels. Each event is evaluated separately; averaging the interruption times cannot satisfy an event-specific limit.

Sequence	Internal challenge description	Alarm information unavailable	Regulation	Criterion disposition
IMM-01	Initial power-coupled disturbance sequence	0 seconds	Continued	Pass
IMM-02	Repeated power-coupled disturbance sequence	0 seconds	Continued	Pass
IMM-03	Enclosure disturbance sequence A	0 seconds	Continued	Pass
IMM-04	Enclosure disturbance sequence B	1 second	Continued	Pass
IMM-05	Pneumatic-port vicinity challenge	0 seconds	Continued	Pass
IMM-06	Mains-to-battery transition observation	1 second	Continued	Pass
IMM-07	Electrostatic disturbance	6 seconds	Continued	Fail: exceeds 2 seconds
IMM-08	Battery-powered disturbance observation	0 seconds	Continued	Pass
IMM-09	Repeated operating-state challenge	0 seconds	Continued	Pass
IMM-10	Final disturbance and recovery sequence	1 second	Continued	Pass
Total	10 single executions	IMM-07 only exceeds limit	No loss recorded	9 pass; 1 nonconforming

D08 04 Deviation assessment and overall summary discrepancy

Despite the IMM-07 observation, the report summary states PASS. The deviation log contains no assessment of the six-second alarm-information loss, no explanation for changing the criterion, and no approved corrective action or confirmation test. There is no basis in the supplied record to treat the event as acceptable merely because pressure stayed controlled or the display returned.

No cause is established. Investigation must retain the capture, alarm context, configuration and recovery information; resemblance to a software change is not causal evidence.

D08 05 Revision and conformity boundary

D14 points to Rev B, but only Rev A is supplied. Correcting that pointer is m03 and does not close the IMM-07 nonconformance. Final records must preserve the original observation and its technical disposition.

No actual standard edition, official immunity level, electrical class or certification is assigned. The record supports an internal functional nonconformance, not an FDA rejection, patient injury or named-standard violation.

D09 Human factors validation record

HF-PTC-2026-01 | Revision A | Authored fictional record

D09 01 Study configuration participants and setting

The validation record identifies PTC-200 hardware B, firmware 3.2 and proposed IFU Rev C as the evaluated configuration. Fifteen trained perioperative staff participated in a simulated procedural room without patients: ten circulating nurses and five surgical technologists. No surgeons were enrolled. All fifteen completed the same six task groups once. The cohort therefore provides 15 participant observations per task group and 90 participant-task opportunities overall; it does not provide 90 independent observations for a particular critical task.

The simulation included the controller, H-200 hose, permitted cuff configurations, mains connection and a means of presenting the low-battery state without exposing a patient to treatment. Participants could consult the supplied IFU. The facilitator introduced the scenario and observed actions but was instructed to withhold task-solving assistance until the protocol's independent outcome had been recorded. This arrangement separates a participant's independent performance from completion achieved after explanation.

The intended population also includes surgeons and other licensed perioperative professionals. The participant roster does not establish whether those roles use the interface in the same way as the enrolled staff. The study's represented population is the enrolled nurse and technologist cohort; no separate surgeon evaluation or completed role-grouping rationale is included.

D09 02 Critical task outcome and assistance rules

The protocol defines independent critical-task success as correct completion using the evaluated interface and available IFU, without a facilitator prompt that supplies the meaning of a display state or the next action. Asking the facilitator to repeat a neutral scenario instruction is distinguishable from assistance that explains the warning or directs a power response. Once task-solving assistance is needed, the independent attempt is unsuccessful even when the participant subsequently finishes the scenario.

For the low-battery task, the participant must recognize the presented low-battery warning, acknowledge it and connect mains or describe the controlled clinical interruption required by the scenario. Continued operation without recognizing the warning does not meet the criterion merely because the pump continues to regulate. The protocol records whether a meaningful response begins before the facilitator supplies a task-solving prompt.

A prompted completion is retained as an observation of how the participant responds to explanation. It may inform root-cause analysis and the design of a corrective action, but it does not reverse the independent outcome. The study supplies no numerical acceptable failure allowance that permits unresolved serious-harm-related critical-task failures. Counts must be reported by task with their denominator and assistance status; pooling successful tasks cannot dilute a task-specific failure.

D09 03 Participant task results

Each of the first five task groups records 15 of 15 independent completions and no observed serious-harm-related use error in that scenario. These results do not cover every possible use error or professional role. The sixth group is assessed separately.

Across all six groups, 87 of 90 opportunities were independently completed and three required assistance. For the low-battery task, 12 of 15 completed independently and 3 of 15 required assistance, or 20 percent. The pooled success count does not establish an acceptable low-battery interface.

Task group	Participants attempting	Independent success	Task-solving assistance	Observed serious-harm-related use errors
T01 Confirm model and intended configuration	15	15	0	0 in this scenario
T02 Select permitted cuff and connect pneumatic circuit	15	15	0	0 in this scenario
T03 Select prescribed setpoint and start/monitor regulation	15	15	0	0 in this scenario
T04 Recognize and respond to high-pressure alarm	15	15	0	0 in this scenario
T05 Set timer and acknowledge its notification	15	15	0	0 in this scenario
T06 Recognize and manage low-battery interruption	15	12	3	3 continued without recognizing the warning

D09 04 Low battery observations and prompt sequence

Participants N04, N09 and T03, representing two circulating nurses and one surgical technologist, interpreted the low-battery icon as a charging indication. Each continued the simulated procedure without acknowledging the warning or connecting mains. Their observations show a common interpretation problem involving the status graphic rather than three unrelated failures to operate the mains plug. The study contains no evidence that a patient injury occurred; the hazard is the potential for an unrecognized power interruption identified by the risk record.

After recording the initial response, the facilitator stated that the indicator meant low remaining battery operation and directed attention to the available mains supply. All three then acknowledged the warning and connected mains. That sequence demonstrates assisted completion after the meaning and response had been supplied. It does not demonstrate that the unchanged graphic communicated the intended information independently. The three prompted attempts remain within the original denominator of fifteen; they are not additional successful trials.

The study records the same interface baseline described in D05 and the same IFU Rev C described in D03. It does not contain a redesigned battery graphic, an alternative warning presentation, a controlled usability change record or an independent retest of a corrected interface.

D09 05 Sponsor summary and unresolved disposition

The sponsor labels all fifteen low-battery attempts successful because everyone eventually completed the scenario. This combines twelve independent and three prompted completions, contradicting the assistance rule. The final task table must retain both categories and justify its validation conclusion.

No completed root-cause assessment, revised interface, independent retest or residual-risk disposition is supplied. The other five task groups remain positive evidence. Correcting the count alone would not establish that the warning and response are effective for the intended users and environment.

D10 Contact map and biological evaluation

BE-PTC-2026-01 | Revision A | Authored fictional record

D10 01 Contact determination for the submitted system

The contact map follows the system boundary in DP-PTC-200 Rev C: one reusable nonsterile controller, hose H-200 Rev B and permitted C-200 M, L and XL Rev A cuffs. The controller and hose do not contact the patient in the intended arrangement and are not intended for a sterile field. Patient contact is confined to the cuff's external textile and edge binding against intact adult skin for no more than 120 minutes per procedure. No blood path, tissue penetration, mucosal contact or implant contact is included in this defined use.

The determination is component-specific. The enclosed silicone bladder transmits pneumatic pressure but is separated from skin by the outer textile. A pneumatic pathway is not a body fluid pathway. Hook-and-loop fastening and seam construction are included in the assembly review so that materials at an edge or joining feature are not omitted merely because the largest surface is textile. This contact determination is an explicit design statement for the submitted configuration, rather than an inference that a controller has no biological considerations.

Component or surface	Contact in intended use	Evaluation boundary
Controller enclosure	No patient contact	Reusable exterior processing is addressed in D11; not a patient-contact test article.
H-200 hose	No patient contact	Defined non-contact routing; no biological claim inferred for a different use.
C-200 outer woven polyester and edge binding	Direct intact-skin contact, no more than 120 minutes	Final finished cuff contact surfaces are included in the biological evaluation.
Enclosed silicone bladder	No direct skin contact in the defined construction	Material and assembly considered in the finished-device evaluation.
Hook/loop and seam thread	Assembly features reviewed with the cuff surface boundary	Material declaration and finished construction are considered; no unexplained omission of edge features.

D10 02 Materials manufacturing and size family rationale

The material declaration identifies the outer woven polyester, enclosed silicone bladder, hook/loop fastening, edge binding and seam thread for the final cuff assembly. The biological evaluation considers the finished construction and manufacturing/processing history rather than relying only on the generic names polyester or silicone. It records review of the material and processing declarations for the contacting surfaces and assembly features. No claim is made that a named polymer is universally safe irrespective of formulation, finishing or processing.

M, L and XL have the same contacting material family and processing sequence in this invented dossier. Their dimensional differences are addressed through the size-family rationale; the evaluation does not introduce an additional cuff supplier or a different skin-contact coating for XL. The rationale links the representative final finished cuff evaluation to all three permitted sizes. That coverage is distinct from

pneumatic performance: common biological materials do not establish that an XL cuff meets its pressure regulation criterion.

D10 03 Reported biological endpoint summaries

BE-PTC-2026-01 Rev A reports cytotoxicity, sensitization and irritation summaries for final finished cuffs. The summaries state that their respective study acceptance criteria were met and identify the evaluated articles as finished cuff material/construction represented by the material and processing declaration. The sponsor uses those summaries together with the contact determination and manufacturing review to support its biological conclusion for the proposed intact-skin exposure.

The supplied record is a summary-level evaluation. Full test methods, laboratory reports, extraction details and raw observations are not included in the submitted sample. The record includes the contact map, endpoint coverage and size-family rationale; the complete cited reports remain listed for normal submission assembly.

Endpoint summary	Reported article and result	What the review can conclude
Cytotoxicity	Final finished cuff; sponsor reports study criterion met	Positive summary evidence; complete methods and raw data remain part of normal report assembly.
Sensitization	Final finished cuff; sponsor reports study criterion met	No failed sensitization endpoint is reported in this record.
Irritation	Final finished cuff; sponsor reports study criterion met	No failed irritation endpoint is reported; conclusion remains limited to the defined contact use.

D10 04 Biological conclusion and separation from reuse evidence

The sponsor's biological conclusion is based on the defined contact category, material and processing review, final finished cuff endpoint summaries and rationale spanning M, L and XL. The supporting report package is identified for submission assembly so that article identity, methods and acceptance can be checked. No failed endpoint is reported in the supplied summaries.

This conclusion does not validate controller cleaning. Cuffs are single patient, single use and are not reprocessed; the controller is reusable but non-contacting in the proposed arrangement. Repeated chemical exposure of the enclosure, cleaning effectiveness and cross-patient processing controls must be evaluated within the intended reusable-device process. Biological evidence for the cuff and an appearance/function study on the enclosure answer different questions and cannot substitute for one another.

D11 Cleaning and reuse validation record

RV-PTC-2026-01 | Revision A | Authored fictional record

D11 01 Intended between patient process and lifetime claim

The reusable PTC-200 controller is intended to be cleaned between patients while remaining outside the sterile field. IFU Rev C specifies 0.5 percent sodium hypochlorite applied by wiping the enclosure and maintaining 3 minutes of wet contact, with precautions against fluid entry into ports. The controller is nonsterile; no sterilization claim or cycle is included. The single use cuffs are excluded from this reprocessing process and are not candidates for reuse under this record.

The labeled five-year life is expressed on a usage basis of 100 processing cycles per year. Its cumulative exposure is therefore 500 between-patient cycles. The service-life statement covers the reusable controller; it is not a five-year life for a cuff or a claim that one cleaning event prepares a single use accessory for another patient. Validation must align the intended concentration, contact duration and repeated exposure with the surfaces and functions covered by the claim.

The process has two questions that require separate evidence: whether the defined procedure achieves the intended cleaning/processing purpose, and whether the controller remains suitable for intended use after repeated exposures. A visual or functional compatibility check can inform the second question. It does not measure removal of soil or demonstrate a microbial reduction endpoint. The evidence inventory should identify which question each study actually addresses before a global validation conclusion is written.

D11 02 Executed study article chemical exposure and observations

RV-PTC-2026-01 Rev A evaluates the exterior of the submitted controller configuration using 0.1 percent sodium hypochlorite and 1 minute of wet contact, repeated for 100 cycles. The study identifies enclosure appearance and controller function checks as its outcomes. It does not execute the 0.5 percent concentration, 3-minute contact time or 500-cycle lifetime basis stated in the IFU. The record supplies no protocol amendment that changes the executed process to the labeled process.

The recorded observations concern visible enclosure condition, legibility and continued device operation under the study's compatibility checks. They are not a cleaning effectiveness study: no challenge soil, removal endpoint, disinfection efficacy endpoint or complete processing effectiveness method is supplied.

The concentration differs by a factor of five, the wet contact duration by a factor of three, and the labeled cumulative cycle count by a factor of five. These ratios describe the mismatch only. They are not interchangeable dose factors and do not establish linear chemical compatibility, equivalent cleaning or an accelerated aging model. Such a bridge would require a reasoned, documented basis tied to the actual materials, construction, process and endpoints.

D11 03 Reported results and supported interpretation

The study reports that its appearance and function checks met their stated criteria after the executed 100 cycles. Those results apply to the tested 0.1 percent, 1-minute process and the observations actually made. No observed enclosure failure, pressure-control failure or cross-patient infection is reported.

The report summary uses the phrase suitable for repeated clinical reuse without separating the tested exposure from the IFU process and lifetime claim. The detailed method does not support that unqualified

extension. There is no study of cleaning effectiveness and no approved bridge from the executed exposure to 0.5 percent for 3 minutes or from 100 to 500 cycles. A statement that all checks passed is therefore narrower than a conclusion that the marketed cleaning process and service life have been validated.

Variable or endpoint	Proposed IFU/life basis	Executed RV evidence	Coverage consequence
Sodium hypochlorite concentration	0.5 percent	0.1 percent	Labeled concentration not represented or bridged.
Wet contact period	3 minutes	1 minute	Labeled duration not represented or bridged.
Cumulative processing cycles	500 over five years at 100 per year	100	Five-year cycle basis not represented or bridged.
Exterior appearance and functional checks	Compatibility throughout intended reuse	Study criteria met under executed method	Positive result limited to the tested process and cycle count.
Cleaning/processing effectiveness	Between-patient processing instruction	No effectiveness study supplied	No measured cleaning or disinfection efficacy conclusion supported.

D11 04 Disposition required before release reliance

The supplied package contains no approved rationale equating the study process with the IFU process and no extension of compatibility observations to the labeled lifetime. The sponsor must decide the intended process and claim, then establish evidence against that controlled baseline. A simple summary wording correction cannot supply an effectiveness endpoint or repeated-exposure coverage that was never evaluated.

The open disposition is specific to the reusable controller's between-patient process. Cuff reprocessing and a sterilization cycle remain outside the intended process. The completed disposition must reconcile the contact map, system boundary, risk controls, actual study conditions and final IFU.

D12 Comparator rationale and equivalence comparison

SE-PTC-2026-01 | Revision B | Authored fictional record

D12 01 Comparison purpose and fictional comparator boundary

This comparison belongs to fictional case ESTAR-TC-005B. TPR-90 is a teaching comparator, not a verified legally marketed predicate. No clearance letter, genuine 510(k) number, product code, classification decision, clinical study or FDA determination is supplied. Table similarities are dossier assertions; they establish neither actual substantial equivalence nor eligibility for a particular pathway.

The exercise compares a single PTC-200 controller, hardware B and released firmware 3.2, with the fictional one-channel TPR-90. The proposed subject system includes hose H-200 Rev B and C-200 M, L and XL Rev A cuffs. These cuffs are sizes of the permitted accessory family, not additional controller hardware models. The comparison concerns temporary control of adult limb blood flow during surgical procedures under trained professional control. It introduces no pediatric indication, automatic limb occlusion pressure function, home use, remote supervision or clinical pressure prescription.

The common pneumatic regulation principle and intended purpose help identify evidence questions. They do not confer comparator performance, verify an untested change or turn engineering limits into clinical recommendations. A real submission needs a verified comparator and justified comparison. Fictional comparator status is a demonstration boundary, not a counted deficiency.

D12 02 Intended purpose and technology comparison

The table separates supplied similarities, known differences and information not established by the fictional comparator dossier. A blank technical history is not filled with invented results. Subject-device specifications originate in the subject design and labeling records; the comparator is described only to the extent needed for this exercise. Where a row identifies an evidence dependency, the actual subject record, rather than the resemblance assertion, controls the readiness decision.

Comparison topic	PTC-200 submitted configuration	TPR-90 fictional dossier	Interpretation and evidence boundary
Purpose and population	Temporary adult limb blood-flow control; professional surgical and procedural use	Same stated adult purpose and professional environment	Intended-purpose similarity is described; no actual FDA equivalence decision follows.
Pneumatic architecture	One channel with pump, valves, transducer and independent cutoff	One channel with analogous pressure sensing and regulation	Common principle does not establish matching failure responses or numeric cutoff performance.
Pressure selection	100 to 350 mmHg in 5 mmHg steps	100 to 350 mmHg; increment not supplied	Range matches; step equivalence is not asserted.
Power	Mains with internal backup battery	Mains and battery	Battery capacity, low-battery display and interruption behavior require subject evidence.
User interface	Revised battery display and estimated remaining-operation indication	Earlier battery-display approach, without numeric usability data	The subject low-battery task results govern the interface assessment.

Comparison topic	PTC-200 submitted configuration	TPR-90 fictional dossier	Interpretation and evidence boundary
Cuffs	C-200 M, L and XL Rev A from the fictional subject manufacturer	Different cuff supplier; materials and size-specific results not supplied	Supplier difference needs subject compatibility, performance and contact-material reasoning.
Connectivity	No network or user data interface; internal authorized-service programming connector	No connectivity described	A shared absence of networking does not prove the security of service access.
Regulatory status	Invented device with no actual authorization	Invented comparator with no verified clearance	A teaching boundary, not a counted sample finding.

D12 03 Differences and subject evidence dependencies

Two stated differences receive specific treatment: the battery display and the cuff supplier. The battery display changes the information available to users when operation may be interrupted. The comparison therefore points to the actual low-battery task observations in D09 and the architecture and change record in D05. It does not substitute the comparator's general battery feature for demonstration that PTC-200 users understand the displayed state. Whether pressure regulation continues during an event is also distinct from whether important alarm information remains visible.

The cuff supplier difference is bounded by the supplied contact map and final-finished-cuff biological evaluation in D10 and the size-specific system bench record in D07. A common adult indication does not erase cuff size, fit, pneumatic behavior or processing differences. The comparison retains the M and L passing observations, the XL result requiring investigation, and the declared limited skin exposure. It neither asserts a failed biological endpoint nor requests additional biological testing solely because the supplier differs.

Firmware 3.2 remains the release baseline. A similar control concept cannot relabel 3.1 formal verification as 3.2 evidence. The comparator's absence of networking cannot resolve service programming controls, nor can a shared mains-and-battery description resolve six seconds of lost alarm information. Each question remains attached to its subject source and finding.

D12 04 Comparison disposition and assembly instruction

Purpose, population, architecture and differences are usefully compared, but the evidence-dependent conclusion remains unresolved. Address failed, conflicting and uncovered subject evidence before a favorable conclusion. Preserve passing results and explain changed configuration coverage; a generic equivalence statement cannot replace that analysis.

A real application needs verified comparator identity and legal marketing status, relevant public decision and labeling information, and a justified intended-use and technology comparison. Its difference analysis must identify supporting subject evidence, remaining questions and each conclusion's basis. No invented identifier may be reused. This prerequisite remains outside the sample's nine counted findings.

D13 Security and service access assessment

CY-PTC-2026-01 | Revision A | Authored fictional record

D13 01 System boundary and access conditions

This fictional security assessment addresses the released PTC-200 firmware 3.2 on hardware B and the authorized service workflow. Normal users have a mains inlet and a pneumatic port. The controller has no network interface, radio, USB, removable media, companion application, cloud service, remote operation or user-accessible software update path. The internal programming connector requires an opened enclosure and a controlled fixture. These are explicit architecture boundaries, not missing networking tests and not a claim that the absence of internet connectivity eliminates all software or security risks.

The assets considered are the firmware image, its configuration and calibration values, pressure-control availability, alarm information and the service release record. The actor considered is a person with physical access to a controller or its service equipment. The sample describes no remote attacker route through a user network because no such route is present in the stated design. It does not claim that an enclosure is tamper-proof, that every physical attack is prevented, or that a general-purpose service workstation is incapable of internet access.

For this dossier, the fixture is offline during programming and is not supplied as a clinical accessory. The device is disconnected from patient use for service. A real assessment would confirm whether the service arrangement or other authorized related equipment changes the device's possible connections. That conditional architecture question is recorded as a boundary to verify, rather than resolved by the words standalone or embedded. No statutory cyber-device classification or binding exemption is declared in this invented record.

D13 02 Illustrative software component inventory

The inventory below is an authored configuration list, not a scan of a real binary and not a claim of an actual commercial supplier's software bill of materials. Every component identifier is fictional. It identifies the components expected in the teaching configuration so that release and service reasoning can be followed. There is one processor and no separate communications processor, mobile client or server. The list does not infer that all lower-level dependencies, build-tool effects or service-tool components have been independently enumerated.

A version in this table identifies the intended 3.2 build composition; it is not evidence that formal testing on the earlier 3.1 release covered that composition. No real CVE, package repository, license determination, cryptographic certification or vulnerability-scan result is supplied. The record makes no assertion of zero vulnerabilities. Production artifact hashes and independently reproducible build records are outside this fictional packet, so the table is used for configuration reasoning within the demonstration only.

Fictional component	Identifier	Function	Configuration boundary
Controller application	PTC-App 3.2	Pressure, alarm, display and timer logic	Subject release; linked to D05 requirements and change history.
Startup and service loader	PTC-Boot 1.0	Startup selection and internal-fixture programming workflow	No network update function; enforcement mechanisms are not independently tested here.

Fictional component	Identifier	Function	Configuration boundary
Hardware abstraction layer	PTC-HAL 2.0	Sensor, valve, display and buzzer interface routines	One hardware B processor; no radio or internet stack.
Embedded support routines	PTC-Runtime 1.0	Local arithmetic and memory support	Invented library identifier; no actual third-party provenance or vulnerability claim.
Configuration integrity routine	PTC-ConfigCheck 1.0	Detect accidental corruption of stored configuration	An integrity check is not represented as cryptographic authenticity protection.

D13 03 Service controls and threat to evidence reasoning

The authored service procedure directs trained service staff to quarantine the controller from clinical use, record its incoming hardware and firmware identity, select the controlled release package, and use the designated programming fixture. It calls for a second-person comparison of intended release and recorded output version before return to service, plus restoration of enclosure integrity and a functional check. These are described procedural controls. This packet does not contain executed service logs, an independent physical penetration test or a verified demonstration of cryptographic image authentication.

Three failure scenarios are considered without claiming observed incidents: an incorrect firmware package selected by service staff; accidental alteration of calibration or configuration during programming; and unapproved physical use of the internal connector. Package selection and the independent version check address the first scenario. Controlled configuration records and the functional check address accidental configuration effects. Restricted service access and fixture custody address unauthorized physical use at a procedural level. The analysis does not equate any of those controls with proof that an attacker cannot bypass them.

Return-to-service checking must include the intended release identity and applicable functional evidence, rather than only whether the display powers on. The present 3.1-to-3.2 formal-verification gap remains M01; the service procedure cannot close it. Similarly, the low-battery usability problem and the electromagnetic alarm-information interruption have their own observed evidence and remain M04 and M03. Neither is relabeled a cybersecurity event without evidence of a security cause. No extra security deficiency is counted simply to populate a cybersecurity chapter.

D13 04 Security disposition and future change triggers

The bounded disposition is that a no-user-connectivity rationale, a component inventory and procedural internal-service controls are supplied. The record does not demonstrate comprehensive security validation or independently establish statutory status. Its value is the traceable distinction between absent external interfaces and the remaining physical service boundary. A real submission author would reconcile that boundary with the actual released design, service equipment, available evidence and the then-current FDA cybersecurity recommendations.

Adding a radio, network adapter, connected accessory, service bridge or remote update path would invalidate the present architecture assumptions and trigger a fresh scope assessment. Changes to the loader, fixture or release procedure would likewise need evaluation. Until such a change is actually proposed, the sample does not demand wireless coexistence data, cloud threat modeling or a network penetration report for a non-existent feature. All statements concern the invented configuration and do not certify that any real device, related system or service organization is secure.

D14 Submission inventory and declaration index

DOC-PTC-2026 | Revision A | Authored fictional record

D14 01 Assembly status and scope of this inventory

This inventory describes the fourteen authored records in expanded fictional case ESTAR-TC-005B. It is an assembly worksheet for an illustrative traditional 510(k) eSTAR readiness review, not an interactive eSTAR file, a submitted application or an FDA technical-screening result. Document presence means an identified record is available for this sample. It does not mean the record is adequate, its internal conclusions are accepted, or all attachments and fields needed for a real submission are complete.

The intended configuration is one controller model PTC-200, hardware B, release 3.2, with hose H-200 Rev B and three permitted cuff sizes. Each report retains the configuration it actually describes. In particular, the formal software record's 3.1 designation is not replaced by the inventory's overall release designation. A reviewer should be able to move from each claim or finding to a specific document and section, and then distinguish a measured result from a proposed requirement, a sponsor conclusion or a review limit.

D14 02 Controlled document index

The index fixes the document codes and revisions available in the sample. The same IDs are used in the review and finding register. Revision letters are document identifiers, not regulatory approvals. A reference to a newer revision must be supported by an actually supplied revised record, not inferred from a declaration. None of the entries below represents a real signature, laboratory accreditation, certification, official submission receipt or actual manufacturer's controlled record.

ID	Record code	Rev	Evidence role and configuration
D01	DP-PTC-200	C	Device baseline, hardware B, release 3.2 and labeled engineering limits.
D02	IU-PTC-200	B	Adult professional intended use and clinical workflow.
D03	IFU-PTC-200	C	Proposed labeling, charging cross-reference and reuse instructions.
D04	RM-PTC-2026-01	B	Risk scenarios and control-to-evidence links.
D05	SD-PTC-2026-01	B	Software architecture, requirements and CHG-032.
D06	SV-PTC-2026-01	A	Formal verification executed on 3.1, hardware B.
D07	PT-PTC-2026-01	B	System bench results on 3.2, hardware B, with cuff and condition limits.
D08	ES-PTC-2026-220	A	Electrical and electromagnetic record on 3.2, hardware B; 10 immunity sequences.
D09	HF-PTC-2026-01	A	Human factors record on 3.2, hardware B; 15 participants and six tasks.
D10	BE-PTC-2026-01	A	Cuff contact map, material/process rationale and biological endpoint summaries.
D11	RV-PTC-2026-01	A	Controller reuse study: 0.1 percent solution, 1 minute, 100 cycles.

ID	Record code	Rev	Evidence role and configuration
D12	SE-PTC-2026-01	B	Fictional comparator analysis and real-submission boundary.
D13	CY-PTC-2026-01	A	No-user-connectivity architecture and internal service controls.
D14	DOC-PTC-2026	A	This inventory and the inconsistent declaration pointer below.

D14 03 Declaration to report revision discrepancy

The sponsor declaration entry is recorded verbatim for this fictional document: Electrical and electromagnetic evidence supporting the submitted configuration: ES-PTC-2026-220 Rev B. The index in D14.02 and the supplied report identity in D08.01 instead identify ES-PTC-2026-220 Rev A. No Rev B report is included in this package. The discrepancy is a document-control inconsistency, not evidence that the submitted Rev A measurements never occurred and not permission to invent the contents of Rev B.

The declaration's pointer must be reconciled with the intended evidence. Where Rev A is intended, the declaration and any linked assembly fields should be corrected to Rev A with a recorded reason. Where Rev B is intended, that report would need to be supplied and its changes reviewed before it could be relied upon. Neither route automatically resolves the substantive IMM-07 alarm-information problem in Rev A. The reviewer therefore records m03 separately from M03 and keeps their closure evidence distinct.

This declaration is a fictional evidence index statement, not an actual declaration of conformity to a particular consensus standard. It supplies no recognized edition, clause matrix, accreditation scope or certificate. A real sponsor would have to establish the appropriate standards basis and supporting evidence for its actual product. The sample does not transform that deliberately bounded absence into a fabricated standard failure or a claim that any edition has been satisfied.

D14 04 eSTAR area coverage and explicit exclusions

Device description and intended-use content are available in D01-D03; risk and software content in D04-D06; bench and electromagnetic evidence in D07-D08; human factors, contact evaluation and reuse evidence in D09-D11; comparison and service-security rationale in D12-D13. This allocation prevents a risk document from being mislabeled a cybersecurity report and prevents a performance report's mention of labeling from hiding its bench evidence. Sources may support multiple questions, but their primary purpose and actual measured content remain visible.

The package intentionally does not supply a genuine predicate clearance, actual submission forms or attestations, administrative payment records, a final interactive eSTAR, a real standards declaration, independent raw laboratory records or clinical outcomes. No sterile claim, sterile barrier package, pediatric indication, implant use, wireless function, artificial-intelligence function or home-use indication is proposed. These exclusions are the scope of the example, not unannounced findings and not proof that those topics never require attention for a real product. Controller reuse and cuff biological contact remain affirmative review areas despite the nonsterile design.

A future actual assembly would need a current template appropriate to the actual route, truthful field responses, the intended attachments, appropriate administrative materials and verification that cross-references open to the right revisions. This sample does not execute those steps. A successful file extraction, a filled inventory or the absence of a parsing error cannot establish technical-screening acceptance, substantive adequacy, or regulatory authorization.

D14 05 Readiness and controlled follow up

The assembly position is not ready on the supplied fictional evidence. Six Major and three Minor findings are identified across the contracted review. A completed response index should name each revised document, retained source section, accountable function and verification of closure. It must distinguish a planned action from an executed correction. The reader should still be able to see why passing timer observations, limited biological summaries and supported configuration features were retained alongside unresolved results.

Changes should be sequenced around the released configuration: resolve engineering and user-interface effects, align the evidence and labeling to that configuration, then perform a final cross-document and assembly reconciliation. Correcting a declaration reference is necessary document cleanup, but it is not a substitute for that work. Conversely, a substantive test correction should not silently overwrite the historical source identity. No signed approval, FDA receipt or completed remediation is asserted by this inventory.