BionicLoop IDE Software Submission Core

Concise reviewer narrative for the frozen investigational software baseline

Baseline tag	`ide-software-freeze-2026-08-21`
Baseline commit	`91c0e98a9bc9429a0486bebdebffc7d8dbbe300e`
Generated	2026-09-08 09:06 EDT
Status	Approved software package for IDE submission

Investigational use only.

Included Documents

1. Core Manifest
2. Integrated Core Narrative
3. Human Factors and Use-Related Risk Summary
4. Known Anomalies and Residuals
5. Cloud Telemetry Submission-Scope Decision
6. Protocol Fingerstick Consistency Issue
7. IDE Submission Decision Register

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IDE Software Submission Core - Manifest

Field	Value
Package	IDE Software Submission Core
Status	Approved FDA-facing software package; operational follow-through is listed in the canonical decision register
Baseline tag	`ide-software-freeze-2026-08-21`
Baseline commit	`91c0e98a9bc9429a0486bebdebffc7d8dbbe300e`
Last product-source commit in frozen baseline	`ae00e754`
Prepared by	Software Developer
Date	2026-09-08

Purpose

This manifest defines the FDA-facing software package and its reading order before the technical appendices.

Included Core Documents

Order	Document	Purpose
1	IDE Software Submission Core	Integrated device, baseline, scope, risk, cybersecurity, testing, anomaly, human-factors, and limitation narrative
2	Human Factors and Use-Related Risk Summary	Study users, critical tasks, use hazards, controls, available evidence, approved evidence boundary, and residual risks
3	Known Anomalies and Residuals	Current unresolved anomalies, accepted residual behaviors, and explicit deferrals
4	Cloud Telemetry Submission-Scope Decision	Clinically approved supportive Scout role and official study-data sources
5	Protocol Fingerstick Consistency Issue	Resolved software-consistency review and external controlled-document/FDA-IRB handoff
6	IDE Submission Decision Register	Canonical approvals, closure records, and predeployment follow-through

Referenced Controlled Material

- IDE Software Technical Appendices Manifest (appendix index)
- BionicLoop Instructions for Use, IFU-BL-001, revision 1.17, approved for IDE submission on 2026-09-04
- Technical Appendix A11, IDE Freeze Execution Report - 2026-08-21

Package Status

The baseline is frozen and verification execution is complete. Build 843 has controlled source and archive identities, exact dependency resolution, passing automated results, installed-build evidence, and focused real-Pod evidence. Build 843 and the ZIP/CSV operating approach were approved on 2026-09-03; IFU revision 1.17 was approved on 2026-09-04. The `RA-023` submission disposition and the evidence, residual-risk, cybersecurity, service-environment, approver, and synchronized-label decisions are closed in the canonical decision register. The controlled multi-G7 exercise remains a predeployment condition, and external submission assembly remains with the study team.

BionicLoop IDE Software Submission Core

Field	Value
Device software	BionicLoop investigational automated insulin-delivery controller
Baseline tag	`ide-software-freeze-2026-08-21`
Baseline commit	`91c0e98a9bc9429a0486bebdebffc7d8dbbe300e`
Last product-source commit in frozen baseline	`ae00e754`
Status	Approved software package for IDE submission; predeployment condition identified in section 6
Date	2026-09-08

1. Executive Summary

The final protocol, *Optimizing Automated Insulin Delivery to Meet Pregnancy Glycemic Targets*, Version 1.0, dated 1 September 2026, describes a significant-risk, 20-participant crossover investigation of Standard and Pregnancy automated-insulin-delivery configurations in nonpregnant female adults ages 18 through 49 with type 1 or type 2 diabetes.

BionicLoop is an investigational iPhone application that receives glucose data from a Dexcom G7, executes the sponsor-controlled Algo2015 dosing logic, and commands an Omnipod DASH insulin pump. The app also provides participant and study-staff workflows for meal announcements, fingerstick blood-glucose entry, device status, alerts, temporary targets, insulin suspension and resumption, clinical configuration, and study-data recovery.

Primary software safety mechanisms are the independent primary and safety controller instances, guarded pump-command application, and programmed backup basal with degraded-state alerting during device-data loss.

The software source baseline is frozen at the tag and commit identified above. Engineering completed freeze execution of the algorithm, automated app, simulation, and the 68 local cybersecurity controls defined by `TV-SEC-001`. All 24 IDE-scope risk-analysis rows have freeze execution evidence mapped in the Requirements Traceability Matrix.

Recorded verification limitations and the accepted predeployment condition are summarized in section 6. Software-package approvals are summarized in section 8.

1.1 FDA Documentation Level

BionicLoop is documented at the **Enhanced Documentation Level** because a software failure or latent defect could contribute to incorrect or delayed insulin delivery and serious injury. Technical Appendix A00 records the rationale and maps the FDA Enhanced Documentation Level content to the controlled package.

2. Investigational Device and Software Baseline

2.1 System Components

The study system comprises:

- BionicLoop app user interface and orchestration
- BionicLoopCore runtime, persistence, safety policy, and algorithm-host logic
- two symbol-isolated compilations of the same unmodified Algo2015 source for the primary and safety controller tracks
- G7SensorKit integration for Dexcom G7 data intake
- OmniBLE integration for Omnipod DASH communication and delivery
- local protected telemetry, active-session step evidence, and clinical-gated recovery export
- supportive BionicScout telemetry and study-support services used as corroborating backup rather than a local dosing dependency

`OmniBLE` and `G7SensorKit` are inherited open-source components. Their exact Build 843 source, including local modifications, is part of the controlled software baseline and is addressed by applicable software requirements, risk management, configuration control, and verification. External regulatory decisions are not used as substitute verification for these components.

2.2 Configuration Identification

The controlled source identity, algorithm hashes, toolchain, dependency resolution, and document revisions are listed in Software Version and Configuration Identification. Commit `ae00e754` is the last product-source change in the frozen baseline; later freeze commits contain test, labeling, and package records. Build 843 is the signed, installed archive with exact tracked dependencies and recorded real-Pod operation. It was approved as the IDE submission build on 2026-09-03.

2.3 Operating Model

The app performs algorithm-driven dosing only; it has no manual test-dose path. The primary inputs are accepted Dexcom G7 readings, validated fingerstick BG entries when permitted, pump status and delivery feedback, and qualitative meal announcements. Pump commands are guarded

by current runtime and pump-state policy. Loss of CGM or pump communication is handled through explicit degraded states, participant alerts, programmed backup-basal behavior, and bounded reconciliation logic.

3. Study-Use Software Scope

3.1 Included

- runtime scheduling, state persistence, relaunch recovery, and guarded dosing
- CGM acquisition, availability, replacement-sensor targeting, and BG entry
- DASH status, delivery, suspension/resumption, and alert normalization
- algorithm execution, command construction, and accepted delivery feedback
- meal-announcement lifecycle and interrupted-dose attribution
- programmed backup basal, masked-fallback lifecycle, and reconnect accounting
- Pregnancy-mode temporary targets with the permanent safety/fallback basis
- participant alerts and study-staff Clinical Settings access controls
- protected local study records, telemetry retention, and recovery export
- software-facing IFU and training references

3.2 Deferred or Not Claimed

- step-0 fingerstick rescue; the frozen baseline remains CGM-only at step 0
- historical CGM reconstruction during fallback replay
- commercial cloud, broad provider/authentication, and Part 11 closure
- production role-based authorization beyond the investigational offline Clinical Settings unlock
- independent manufacturer-level validation of Dexcom G7 or Omnipod DASH hardware or firmware; the applicable Build 843 software integrations are within the controlled software scope and supporting real-device observations are retained, but no separate formal hardware-validation study is claimed
- a separate formal participant usability or summative human-factors study

The software package uses protected local records and the clinical-gated exact-session recovery ZIP as primary session-reconstruction evidence, with Scout as corroborating backup. The scope boundary is defined in Cloud Telemetry Submission-Scope Decision.

4. Software Risk and Cybersecurity Posture

4.1 Principal Software Risks

The principal hazards are incorrect or mistimed insulin delivery (`RA-001`, `RA-004`, `RA-005`, `RA-014`, `RA-017`, `RA-020`, `RA-021`, `RA-022`); use of stale or unavailable glucose and pump state (`RA-002`, `RA-003`, `RA-012`, `RA-015`, `RA-018`, `RA-023`); loss or duplication of insulin-delivery feedback (`RA-008`, `RA-014`, `RA-016`, `RA-017`, `RA-020`); incorrect backup-basal reconciliation (`RA-003`,

RA-015, RA-018, RA-020); unrecognized interruption or alert conditions (RA-001, RA-010, RA-011, RA-018); unauthorized or unsafe Clinical Settings changes (RA-013, RA-019, RA-021, RA-022); loss of study records (RA-008, RA-009, RA-019, RA-024); and misleading UI state (RA-007, RA-008, RA-010, RA-011).

Controls include:

- guarded algorithm execution and pump-command application
- explicit freshness, identity, continuity, and delivery-evidence checks
- exactly-once issued-dose attribution keyed to the request step
- bounded fallback replay and insulin-conservation checks
- programmed backup basal and masked-fallback recovery behavior
- validated manual-BG timing and single-consumption rules
- normalized alert severity, deduplication, persistence, and escalation
- local single-use Clinical Settings unlock counters and expiration
- protected, backup-excluded clinical records and recovery staging
- traceability from RA-* hazards through SRS-*, SDD-*, TV-*, and formal evidence

The detailed hazard analysis is Appendix A03. Residual policies and anomalies are summarized in section 6 and in the controlled anomaly register.

4.2 Cybersecurity

The freeze local-control lane passed all 68 tests defined by TV-SEC-001. It covered protected retention, migration, export staging, backup exclusion, clinical share gating, session-isolated recovery export, and absence of participant Files-sharing/open-in-place keys.

Build 843 passed the dependency checks, pump cryptographic/session vectors, core, canonical app, and TV-SEC-001 security suites. Its signed archive identity, installed-build identity, and focused real-Pod use are recorded.

The TV-SEC-001 result does not include inherited supplier controls, commercial cloud, Part 11, broader provider/authentication policy, or continuous vulnerability-management services. Scout is supportive for the software package; available sequence-correlated cloud records are retained as corroborating backup. Any later decision to rely on Scout for required endpoint or safety data would reopen the narrow contract and cloud verification scope.

5. Prior Testing and Current Verification

5.1 Freeze Results

Lane	Execution result	Recorded limitation or follow-up
STP-ALG-001	Behavioral suites passed; coverage and host regression completed; freeze linkage companion passed 6/6	ALG-DEV-SA-006 closed by companion evidence
STP-AUTO-001	Original app target: 997 total, 996 passed, 1 intentional IFU reference-table generation helper skip gated by an export directory, 0 failures; original UI target: 41 passed and 3 harness deviations; corrected UI companion: 44/44 passed	AUTO-DEV-001 and AUTO-DEV-002 closed by companion evidence
STP-SIM-001	Core, pod, alert, and real-engine simulation lanes passed	None identified in execution
TV-SEC-001	All 68 local controls defined by TV-SEC-001 passed	None identified in scoped execution
Build 843 IDE submission archive	Dependency controls 6/6, OmniBLE crypto/session 8/8, Core 471/471, canonical app 997 executed with zero failures and one intentional IFU reference-table generation helper skip gated by an export directory, TV-SEC-001 security 68/68; signed archive, installed identity, real-Pod operation, and recovery ZIP observed	Approved for IDE submission 2026-09-03; real-Pod records are supporting evidence and no separate formal hardware-validation study is claimed

In this report, a "companion" run is a supplemental verification pass against the same frozen source that corrects or supplements a deviation identified in the original run without changing the immutable original evidence records.

The intentional skip is an IFU reference-table generation helper that runs only when its export directory is supplied. It does not omit a dosing requirement or runtime verification.

Technical Appendix A11, the Freeze Execution Report, preserves the original execution counts and deviations. The Formal Evidence Index links the companion and designation records that close all four non-product deviations.

5.2 Traceability Status

RTM version 1.86 maps freeze evidence to all 24 IDE-scope risk-analysis rows in its canonical current-state matrix. Rows involving retained hardware, alerts, cloud transport, or deviations identify their applicable limitations and follow-up in the matrix and remaining-work checklist.

6. Known Anomalies, Deviations, and Residual Limitations

6.1 Verification Deviations

Four non-product deviations are closed. The original execution records remain preserved.

- ALG-DEV-SA-006: closed by a freeze companion that passed all six static-analysis/linkage assertions and linked the frozen SHA to SRS-ALG-001 and SRS-ALG-002.
- AUTO-DEV-001 and AUTO-DEV-002: closed by test-harness-only corrections and a complete serial UI companion run with 44/44 tests passed.
- CYBER-DEV-001: closed on 2026-09-03 by designation of Build 843 with the controlled CryptoSwift 1.10.0 resolution; archive-826 history remains preserved. The corrections did not change participant-facing or dosing behavior. The original execution records remain unchanged for audit history.

6.2 Material Residual Limitations

- Formative real-Pod observations are described as supporting evidence. The package does not claim a separate formal hardware-validation study.
- Fallback replay may preserve total insulin while retaining limited within-window attribution precision (RA-003, RA-016, RA-017, RA-020).
- Assumed-delivered policy can conservatively over-account insulin when the old pod cannot provide final evidence; the assumption is explicitly labeled (RA-017).
- Some backup-basal model outputs remain operator-review estimates when the old pod is unavailable and are not treated as confirmed pump delivery (RA-003, RA-015, RA-020).
- CGM outage and manual-BG behavior depend on trained response to alerts and timely valid fingerstick entry (RA-002, RA-012, RA-015, RA-018).
- No separate formal participant usability or summative human-factors study is claimed for the use risks in RA-010, RA-011, and RA-012; the available engineering UI, formative real-device, and clinical-review evidence boundary was clinically approved on 2026-08-27.
- Scout is supportive and outside local dosing control (RA-008, RA-009, RA-024).
- Manual or device-lifecycle-triggered replacement acquisition has no authoritative Dexcom handoff identity and can encounter another nearby G7 advertiser. Staleness alone never releases the bound sensor. Physical isolation for planned replacement and post-connection comparison reduce risk, but comparison does not gate the first accepted reading. The September 3 adversarial review also identified replacement-episode loss through CGM setup reentry and a non-atomic concurrent-candidate path; no wrong-sensor adoption was observed in the supporting field event. The accepted D06 disposition defers the controlled RA-023 exercise and final disposition until before first participant deployment. No participant deployment may occur until objective testing supports use of unchanged Build 843 or a corrected, classified, verified study build is available.

The full anomaly and residual register is part of the Core package.

7. Human Factors, Training, and Labeling

The final protocol describes nonpregnant female participants ages 18 through 49 with type 1 or type 2 diabetes and trained clinical/study personnel. Use occurs during clinic setup and supervised outpatient/home activity with an iPhone, Dexcom G7, Omnipod DASH, glucose meter, and study escalation support.

Safety-critical tasks include device setup, interpreting status and alerts, announcing meals, entering and confirming fingerstick BG, replacing a sensor or pod, responding to communication loss, suspending and resuming insulin, reviewing temporary targets, and contacting study staff when instructed.

The software has engineering UI tests, formative real-device observations, operator protocols, and a workflow-based IFU. These support design evaluation; the package does not claim a separate formal participant usability or summative human-factors study. Clinical review approved this evidence description on 2026-08-27. The detailed use-related risk summary identifies the available evidence and residual use risks.

The final protocol is titled *Optimizing Automated Insulin Delivery to Meet Pregnancy Glycemic Targets*, Version 1.0, dated 1 September 2026. Software review verified that its descriptions of fingerstick handling, meal availability during CGM interruption, target configurations, Pregnancy meal setting, supported weight range, Same-Participant Reset, G7 startup, official study-data sources, and software-evidence boundaries are consistent with Build 843. The final protocol source remains under study-team document control.

The current labeling reference is IFU-BL-001, revision 1.17, approved for IDE submission on 2026-09-04. The app and final device labeling identify the software as investigational. The synchronized device-labeling attachment names BionicLoop 1.0 Build 843 and IFU-BL-001 revision 1.17.

8. Software-Package Approvals

The IDE Submission Decision Register is the authoritative software-package approval record. Clinical direction for the target sets and all eight software-consistency recommendations is recorded. Build 843 and the ZIP/CSV collection, transfer, and storage approach were approved on 2026-09-03; IFU revision 1.17 was approved on 2026-09-04; and the RA-023 submission disposition, residual risks, verification evidence, traceability, cybersecurity scope, participant Scout service environment, final software-package approver, and synchronized device label are closed in the register. Software consistency was verified against the final protocol, consent, and device labeling.

9. Technical Appendices

The IDE Software Technical Appendices - Manifest provides the following review path:

- A00, Enhanced Documentation Level and FDA Content Crosswalk: documentation-level rationale and package mapping.
- A01, Software Requirements Specification: implemented software requirements.
- A02, Software Design Description: architecture and control design.
- A03, Risk Analysis: hazards, controls, residual ratings, and benefit-risk.
- A04, Software Verification and Validation Plan: verification methods and protocols.
- A05, Requirements Traceability Matrix: requirement/design/test/evidence links.
- A06, Cybersecurity Plan: local, device, dependency, and deferred cloud controls.
- A07, Formal Evidence Index: formal execution bundles and results.
- A08, Software Composition and Dependency Inventory: software-component identities.
- A08A, Build 843 Dependency Verification: exact external-dependency verification.
- A08B, Build 843 SBOM and Advisory Review: machine-readable composition and dated review boundary.
- A08C, IDE Cybersecurity Closure Matrix: completed, open, and deferred cybersecurity controls.
- A09, IFU-BL-001: revision 1.17 participant and study-staff labeling, approved for IDE submission on 2026-09-04.
- A10, Version and Configuration Identification: source, toolchain, and build inputs.
- A10A, Build 843 Tester Release Record: archive, signing, upload, and installation identity.
- A10B, Build 843 Working Hardware Evidence Review: hardware and recovery-export support evidence.
- A10C, Build 843 Freeze Delta and Study-Build Designation: executable delta assessment supporting the 2026-09-03 submission-build approval.
- A11, Freeze Execution Report: original formal runs, deviations, and companions.
- A12, Post-Approval Change-Control Procedure: change classification and approvals.
- A13, Sponsor and Nonsoftware Ownership Map: nonsoftware IDE owners and gaps.
- A13A, Clinical Policy Confirmation: accepted fallback and weight-range decisions.
- A14, Cloud Telemetry Scope Decision: Scout role and authoritative-data-source decision.
- A15, Protocol Fingerstick Consistency Issue: resolved in the final protocol, consent, and IFU document set.
- A16, Clinical Approval of Software IDE Decisions: seven approved software/IDE statements, official study-data/safety-report sources, and the August 31 approval to implement all eight software-consistency recommendations.
- A17, Insulin Delivery CSV Data-Management Procedure: approved ZIP/CSV collection, transfer, and storage approach with detailed integrity, retention, and chain-of-custody controls.
- A18, Final Software Approvals: Build 843 and the ZIP/CSV operating approach approved on 2026-09-03; IFU revision 1.17 approved on 2026-09-04.

Internal administrative, execution, and working records are classified separately and are not part of this primary FDA narrative.

IDE Human Factors and Use-Related Risk Summary

Field	Value
Status	Use-related risk summary; no summative human-factors validation report is included
Baseline	`ide-software-freeze-2026-08-21` / `91c0e98a9bc9429a0486bebdebffc7d8dbbe300e`
Date	2026-09-08
Clinical disposition	Available engineering UI, formative real-device, and clinical-review evidence is accurately described; no separate formal participant usability study is claimed

1. Purpose and Evidence Boundary

The frozen investigational software baseline's use environment, safety-critical tasks, use-related hazards, controls, formative evidence, and residual use risks are identified below.

Engineering unit, UI, simulation, formative real-device, and operator testing are evidence of design evaluation. They are not formal summative human-factors validation. No completed summative human-factors validation report is available in this controlled package.

2. Intended Study Users

The final protocol, *Optimizing Automated Insulin Delivery to Meet Pregnancy Glycemic Targets*, Version 1.0, dated 1 September 2026, describes:

- nonpregnant female participants, ages 18 through 49, with type 1 or type 2 diabetes who meet study eligibility criteria
- trained clinical and study personnel who provision the phone, configure clinical settings, train participants, review status/evidence, and manage study escalation

The source protocol remains under study-team document control.

3. Use Environment

- supervised clinic setup and training
- outpatient and home use, including routine movement away from the phone or devices and periods of weak Bluetooth connectivity
- iPhone operation with Dexcom G7, Omnipod DASH, a study glucose meter, and access to study-team support

- relaunch, background/foreground transitions, device replacement, temporary network loss, and temporary CGM or pump communication loss
- investigational use with protocol training, monitoring, and escalation

4. Safety-Critical User Tasks

Task	Potential use error	Primary controls
Confirm current glucose, Pod, and algorithm status	Misread stale or transient device state	Freshness rules, status hierarchy, disconnect display debounce, explicit alerts, VoiceOver labels
Announce a meal	Submit during suspension, forced-open mode, active delivery, or unresolved state; misunderstand whether insulin was delivered	Preflight gating, exact reason copy, in-modal progress, cancellation and reconciliation evidence, exactly-once attribution
Enter fingerstick BG	Enter wrong value, submit twice, use stale value, or assume entry was already consumed	Numeric range validation, separate exact-value review, step-scoped pending state, single consumption, pending/used chart distinction
Respond to CGM loss	Delay required BG entry or assume automated dosing continues unchanged	BG due countdown, escalating alerts, gold BG control emphasis, backup-basal bridge, IFU instructions
Replace or recover a G7 sensor	Attach to another person's G7	Planned-replacement isolation, authenticated acquisition, staleness-never-adopts rule, acquisition guidance, and trained post-connection comparison; the accepted D06 disposition requires controlled testing of automatic replacement triggers and first-reading behavior before participant deployment
Replace or recover a Pod	Replace a transiently disconnected pod or misunderstand delivery reconciliation	Debounced display, pod identity checks, explicit recovery states, no silent session restart, retained evidence
Suspend and resume insulin	Forget to resume or announce a meal while suspended	Relocated control, reminder, Home paused status, direct Resume action, 15-minute escalation, meal rejection before execution
Start or end a Temporary Target	Use unintended target/duration or leave an incomplete draft	No preselection, review/confirm step, unsaved-change warning, visible end time, persisted expiry and automatic return

Task	Potential use error	Primary controls
Change Clinical Settings	Unauthorized or accidental dosing-configuration change	First-save boundary, subject-scoped single-use offline unlock, expiration, review/save flow, study-staff operation
Recover study records	Share wrong participant/session files or expose raw local records	Clinical-gated export, exact-session ZIP isolation, protected staging, partial-content disclosure, no participant Files sharing

5. Use-Related Hazards and Risk Controls

Hazard theme	Related risk IDs	Control summary	Residual consideration
Incorrect insulin from wrong/stale input	RA-002, RA-003, RA-004, RA-012, RA-014	Input validation, freshness and pump-state gates, reference-host command construction, exact-step meal/BG policy	User timing and device availability remain variable
Insulin interruption not understood	RA-011, RA-015, RA-018	Alert severity/precedence, Home status, fingerstick-supported outage guidance, backup-basal behavior, suspend/resume recovery	Notification permission and user response affect timeliness
Delivery duplicated, omitted, or misattributed	RA-005, RA-016, RA-017, RA-020	Request-step identity, persisted issued-dose state, evidence precedence, bounded replay, exactly-once consumption	Assumed-delivered policy can conservatively over-account when evidence is irrecoverable
Wrong device adopted	RA-007, RA-023	Active-pod identity controls are separate. G7 replacement may begin manually or from defined device-lifecycle events; staleness alone does not start replacement. Authenticated discovery, physical isolation for planned replacement, and trained post-connection comparison reduce risk, but comparison does not gate the first accepted reading and automatic triggers may occur without planned isolation.	D06 and D07 accept the submission disposition and residual risk; no participant deployment may occur before controlled multi-device testing and final deployment disposition
Unsafe configuration or reset	RA-013, RA-019, RA-021, RA-022	Clinical unlock, save review, reset guardrails, explicit target/duration, range checks	Use depends on trained study-staff configuration and controlled access

Hazard theme	Related risk IDs	Control summary	Residual consideration
Misleading display or missing evidence	RA-008, RA-010, RA-024	Source-tagged status, discrete chart samples, pending/used BG distinction, complete active-session step archive, recovery ZIP	Formal visual/operator evidence is incomplete
Study-data confidentiality or loss	RA-009, RA-024	Protected storage, backup exclusion, no Files sharing, retained sequence, clinical-gated export	Scout is supportive; official outcomes come from Dexcom Clarity and the BionicLoop CSV, and safety information is recorded in staff-entered electronic CRFs

6. Training and Investigational-Use Mitigations

- one-on-one training by qualified study personnel before outpatient use
- participant teach-back and competency confirmation described by the protocol
- instruction on Dexcom G7, Omnipod DASH, meal announcement, fingerstick BG, alerts, device replacement, suspension/resumption, and escalation
- study-team follow-up and ready access to glucose meter, carbohydrate, glucagon, and replacement supplies
- investigational-use labeling and protocol restrictions
- IFU workflows and alert-response guidance
- study monitoring and contact pathways

Training records, trainer qualification records, completed competency records, and site-specific escalation procedures are sponsor/site records and are not included in this controlled package.

7. Available Formative, UI, and Operator Evidence

- app unit and UI tests for Home, meals, BG entry, Clinical Settings, Temporary Target, suspension/resumption, alerts, and recovery states
- simulation and pod-simulation scenarios for interruption, relaunch, reconciliation, and insulin conservation
- formative real-device observations used to identify and correct use and display problems before the freeze
- supporting study-staff observations of selected real-device workflows on the designated build
- an operator worksheet retained as a supporting workflow record, not as a separate formal hardware-validation claim
- IFU-BL-001 workflow narrative, screenshots, alert table, and study-staff reference

Operator-reported results remain supporting evidence until the exact build, device or subject, operator, UTC window, result, and signature are attached and accepted.

8. Evidence Not Claimed or Retained Outside This Package

- no separate formal participant usability or summative human-factors study is claimed; this evidence boundary was clinically approved on 2026-08-27
- documented critical-task validation protocol, acceptance criteria, and report
- signed retained physical/operator evidence for any hardware or visual claims kept in submission scope
- approved participant and staff training records and competency criteria

9. Residual Use Risks

- participants may delay responding to a BG request, device alarm, or insulin suspension reminder
- transient Bluetooth states can be difficult to distinguish from device loss, despite display debounce and status guidance
- a participant may misunderstand assumed-delivered or replayed insulin evidence without training
- notification permission or OS behavior may delay background notification even though in-app status remains available
- data recovery and device replacement require trained study-staff procedures
- participant consent and training wording must remain consistent with the distinct fingerstick mode described by the protocol and app

10. Required Disposition

The study team accepted the package description of engineering UI testing, formative real-device testing, and clinical review without claiming a separate formal participant usability study. IFU-BL-001 revision 1.17 is approved for IDE submission. Remaining software-package action is residual-use-risk acceptance.

IDE Known Anomalies and Residuals

Field	Value
Status	Unresolved anomalies, resolved field defects, accepted residuals, and deferrals
Baseline	`ide-software-freeze-2026-08-21` / `91c0e98a9bc9429a0486bebdebffc7d8dbbe300e`
Last product-source commit in frozen baseline	`ae00e754`
Date	2026-09-08

A. Unresolved Anomalies and Evidence-Control Items

ID	Cross-references	Description	Impact	Current control/status	Disposition category
`ANOM-002`	`RA-003`, `RA-016`, `RA-017`, `RA-020`	After some connection gaps without a pending issued dose, delivery can retain limited within-window attribution precision	Insulin conservation is retained, but a recovered share may not identify the exact original slot	Replay evidence is labeled and bounded; no insulin is silently dropped	Residual-risk decision
`ANOM-006`	-	An archive can report build `1` when Git-derived build stamping falls back	Weakens build-to-evidence identity	Physical-run preflight requires tag/SHA, expected build, installed build, install ID, subject/device, and UTC window	Enforce preflight for every claimed physical run
`ANOM-`	`RA-023`, `SRS-CGM`	Reopening CGM setup during an active replacement acquisition can	Weakens replacement-state continuity and the ten-	September 3 review traced the observed `manual` to `initial_acquisition` transition to this UI-manager replacement path; no wrong-sensor adoption was observed	Accepted for submission under `D06`/`D07`; controlled exercise and final

ID	Cross-references	Description	Impact	Current control/status	Disposition category
007	-006	install a fresh G7 manager and reset the retained prior-sensor, trigger, and episode-time evidence	minute/evidence audit trail		disposition required before participant deployment
RES-004	RA-015	Backup basal also engages when current CGM freshness cannot be established, not only when CGM is confirmed stale	The behavior is broader than a stale-only interpretation	Automated freeze coverage exists; clinical behavior confirmed on 2026-08-21	Documented residual behavior
RES-009	RA-016, RA-017	A previously consumed request tuple can resurface in pump-input telemetry after recovery	Current C++ gate rejected the tuple, so no second insulin ingestion was observed; telemetry may imply duplicate delivery	Request-step consumption control prevents duplicate ingestion	Evidence-hygiene residual
RES-010	RA-023	Manual or device-lifecycle-triggered replacement acquisition has no authoritative intended-sensor identity and can encounter another nearby G7 advertiser	Wrong-person glucose could influence automated dosing if the wrong sensor were adopted	Staleness alone never releases the bound sensor, and adoption requires authenticated glucose discovery. Physical isolation applies to planned replacement. Post-connection comparison is a detection control, not a gate on the first accepted reading. The September 3 review also identified non-atomic concurrent-candidate handling that has not been physically reproduced.	Submission deferral accepted under D06; no participant deployment before the controlled exercise and final disposition of ANOM-007 and the concurrent-candidate finding

B. Resolved Field Defects in the Frozen Code

ID	Cross-references	Historical defect	Frozen-baseline resolution	Evidence status
ANOM-001	RA-010, RA-015	Transient DASH reconnect could briefly show `No Pod`	Routine disconnects use display debounce; immediate clearing is reserved for genuine pod-gone events	Freeze automated coverage mapped; operator observation remains support until retained if claimed
ANOM-003	RA-018	A sustained CGM outage could leave programmed backup basal masked after the controller forced open	Fingerstick-supported CGM-outage controls add due scheduling, escalating guidance, a backup-basal bridge, and immediate re-close after eligible BG or CGM return	Freeze automated and simulation execution mapped; physical outage claim remains deferred unless signed
ANOM-004	RA-020	Backup basal delivered during a connected CGM-outage release window was not credited to algorithm accounting	Frozen code uses live per-step credit and bounded schedule-weighted, quantized pod-away replay with persisted conservation context	Freeze AUTO/SIM evidence mapped; clinical 0.01 U positioning is confirmed
ANOM-005	RA-014	A combined meal step could omit the basal component from the pump command, causing next-step feedback rejection	Frozen code commands bolus + basal + meal exactly; `TV-ALG-012` reproduces the defect and proves accepted feedback	Freeze algorithm execution passed; physical command/feedback claim remains support until retained

C. Accepted or Documented Residual Behaviors

ID	Cross-references	Behavior	Rationale and limitation
RES-001	-	When a prior pod is retired, expired, or unavailable, known in-flight insulin may be recorded as assumed delivered under clinical policy	Prevents silent disposal and is explicitly labeled; may conservatively over-account if the dose did not complete
RES-002	-	A merged recovered share is booked at the algorithm-compatible request-step position rather than exact wall-clock delivery time	Preserves the C++ reconciliation contract; chart/evidence uses request-step attribution

ID	Cross-references	Behavior	Rationale and limitation
RES-003	-	Participant Files sharing/open-in-place was removed	Historical residual is retired; local data use protected clinical-gated paths
RES-005	-	Primary and safety diagnostic text files can share a name when sessions start in the same wall second	Diagnostic-only; dosing state and structured telemetry remain isolated
RES-006	-	Runtime inline resolvers execute reconciliation policy; the pure classifier is a verification model, not production authority	Sponsor-accepted design; runtime, property, simulation, and parity tests verify the executed path
RES-007	-	Modeled fallback exposure is not always clamped to a known pod service stop or fault time	Operator-review estimate may over-project; unreconciled modeled exposure is not treated as confirmed algorithm input
RES-008	-	`resumed_without_reconciliation` groups several pod-liveness cases	Dosing disposition is the same; evidence label has limited granularity

D. Closed Verification Deviations

The three deviations below were closed by controlled companion executions. The original execution records remain preserved.

ID	Closure
ALG-DEV-SA-006	Freeze static-analysis/linkage companion passed 6/6 with literal SHA and requirement linkage.
AUTO-DEV-001	Profile-specific test seeding was corrected; the complete serial UI companion passed 44/44.
AUTO-DEV-002	The assertion now measures the common action container; the complete serial UI companion passed 44/44.
CYBER-DEV-001	Closed 2026-09-03 by designation of Build 843 with the controlled CryptoSwift 1.10.0 resolution; archive-826 mismatch history remains preserved.

These were evidence-linkage or test-harness defects, not product failures.

E. Deferred Scope and Submission Dependencies

- step-0 fingerstick rescue

- historical CGM reconstruction for fallback replay
- unsigned hardware-only and supplemental alert claims
- commercial cloud, broader provider/authentication, and Part 11 closure
- formal participant usability or summative human-factors study is not claimed; the available evidence boundary was clinically approved on 2026-08-27
- completion of the `D06` controlled multi-device replacement exercise and final deployment disposition before first participant deployment

Register Discipline

New unresolved software defects must enter the controlled bug tracker and this reviewer register if they survive to a future baseline. Working observations must follow the controlled evidence-promotion process before use as formal evidence.

IDE Cloud Telemetry Submission-Scope Decision

Field	Value
Status	Clinically approved: Scout supportive
Decision owners	Sponsor representative with clinical-investigator input
Date opened	2026-08-21
Package position recorded	2026-08-25
Clinical approval and source clarification	2026-08-27
Updated	2026-08-27

Issue

Prior software scope language deferred cloud and device-to-cloud verification, while the Cybersecurity Plan described secure cloud telemetry as a primary study transport. Those statements could not govern the same package.

The software package uses the supportive Scout scope. Clinical approval and the authoritative clinical data sources were recorded on 2026-08-27.

For the IDE software package, Scout is classified as supportive. The device-local clinical-gated recovery ZIP is the primary session-reconstruction record used for software evidence, and Scout telemetry is corroborating backup for monitoring, correlation, and gap investigation. Temporary Scout delay or loss does not affect local algorithm execution or dosing.

The clinical correspondence identifies the official study sources in the decision table below.

Approved Scope

If Scout is not relied upon for safety decisions or required endpoint data:

- describe Scout as supportive monitoring and engineering/operational evidence
- identify the authoritative sources for dosing, safety, and endpoint data in the protocol, data-management plan, and submission
- state that temporary Scout delay or loss does not affect local dosing
- retain local protected step evidence and recovery export as support controls

- defer broader cloud, provider/authentication, Part 11, and commercial closure with explicit rationale
- ensure the IFU and monitoring plan do not instruct staff to depend on Scout for a safety action that lacks another authoritative path

Approved sources and purposes:

Required identification	Sponsor response
Software verification/session reconstruction	Protected local step archive and clinical-gated exact-session recovery ZIP; reconcile to pump records where the protocol requires
Official CGM outcome source	Dexcom Clarity
Official insulin-delivery outcome source	BionicLoop app exported CSV file
Official adverse-event and other safety-information source	Electronic case-report forms entered by study staff
Scout support purpose	Study monitoring, troubleshooting, corroborating software evidence, sequence/gap review, and recovery assistance; not a local dosing dependency

Decision Record

Field	Decision
Decision / date	Scout supportive; engineering package position recorded 2026-08-25 and clinically approved 2026-08-27
Rationale	The controller retains protected local step evidence and a clinical-gated exact-session recovery export; local dosing does not depend on Scout availability. Scout remains valuable corroborating evidence and monitoring support.
Authoritative data sources	Software evidence: local protected records/recovery ZIP and formal verification bundles. Official study outcomes: Dexcom Clarity for CGM and the BionicLoop exported CSV for insulin delivery. Adverse events and other safety information: staff-entered electronic case-report forms.
Required Scout contract/evidence	No Scout round trip is required as the primary software-verification record. Retain available sequence-correlated Scout data as corroborating backup and investigate material gaps.
Deferred cloud scope	Commercial cloud, broader provider/authentication, Part 11, and production-role closure remain deferred unless the relied-upon study scope is later widened.

Field	Decision
Approval reference / date	Camille Powe, MD email, `Re: A few final software decisions for the IDE package`, 2026-08-27
Controlled decision record	Clinical Approval of Software IDE Decisions

Sequence-correlated phone-to-Scout observations may be retained as operational transport evidence and used to investigate gaps. They are not required to establish local dosing execution or reconstruct a software session when the protected local archive and exact-session recovery ZIP are available.

IDE Protocol Fingerstick Consistency Issue

Updated: 2026-09-04

Field	Value
Status	Closed in the final protocol and consent document set
Source	`Clinical Protocol BLS Clean-final.docx`; *Optimizing Automated Insulin Delivery to Meet Pregnancy Glycemic Targets*, Version 1.0, version date 1 September 2026, 41 pages; SHA-256 `4bfb09542230c94c00dc5b5331a969657b5961b1c4bbd5a2759519a00f71d264`
Affected software areas	Manual BG, CGM outage, algorithm mode, alerts, transition behavior
Clinical approval	Camille Powe, MD approved the distinct safeguarded fingerstick direction on 2026-08-27 and approved implementation of the related protocol/consent recommendations on 2026-08-31

Historical Protocol Discrepancy

The June protocol stated that entered fingerstick BG measurements would be treated as Dexcom CGM data. That statement did not describe the implemented software accurately.

Implemented Behavior

The frozen software does not treat a fingerstick value as an ordinary Dexcom CGM sample. It uses a distinct BG-based closed-loop path with controls that include:

- manual range and completeness validation
- explicit exact-value user confirmation
- step-scoped pending validity and exactly-once consumption
- BG-specific timing and due/overdue scheduling during sustained CGM outage
- BG-specific alerting and Home presentation
- shared input to both algorithm copies only on the qualifying step
- explicit transitions between CGM-based, BG-based, and forced-open behavior
- no step-0 BG rescue in the frozen baseline

The historical wording therefore overstated equivalence between a fingerstick BG and Dexcom CGM data.

Verified Final Protocol Direction

> If Dexcom CGM data are unavailable, a participant may enter and confirm a fingerstick BG. BionicLoop processes the value through a distinct BG-based closed-loop mode with BG-specific timing, validity, alert, and transition safeguards. The value is available to the next eligible algorithm step, is consumed once, and may result in automated insulin delivery. The Dexcom G7 should be restored or replaced as soon as possible.

The final protocol describes the distinct safeguarded fingerstick mode, next eligible step, and exactly-once consumption consistently with this direction. The clinical protocol remains controlled outside this software repository.

Required Disposition

Decision	Owner/status
Confirm the intended clinical role of fingerstick BG during CGM outage	Approved by Camille Powe, MD on 2026-08-27
Approve direction to replace the Dexcom-equivalence statement with wording consistent with implemented behavior	Approved by Camille Powe, MD on 2026-08-27
Confirm the final consent and IFU provide participant-facing CGM-outage instructions	Closed by the final consent document and current IFU revision 1.17

The software consistency issue is resolved in the final protocol, consent, and IFU document set. The approved clinical direction is retained in the Clinical Approval of Software IDE Decisions. The broader June-document review and proposed wording are recorded in the Software Consistency Crosswalk.

IDE Submission Decision Register

- **Purpose:** Canonical list of software-package decisions requiring sponsor-designated disposition before submission
- **Baseline:** `ide-software-freeze-2026-08-21` / `91c0e98a9bc9429a0486bebdebffc7d8dbbe300e`
- **Status:** Software-package decisions closed; pre-deployment `RA-023` exercise and final IDE assembly remain operational follow-through
- **Date:** 2026-09-08
- **Latest clinical-document review:** Clinical Documents Software Consistency Crosswalk

Open Software-Package Decisions

None. All software-package decisions are closed by the controlled records below.

Accepted D06 Disposition

The accepted submission disposition retains `RA-023/RES-010` as a provisional Medium residual (`S3 x P1`) and completes the controlled multi-device exercise before first participant deployment rather than before IDE submission. No participant deployment may occur before the exercise passes and the final RA-023 disposition is recorded.

The required pre-deployment exercise must use an intended G7 and at least one active nearby non-intended G7. It must cover intentional replacement, relaunch and CGM-screen reentry, retry after the no-adoption timeout, producible automatic replacement triggers, candidate ordering, and confirmation that reading staleness alone never starts replacement acquisition. Objective acceptance criteria must address sensor adoption, processed glucose, algorithm input, episode persistence, and whether post-connection comparison is detection-only.

The implementation and control limitations requiring disposition are recorded in Risk Analysis 1.53, SDD 1.84, SVVP 1.91, and RTM 1.86. The 2026-09-03 Build 843 observation of a timeout followed by authenticated intended-sensor adoption is supporting evidence but does not establish nearby-sensor discrimination or close those findings. No product source change is required for IDE submission. The exercise result determines whether unchanged Build 843 is accepted for participant deployment or a separately classified and verified post-submission correction is required.

Closed Decisions

D01 - IDE Submission Build

- **Decision:** BionicLoop `1.0 (843)` / `1455cda7` is approved for IDE submission.
- **Closure record:** Final Software Approvals - 2026-09-03
- **Status:** Closed by controlled clinical/sponsor correspondence.

D02 - Final Protocol Identity

- **Decision:** Treat `Clinical Protocol BLS Clean-final.docx`, Version 1.0, dated 1 September 2026, as the final protocol source for software-package consistency and external attachment identity.
- **SHA-256:** `4bfb09542230c94c00dc5b5331a969657b5961b1c4bbd5a2759519a00f71d264`
- **Status:** Closed. Material software descriptions are consistent with Build 843.

D03 - Target Sets and Pregnancy Meal Setting

- **Decision:** Standard permanent targets 110/120/130 mg/dL; Pregnancy permanent targets 90/100/110 mg/dL; time-limited Pregnancy Temporary Targets 120/130 mg/dL for 30/60/90/120 minutes; automatic return; unchanged permanent Pregnancy safety/backup basis; and the Standard-to-Pregnancy 90% meal-setting proposal with clinical review before save

- **Closure record:** Clinical Approval of Software IDE Decisions - 2026-08-27 and 2026-08-31
- **Status:** Closed by controlled clinical correspondence; the final protocol incorporates the approved behavior.

D04 - Final Consent Identity

- **Decision:** Treat `Consent Form BLS Clean –final.docx`, consent version date 1 September 2026, as the final consent source for software-package consistency and external attachment identity.
- **SHA-256:** `6a0e1759997944522fa5dd9ba8dd9e9928cccb64ed7e6e4455b65f40c56a22cf`
- **Status:** Closed. The consent supplies the participant-facing fingerstick disclosure; the protocol and IFU carry the detailed outage instructions.

D05 - Initial Final Device-Labeling Identity

- **Decision:** Treat `Device Label_clean–final.docx` as the final software/device-labeling source. It identifies BionicLoop 1.0 (843) and IFU-BL-001 revision 1.16.
- **SHA-256:** `e57838b3246965815af585887d9643b75987cc5ef459c854d04fbcf490b7e953`
- **Status:** Closed for the reviewed September 3 document set and superseded by the synchronized revision 1.17 attachment recorded under `D14`.

D06 - RA-023 Submission Disposition

- **Decision:** Complete the controlled multi-G7 exercise before participant deployment rather than holding IDE submission, and retain the documented provisional `S3 x P1` residual-risk rating for submission. The exercise will inform the final participant-deployment disposition.
- **Closure record:** Tara Bresnahan, RN email in the controlled `Bionic Loop Software – Final Approvals` thread, 2026-09-04.
- **Status:** Closed for submission. The exercise and final deployment disposition remain required before participant deployment.

D07 - Residual Risks and Known Limitations

- **Decision:** Accept the documented software and use-related residual risks and known limitations.
- **Closure record:** Edward R. Damiano, PhD email in the controlled `Bionic Loop Software – Final Approvals` thread, 2026-09-07 EDT.
- **Status:** Closed.

D08 - Verification Evidence and Traceability

- **Decision:** Accept the verification evidence and traceability for Build 843.
- **Closure record:** Edward R. Damiano, PhD email in the controlled `Bionic Loop Software – Final Approvals` thread, 2026-09-07 EDT.
- **Status:** Closed.

D09 - Cybersecurity Scope and Controls

- **Decision:** Accept the documented cybersecurity scope and controls.
- **Closure record:** Edward R. Damiano, PhD email in the controlled `Bionic Loop Software – Final Approvals` thread, 2026-09-07 EDT.
- **Status:** Closed. Documented deferred and supportive-service boundaries remain part of the accepted scope.

D10 - ZIP/CSV Collection, Transfer, and Storage

- **Decision:** Use of the recovery ZIP for CSV collection, transfer, and storage is approved. The existing data hierarchy and Appendix A17 define the detailed operating controls.
- **Closure record:** Final Software Approvals - 2026-09-03
- **Status:** Closed by controlled correspondence. Final protocol/data-plan references are incorporated in the final protocol recorded under `D02`.

D11 - Final Software-Package Approver

- **Decision:** Edward R. Damiano, PhD is authorized to provide final software-package approval. Controlled correspondence references replace handwritten signature fields in the software package.
- **Closure record:** Tara Bresnahan, RN authorization on 2026-09-04 and Edward R. Damiano, PhD acceptance and final package signoff on 2026-09-07 EDT, both in the controlled `Bionic Loop Software – Final Approvals` thread.
- **Status:** Closed.

D12 - Build 843 Scout Service Environment

- **Decision:** Confirm `CC-DEV` as Build 843's participant Scout service environment. Scout remains supportive and does not affect local dosing.
- **Closure record:** Tara Bresnahan, RN email in the controlled `Bionic Loop Software – Final Approvals` thread, 2026-09-04.
- **Status:** Closed. A different compiled service environment would require a new build identity and impact assessment.

D13 - IFU Revision 1.17

- **Decision:** Prepare and submit IFU-BL-001 revision 1.17 with the six staged editorial and document-control corrections. The revision does not change Build 843 behavior.
- **Closure record:** Final Software Approvals - September 2026
- **Status:** Closed by controlled correspondence on 2026-09-04. Tara Bresnahan, RN supported the changes, and Camille Powe, MD directed the team to make the changes and submit revision 1.17.

D14 - Synchronized Device Labeling

- **Decision:** Accept `008_Device_Labeling.pdf` as the synchronized final device-labeling attachment. It identifies BionicLoop 1.0 Build 843 and IFU-BL-001 revision 1.17 dated 2026-09-04.
- **Controlled identity:** 3 pages; 230,910 bytes; SHA-256 `561c4cd26171888454c27d2350162680a867190754a448fd4096d1dd8b10fe0c`.
- **Controlled locator:** Study-team Dropbox submission folder, `IDE Submission Package/008_Device_Labeling.pdf`.
- **Status:** Closed by software identity verification on 2026-09-08.

Completed Clinical Decisions

The controlled clinical records already close the fallback allocation, unavailable-CGM-freshness, participant-weight range, target-set behavior, supportive Scout scope, physical-use claim boundary, human-factors claim boundary, and clinical direction for the eight software-consistency changes. They are not repeated as open clinical decisions here. The accepted `D06` pre-deployment exercise, release artifact generation, and final IDE assembly are operational follow-through rather than open software-package decisions.