

HALO 4.0 Release Notes
Final
Version 1.0
Department: Release Management

Document Approvals

Name	Date and Signature	Role/Meaning
Richard Salter		Release Manager (Author)
Martin Holm-Petersen		System Owner



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1. Overview

Insife “HALO” 4.0 contains new features described in the “**New Features and Enhancements**” section. Section “**Issues Addressed**” mentions all the issues addressed in this release.

1.1. Upgradability

HALO 4.0 can be upgraded from any previous HALO release. It can also be deployed as a standalone full installation.

1.2. Features affected in this release

The following features are affected in this release. For a detailed description of changes, please refer to section 3 below:

Newly introduced modules:

- Device Management Module
- Defective Product Module

Significantly Enhanced Modules

- ICSR Module
- Submission Management Module

Other significant updates

- Child record linkages
- Workflow enhancements
- Cloning capabilities
- Product management
- Revised validation framework
- Enhanced Data Access controls
- Case Search enhancements
- Case Assignment automation
- Conditional task steps
- Auto routing
- Template placeholder enhancements
- Duplicate Search enhancements
- Follow up selective intake screen updates
- Batch action enhancements
- New regulatory report print capability
- Audit log extension

2. Compatibility

HALO 4.0 is compatible with the following systems:

- Argus 8.2.1.1 and Argus 8.2.3 (Please contact us for compatibility with earlier/ later versions)
- ARISg 7.2 (Please contact us for compatibility with earlier/ later versions)
- Browser Compatibility

HALO requires a JavaScript enabled browser and supports the current and prior major release of **Google Chrome**, **Mozilla Firefox**, and **Microsoft Edge**. HALO leverages Oracle APEX framework and is compatible with browsers supported by it.

OBS: Support of **Microsoft Internet Explorer** is no longer supported in HALO 4.0

The following Oracle Support documents should be considered for compatibility:

[Oracle Software Web Browser Support Policy](#)

<https://docs.oracle.com/en/database/oracle/application-express/20.2/htmig/apex-installation-requirements.html#GUID-02BE4A34-B631-412C-8A82-EB92DABBACE0>

At the time of release, Chrome was on version 100 and Edge on version 99

3. Changes since last release

The following features have been updated in this release:

Area/Process/Group	Title	Description	Impact
Device Management	Device Management Module	A completely new module has been introduced for the purpose of Device incident intake, processing, management, and reporting	Minor New module, no impact to existing customers
Defective Product	Defective Product Module	A completely new module has been introduced for the purpose of Defective Product incident intake, processing, management, and reporting	Minor New module, no impact to existing customers
Correspondence	Correspondence workflow type	A type of workflow has been introduced for the purpose of the generation and tracking of communication both outward from, and inwardly to the application	Minor New workflow type, no impact to existing customers
ICSR	ICSR Module	The ICSR module has been overhauled to ensure full alignment with E2B R3 standards, and general enhancements to the layout and usability of the applicable UI pages, including the introduction of a Summary view	Medium While no existing fields or data points have been removed, the applicable pages have been enhanced quite significantly. Review of training and documentation may be required
Submission Management	Submission Management Module	The Submission management module has been enhanced to provide greater inbound and outbound tracking and additional formats have been added	Minor New functionality only, no existing functionality has been deprecated
Case Forms	Record linkages	New functionality has been added for Linked Records alongside the existing Parent/ Child linkages	Minor New functionality, no impact to existing customers

Workflow	Workflow enhancements	A new Manual workflow assignment button has been added, along with auto assignment configurations (see Case Assignment)	Minor New functionality, no impact to existing customers
Case Forms	Cloning capabilities	New functionality has been added for Case Cloning	Minor New functionality, no impact to existing customers
Product Management and Case Forms	Product management	The underlying structure of the Product data tables has been updated in HALO 4.0 to align to industry standard definition ISO IDMP. The product coding methodologies for each of the applicable forms has also been enhanced to make full usage of the available data set	Major All existing product data will need to be migrated into the new structure. Review of training and documentation may be required (for both the set up and usage of the Product coding features)
Case Forms	Revised validation framework	The validation framework has been enhanced to allow increased configuration, identification of applicable fields, and user-friendly error messages	Minor New functionality, no impact to existing customers
System Configuration	Enhanced Data Access controls	New functionality has been added to allow the assignment of multiple Organizations to a User	Minor New functionality, no impact to existing customers
Case Search	Case Search enhancements	New functionality has been added for: <ul style="list-style-type: none"> • Keywords search on case level and document level • Search within documents • Boolean operators (and, not, or "") in free text fields 	Minor New functionality, no impact to existing customers
Case Forms	Case Assignment automation	New functionality has been added to assign automatically to designated users, according to configured business rules	Minor New functionality, no impact to existing customers
Workflow	Conditional task steps	New functionality has been added for workflow steps to be conditional and only run when errors occur	Minor New functionality, no impact to existing customers

Workflow	Auto routing	New functionality has been added to enable automation steps to run immediately when the user routes to an automated step when required rather than in background	Minor New functionality, no impact to existing customers
Correspondence	Template placeholder enhancements	A number of enhancements have been made to the placeholder configuration capabilities within templates, to enable HTML based templates	Minor New functionality only, no existing functionality has been deprecated
Case Forms	Duplicate Search enhancements	A number of enhancements have been completed on the Duplicate Search algorithm to enable greater performance and accuracy, along with the ability for the intake to be recorded.	Minor New functionality only, no existing functionality has been deprecated
Case Forms	Follow up selective intake screen updates	The follow up Intake screen has been enhanced to allow for reviewing data from original and follow-up case and accept/reject change by section	Minor New functionality only, no existing functionality has been deprecated.
Batch View	Batch view enhancements	A number of enhancements have been made: <ul style="list-style-type: none"> • Multi select assignment of actions • Batch assessment • Review fields flagged • Batch tagging • Filter issues resolved 	Minor New functionality, no impact to existing customers
Device Forms	New regulatory report print capability	New functionality has been added to enable generation of a PDF version of a Device regulatory report	Minor New functionality, no impact to existing customers
Audit	Audit log extension	The audit log has been extended to cover all of the newly added fields and forms in HALO 4.0	Minor New functionality, no impact to existing customers

4. Bugs resolved in HALO 4.0

Area/Process/Group	Title	Description	Impact	Issue traceability
E2B Generation	E2B R3 generation only supports Sender details from the GOM_E2BR3_C table	E2B R3 generation only supports Sender details from the GOM_E2BR3_C table - it defaults to pick from the Reporting destination configuration	None - Fix only	HLP-33
Data Loader	Data Loader: PARENT WORKFLOW tag does not work (XLSX_PARSER)	The Data loader parent link feature (allowing the linking of a parent record using the PARENT WORKFLOW and PARENT) tags is not working in HALO 3.0. The issue seems to be with the PARENT WORKFLOW element which is not properly read by the loader.	None - Fix only	HLP-43
Training	Updated to set due date on training record according to the Training configuration record	Before: Training records created by the BOT would get the default due date configured for the training workflow After: Training records created by the BOT gets the due date set on the parent record ("Setup training" record)	None - Fix only	HLP-46
ICSR Attachments	ICSR: Update ICSR attachments (Literature and Add. docs) to use standard HALO S3 storage instead of DB BLOBs + ICSR Import REST API updates	Various updates to utilise standard storage	None - Fix only	HLP-63
Audit Log	Audit log support for +4000 size fields	These are not audited but revisioned, include in the specification as a result.	Documentation Only	HLP-74

E2B Import	D_7_1_r_3 element parent element bug fix	Mapping issue resolved.	None - Fix only	HLP-154
Login	Bug in login process when logging into cloned environment where the Azure token endpoint is configured	Process updated to timeout after 20 seconds. The error is logged but will not block the normal login (user will not have access to Azure/ OneDrive, but can login and thereby update the incorrect endpoint with admin privileges)	None - Fix only	HLP-178
ICSR Case Processing	ICSR form - H.1 CLOB support	Minor update to page 630 to support storage of CLOB size text values in H_1, H2 and H_4.	None - Fix only	HLP-199
Email Notifications	Email notifications are not automatically disabled for de-activated or deleted users in HALO	Issue now resolved via minor filter updates.	None - Fix only	HLP-345
ICSR Import	Medicines data fields - R2 values displayed	R2 options are appearing in the forms e.g., patient sex. Can we not include R2 values alongside R3 as this will cause confusion for users and they will select non R3 values by accident. Now set as blank.	None - Fix only	HLP-352
Entities and Agreements	Entities and Agreements form > Product tab > Selected products does not render correct when case is read-only	The label and data are shown overlapped. Regular expression updated to resolve.	None - Fix only	HLP-379
Scheduler Window	Scheduler window does not open (code lists hangs)	Issues with code list resolved.	None - Fix only	HLP-761
Case Processing	Nullification processing fails where sender is the same as the existing	The duplicate search automation is updated to auto-accept true FUs (same WWUID) - the FU data are added in a new revision in the existing case. Workflow step of the FU is completed (case will be routed to FU workflows by the routing rules), and the initial/ existing case is up versioned, and workflow restarted. If nothing stops the case,	None - Fix only	HLP-870

		workflows will auto-completed (i.e., case might be picked up for QC check - if it is a nullified case, it will always stop in QC).		
ICSR Batch Processing	HALO/APEX bug: The batch screen (i.e., ICSR processing > batch) initially only show few records	The batch screen shows only a few records (typically two) even though more rows are present. Every time you click "Go" it loads more and more records - it seems to be an APEX Interactive Grid bug. This is critical, as the batch screen is not really useable without all rows being shown. Now resolved.	None - Fix only	HLP-871
Validation	Use of ' in Data element validation descriptions result in error when evaluating the validation	Process updated to remove ' in the data element name and description fields before processing the validation rule.	None - Fix only	HLP-89

5. Features removed from HALO 4.0

Support of Internet Explorer browser.

6. Known issues & workarounds

Area/Process/Group	Title	Description	Workaround	Issue traceability
Case Processing	Narrative Incident Summary - Narrative Truncated	In the Narrative form, the second box named "Narrative in native language (H.1 local substitution) does not allow the user to save any information	The data will be saved by clicking on the 'Save' button twice	HLP-1023
Product Configuration	It is not possible to edit AUTH_TYPE_ID on the Medicinal Product form	The field is read only so cannot be updated by an end user	Via a support request, AUTH_TYPE_ID needs setting to Public. (This ensures all records in MPD_MP have AUTH_TYPE_ID NOT NULL, and then get added to the PI.)	HLP-1044

7. Contact

Contact Insife service desk (support@insife.com) for any query related to installation or changes in this release.

8. Change Log

Revision	Date	Author	Description
1.0	25-APR-2022	Richard Salter	New document