HALO 4.0.2 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" 4.0.2 is a minor release enhancing the capabilities of HALO 4.0 and 4.0.1. It contains a small 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 4.0.2 can be upgraded from any previous HALO release (on top of a HALO 4.0.1 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 104.

4. Changes since the last release

The following features have been updated in this release:

Area/Process/Group	Title	Description	Impact
Audit Log	Audit Log	Audit log enhanced to better support repeatable sections, making it easier to see before and after values. In addition, the performance of the audit log is improved.	**Minor** New functionality, no impact to existing customers
Device case output API	MIR Output	The API has been extended so that it can be switched between MIR EC Standard or Patient HCP Standard	**Minor** New functionality, no impact to existing customers
Workflow Configuration	Workflow improvements	Several cosmetic and usability issues improved within the workflow configuration framework. All existing functionality remains supported.	**Minor** New functionality, no impact to existing customers
Workflow Configuration	Master records listing	Worklists are made more detailed and specific in 4.0.2 for Substance groups, Signals, Signal Detection, ICSRs, Correspondence, Data collection programs, Submissions, Medicinal Products, Device Products, Product licenses, Device incidents, Device trend incidents, Agreements, Entities, Product families	**Minor** New functionality. Existing customers should assess if they want to take the new lists into use or stay with the old, standard views Switching to the new lists, requires basic business configuration (code list updates)
Workflow Configuration	Due date calculation	The task due date now gets updated when changing master due date	**Medium** Existing customers should review current configuration

Device Case Management	Batch Intake	Batch intake screens added for bulk import management	**Minor** New functionality, no impact to existing customers
Signal Management	Module alignment	Alignment and consolidation of the Signal Management components	**Minor** Alignment of existing functionality, no impact to existing customers
Organization and Agreements	Revised structure	The two entities have now been separated in the database, UI and API implementation (splitting organizational entities and agreement details)	**Medium** The technical upgrade handles migration of agreement related data from the organizational entity forms to the new agreement forms, but customers must decide on how to configure workflows to utilize the new form: Add the agreements form (in addition to the organizational entity form) Switch to agreement only Keep organization forms only
ICSR Case Management	DOB conversion into patient age and unit	As an optional switch enabled new function, the DOB can be converted into patient age and unit for any newly ingested cases	**Minor** New functionality, no impact to existing customers
ICSR Case Management	Product coding	The Auto-coding refresh button has been removed (now automatic) to enhance overall usability	**Minor** New functionality, no impact to existing customers
Product Management	Product Management	Various usability and UI enhancements to the product management pages	**Minor** New functionality, no impact to existing customers
Reporting	PBRER Remplate	A new PBRER template has been added to Aggregate reporting for post-market reporting to EEA countries	**Minor** New functionality, no impact to existing customers

Reporting	PADER Remplate	A new PADER template has been added to Aggregate reporting for post-market reporting to USA	**Minor** New functionality, no impact to existing customers
Submission Management Module	Submission Management	Minor UI and usability updates	**Minor** New functionality, no impact to existing customers
Risk Management Module	Risk Management	Minor UI and usability updates	**Minor** New functionality, no impact to existing customers
User Administration	User Administration	Minor UI and usability updates	**Minor** New functionality, no impact to existing customers
Data Loader	Data Loader	Various usability and UI enhancements to the data loader tool	**Minor** New functionality, no impact to existing customers
Communication Module	Email outputs	Enhanced to manage multiple attachments in both outbound- and inbound emails	**Minor** New functionality, no impact to existing customers

5. Bugs resolved in HALO 4.0.2

Area/Process/Group	Title	Description	Impact	Issue traceability
E2B R3 Profile	Pick sender address details from the submission record owner	R3 E2B profiles (EMA, Korea, China) picks the address details for the sender section from the E2B fields of the reporting destination. This was updated to pick the address from the Organization owning the Submission record.	None - Fix only	HLP-2125
Product Maintenance	Pharmaceutical Products > Active ingredient issue	In the Pharmaceutical Products maintenance screen, the active ingredient display only the number and not the name	None - Fix only	HLP-1841
Product Maintenance	Pharmaceutical Products > Not possible to delete an entry	It was not possible to delete and entry in the Pharmaceutical Products maintenance screen, this has been resolved.	None - Fix only	HLP-1837
Product Maintenance	Combination product details form issue	The form was not functional due to a coding issue, this has been resolved	None - Fix only	HLP-1499
ICSR	Alpha numeric character not handled in Target_Override during data import	Alpha numeric characters were not handled in Target_Override, this has now been resolved	None - Fix only	HLP-1933
ICSR	Narrative > Blank spaces removed	ICSR Narrative fields (page 630) removes all blank spaces after "." character, this has been resolved.	None - Fix only	HLP-1712
ICSR	Patient/Parent Form field names	In Patient/ Parent form, in the past drug history tab, the button under indication says, 'Re-code event' and not 'Re-code indication' as expected The text is also an issue under drug indications. This has been resolved.	None - Fix only	HLP-1507

ICSR	ARISG Export > Device lot. numbers	ARISg export scripts updated to include Device lot numbers. Previously, only drug lot numbers were exported for combination products.	Minor - lot no. should be pulled specifically for devices (when available)	HLP-1495
ICSR	Product Not Getting Coded in an Unblinded Case	An issue was identified with product coding when the Case blinding status/ Investigational Product Blinded (G.K.2.5) are set to UNBLINDED/ No, respectively. When a case has any product as unblinded, it is not possible to code new products, or recode that same product via the refresh button next to Coding details.	None - Fix only	HLP-1228
ICSR	Age Group (D.2.3) Not Updating After Entering a New Age at onset (D.2.2a) Value	If age at onset (D.2.2a) is entered without entering the patient's date of birth, then changed the Age at onset (D.2.2a) and save the case, the Age Group (D.2.3) was not auto calculated/ updated to the correct new value (Child) and remained as Adult.	This issue was Rejected due to re-clarification of the requirements (see updated specification)	HLP-1194
Entities/Agreements	Entities/Agreements form issues	Entities/ Agreements form: tab 'Organizations' does not display the complete list of entities	None - Fix only	HLP-1382
Submission	Scheduler closing unexpectedly between licenses	Currently, the scheduler will choose "randomly" between all applicable licenses. For rules where "Schedule on similar" ingredients is enabled, this means that it might pick another product than the one in the case - as long as it is having the exact same product. To resolve this, the product filter is updated to exclude the similar ingredient list unless there is not direct hit.	None - Fix only	HLP-1609
Submissions	Product sort order	Product sort order in the submission is picking the second suspected product (when creating ICSRs records manually). New controls have been added to enable the sequence to be moved up and down for each item.	None - Fix only	HLP-1314

Submissions	Submission details form does not get automatically updated	In the Submission workflows, the field License Application - or Auth- number in the Submission details form does not automatically update after selecting a new product license. The previously selected license number remains. This has been resolved.	None - Fix only	HLP-1326
Submissions	Submission details form validation	Submission details form has been updated so that the validation rules on "Save".	None - Fix only	HLP-1516
Aggregate Reporting	Aggregate reporting workflow > Functionality menu > Line Listing error	The report was erroring when called due to a code issue, this has been resolved	None - Fix only	HLP-1180
PADER Related	Various issues	A number of issues related to the selection of the appropriate data have been resolved	None - Fix only	HLP-835
Workflow	Task actions title issue	Task actions failed when record title include specific character(s); this has been resolved	None - Fix only	HLP-704
Workflow	Task Scheduler closes when deleting a schedule	The Task Scheduler closed when deleting a schedule, this has been resolved	None - Fix only	HLP-694

6. Features removed from HALO 4.0.2

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
File Upload	Error on file upload	When uploading a file to HALO, a user occasionally receives a message that the file already exists.	Contact support to ensure the correct file is aligned	HLP-2351
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
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	HLP-1261
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.	After creating a new product manually, request the field to be updated by the support team	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	Training Point	HLP-695

Workflow	Workflow Tasks Overview	Workflow Tasks Overview shows Role ID instead of Role Name in column Wf task assignment 1	Training Point	HLP-158
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	Training Point	HLP-1976

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	31-AUG-2022	Richard Salter	New document