HALO 4.1 Release Notes
Final
Version 1.0
Department: Release Management

Document Approvals

Name	Date and Signature	Role/Meaning
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1. Overview

Insife "HALO" 4.1 is a minor release enhancing the capabilities of HALO 4.0, 4.0.1 and 4.0.2. It contains a number of updates as detailed in section 3 to support some key identified bugs and issues, along with some limited new/ updated features.

2. Upgradability

HALO 4.1 can be upgraded from any previous HALO release (on top of a HALO 4.0.2 upgrade). It can also be deployed as a standalone full installation.

3. Compatibility

HALO 4.0.2 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** was no longer supported from 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 107 and Edge on version 105.

4. Changes since the last release

The following features have been updated in this release:

Area/Process/Group	Title	Description	Impact
Aggregate Reporting	Aggregate Report Configuration	New field / switch to determine whether the PADER report uses submission date or latest receipt date when filtering records. Various other editorial page updates.	**Minor** New functionality, no impact to existing customers
Workflow	Standard Workflow Overview not working as expected - Checkbox behaviour	The checkboxes have been enhanced to filter as per expected behavior of each. New configuration switches added to set the default selection.	**Minor** New functionality, no impact to existing customers
Communication Module	Email Integration	New functionality added for integration with Azure mailboxes: - Capability to manage multiple email boxes - Auto generation of template-based acknowledgement mail - Ability to send body as XML	**Minor** New functionality, no impact to existing customers
Device Follow Up	Device Follow Up Intake Logic	Criteria for automatic Follow-up and auto-merging updated: 1. WWUID matches an existing record 2. Sender for the case is the same (ICSR logic) OR the record is tagged with "Auto-merge" In addition, adding flagging of records that are linked as follow-up but not auto merged	**Minor** New functionality, no impact to existing customers
Record Locking	Factory Lock	Updated to ensure that a factory locked and assigned record can be re-assigned by the workflow manager	**Minor**

			New functionality, no impact to existing customers
Case Allocation	Auto Allocation	New capability to specify a 'Maximum task auto-assignments' value for user specific cap for auto-assignment	**Minor** New functionality, no impact to existing customers
Patient HCP Schema	Patient HCP 1.6.2	Schema extended to ingest, manage and export the fields added to the Schema as part of Patient HCP 1.6.2	**Medium** Extended schema only (no deprecation) though regression testing of any Device integration should be completed
Data Loader	Parent Link	Adaptation of the Data Loader functionality to align with the functionality of linking records in HALO	**Minor** New functionality, no impact to existing customers (existing linking options still supported)
User Management	Assign multiple roles to a user	Functionality has been added to assign multiple roles to a user at once	**Minor** New functionality, no impact to existing customers
Manufacturer Interface	Exchange of Manufacturer ID	Capability added to HALO and the interface in/out to optionally exchange third party Manufacturer ID	**Minor** New functionality only executed once enabled, no impact to existing customers
Case Forms	ICSR and Device Requirement Details	Separate tabs split to have dedicated displays for ICSR and Device	**Minor** Existing customers should assess if existing Device rules should be migrated to the new tab (optional)
Data Warehouse	Data Warehouse	A new DW has been added for the purpose of interfacing with reporting and analytics solution. This first instance has Devices based tables only	**Minor** New functionality, no impact to existing customers

All modules / record types	View/Edit Record	A reload button has been added to this page	**Minor** New functionality, no impact to existing customers
HALO UI	Various Screens	Updates made: Show tags on records in complete state Blocking popups improvements (switched for IMDRF Codes) MedDRA display updates Coded drug name field for each indication/substance/dosage Adding new reaction terms allows alert term or always serious check boxes to be ticked	**Minor** New functionality, no impact to existing customers
Organizational entities	Entity Form	"State" field has been added to the Organizational Entity Form	**Minor** New functionality, no impact to existing customers
Coding	Batch Auto Coding	Functionality added to enable Batch Auto Coding of cases	**Minor** New functionality, no impact to existing customers
List Values	Sort Order	General update to sort List Values based on the value/name by default if no sorting is provided	**Minor** If configured sorting is still the first option. Only if no sorting is configured in the code list it will sort
Device Module	FSCA	New forms and interface capabilities to manage FSCA cases	**Minor** New functionality, no impact to existing customers
Device Module	MIR Export	Switch added to allow selection of MIR EC Standard or Patient HCP	**Minor** New functionality, no impact to existing customers
Device Module	Outbound Submissions	Addition of a Device specific Outbound Submission Scheduling engine	**Minor** New functionality, no impact to existing customers

Requirements Intelligence	Form Updates	Regulatory documents form: Added "Published date" in addition to the existing Effective date. Publish date is displayed first	**Minor** New functionality, no impact to existing customers
Product Module	Product Index for License Trade Name	New combination on the Product Index for License Trade Name	**Minor** New functionality, no impact to existing customers
Product Module	HALO Code Visibility	HALO Code added to various list views	**Minor** New functionality, no impact to existing customers
Product Module	Product Name Variation	New (read-only) page for Product Name Variation	**Minor** New functionality, no impact to existing customers
Product Module	Product Browser	Links from Product Index browser to PI Page - Sci. Ing Group (NPCG) - Product Group/Family (PBG) - Substance	**Minor** New functionality, no impact to existing customers
Product Module	Substance Browser	Hyperlink added to the substance browser to click through to associated products	**Minor** New functionality, no impact to existing customers
Product Module	PBG	Create date for PBG has been made visible	**Minor** New functionality, no impact to existing customers
Product Module	NPCG	When creating an NPCG the record title is forced to always be the NPCG name It is now not possible to create NPCG with only one substance contained	**Minor** New functionality, no impact to existing customers
Product Module	Substance group	Ordering changes so that substance group entry is shown at the top and other entries alphabetical	**Minor** New functionality, no impact to existing customers

ICSR	Visibility of narrative free text	The narrative (H.1) content now opens in a pop-up window (read only) when clicking at the Help button next to the narrative field. This pop-up window keeps open when navigating to other case tabs and disappears when the ICSR record is closed or when the user actively closes the pop-up	**Minor** New functionality, no impact to existing customers
ICSR and Device	AI Functionality	AI functionality is now available as an optional new configuration to provide: • A device model that classifies the narratives into Annex A, E and F codes • A medicines model that extracts drugs and reactions from the narrative and determine drugs and reactions from the drug dictionary and the MedDRA dictionary	**Minor** New functionality, no impact to existing customers
Search / Worklists	Previous Search Filters	Retained previous search has been removed from Search Filters	**Minor** New functionality, no impact to existing customers

5. Bugs resolved in HALO 4.1

Area/Process/Group	Title	Description	Impact	Issue traceability
File Upload	Error on file upload	When uploading a file to HALO, a user occasionally receives a message that the file already exists.	None, fix only	HLP-2351 HLP-1910
Product Maintenance	Product Auth Type is invisible on Product Details form and unset	Product Auth Type is invisible on Product Details form and unset. This means it is ignored by the Product Index. Product Type 85 (Invalid) is also set in error. Now fixed.	None, fix only	HLP-2138 HLP-2139
Workflow	Workflow Records Overview	Workflow Records Overview - Active Task filter should show only relevant workflow steps. This works for the Current Task column, but not for other columns. Now fixed.	None, updated functionality	HLP-695
Workflow	Standard Workflow Overview	Standard Workflow Overview not working as expected - Checkbox behaviour. Checkbox "Completed" (unchecked) - shows open records. Checkbox "Workflow" (unchecked) - shows completed records. → combination Checkbox "Completed" (unchecked) + Checkbox "Workflow" (unchecked) shows all records. Now fixed.	None, fix only	HLP-1976
HALO UI	Date Formats	Some date fields were not consistent with the standard 3 box format (for partial date entry), causing some update issues. Some overlapping text display issues also resolved.	None, fix only	HLP-2651 HLP-2617 HLP-2566
Organizational entities	Entities Form	When user updates a value in the Entities Form it does not show up on audit trail. Now fixed.	None, fix only	HLP-2575

Home Screen	My Tasks	The view has been updated so that it only displays tasks for the current user	None, fix only	HLP-2539
Workflow	Workflow Management	Workflow managers not able to change assigned user on locked records. Now fixed.	None, fix only	HLP-2529
Device Module	GMDN CT Picker	Various functionality issues with the GMDN CT Picker resolved	None, fix only	HLP-2427
Workflow	Submissions	When re-activating a nullified record, the automatic note added stated "Deactivated" instead of "Re-activated". Now fixed.	None, fix only	HLP-2286
HALO UI	Overview Screens	HALO 4 Overview Screens missing the Master Country. Now fixed.	None, fix only	HLP-2034

6. Features removed from HALO 4.1

Support of Internet Explorer browser was removed from the HALO 4.0 onwards.

7. Known Issues & Workarounds

Area/Process/Group	Title	Description	Workaround	Issue traceability
ICSR	C.1.2/C.1.4/C.1.5 Editable	In the ICSRs (medicines intake) > ICSR Intake & ICSR Processing workflows, pressing the 'Tab' key when entering the year in the Date Report Was First Received from Source, Date of Most Recent Information for This Report (C.1.5)* and Date of Creation fields lets the user input text into these fields	Training Point (usability issue only – when a case is locked / read-only users cannot modify the fields, so the error does not impact data integrity)	HLP-1261
ICSR	Patient Information	The patient 'weight' field does not contain decimal places	The required information is visible on any imported ICSR record via the attachment	HLP-1293
Workflow	Workflow Tasks Overview	Workflow Tasks Overview shows Role ID instead of Role Name in column Wf task assignment 1	Training Point	HLP-158
Product Module	Manage Admin Routes:	The user is prevented from creating a new route of administration upon clicking the + (create new) button. The message "Admin Route Name must have some value" is displayed, but it is not possible to enter anything as the field does not allow input prior to getting to new record creation.	Click on an existing entry on the left of the screen before clicking the + button	HLP-2956

All modules / record types	Case locking	If a user jumps between records (i.e., using the linked records section), locks on the initial record are not automatically released (as the record is not being closed)	Training point / locks on inactive cases will be removed automatically after half an hour	HLP-2822

8. Contact

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

9. Change Log

Version	Date	Author	Description
1.0	30-NOV-2022	Richard Salter	New document