

Software Release Report

Title		
SW Release report for ISCUSflex NG software rev M (3.0.11.53)		
Document number	Project number	Unique ID
D9163-18	192	
Approved: Date/Sign		Approved: Date/Sign
2026-08-25 <i>Magnus Hedberg</i>		2026-08-25 <i>Magnus Hedberg</i>
Author, Magnus Hedberg		Approver

1. Article

This document specifies the configuration items for the following software product

Reference number (Article number)	Revision	Name
8050256	M	ISCUSflex Win Application Software
8050255	F	ISCUSflex WIN Appl SW component

2. Configuration Items

2.1. SOUP

Item	the title	the manufacturer	the unique SOUP designator
Operating System	Windows 11 Pro	Microsoft	Version 25H2 OS build 26200.8524
.Net Framework	.NET Framework 4.8	Microsoft	Ver 4.8.09221
Database	SQL CE Server	Microsoft	Ver 3.5.1.0
System	Common Language Runtime	Microsoft	Ver 4.0.30319.42000

2.2. Configuration Documentation

The system has been built using Visual Studio 2022 (version 17.14.31, April 2026).

C# Tools 4.14.0-3.25412.6+c167adef821b9ba2f1c44c227a5e79ca11876461

Microsoft .NET Framework Version 4.8.09032

Source code from GIT, version 3.0.11.53

2.3. Software System

Item	Version
AdapterLib_Iscus.dll	1.0.0.0
AdapterLib_FORSCUS.dll	1.0.0.0
CMASeriesLib.dll	1.0.0.0
CMAWinCEControls.dll	1.0.0.0
Common_FORSCUS.dll	1.0.0.0
CommonTools.dll	1.0.0.0
Core_FORSCUS.dll	1.0.0.0
DBAdmin_FORSCUS.dll	1.0.0.0
DBLib_FORSCUS.dll	1.0.0.0
IscusLib.dll	1.0.0.0

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DBLib_FORSCUS.dll	1.0.0.0
IscusLib.dll	1.0.0.0

Item	Version
Microsoft.Windowsce.Forms.dll	3.5.7283.0
IscusSimulatorAdapter	3.0.11.53
IscusTest.exe	3.0.11.53
Loader_Iscus.exe	3.0.11.53
OSAccess.dll	3.0.11.53
RemoteHWAdapter_FORSCUS.dll	1.0.0.0
ServiceGUI_FORSCUS.dll	3.0.11.53
StatusBar_FORSCUS.dll	3.0.11.53
UserGUI.dll	3.0.11.53
ViewLib_Iscus.dll	3.0.11.53
ViewLogFiles.exe	3.0.11.53
XE-50.dll	3.0.11.53
Language files	
cs\Common_Iscus.resources.dll	3.0.11.53
cs\Loader_Iscus.resources.dll	3.0.11.53
cs\UserGUI.resources.dll	3.0.11.53
da\Common_Iscus.resources.dll	3.0.11.53
da\Loader_Iscus.resources.dll	3.0.11.53
da\UserGUI.resources.dll	3.0.11.53
de\Common_Iscus.resources.dll	3.0.11.53
de\Loader_Iscus.resources.dll	3.0.11.53
de\UserGUI.resources.dll	3.0.11.53
es\Common_Iscus.resources.dll	3.0.11.53
es\Loader_Iscus.resources.dll	3.0.11.53
es\UserGUI.resources.dll	3.0.11.53
fr\Common_Iscus.resources.dll	3.0.11.53
fr\Loader_Iscus.resources.dll	3.0.11.53
fr\UserGUI.resources.dll	3.0.11.53
it\Common_Iscus.resources.dll	3.0.11.53
it\Loader_Iscus.resources.dll	3.0.11.53
it\UserGUI.resources.dll	3.0.11.53
nl\Common_Iscus.resources.dll	3.0.11.53
nl\Loader_Iscus.resources.dll	3.0.11.53
nl\UserGUI.resources.dll	3.0.11.53
no\Common_Iscus.resources.dll	3.0.11.53
no\Loader_Iscus.resources.dll	3.0.11.53
no\UserGUI.resources.dll	3.0.11.53
ro\Common_Iscus.resources.dll	3.0.11.53
ro\Loader_Iscus.resources.dll	3.0.11.53
ro\UserGUI.resources.dll	3.0.11.53
ru\Common_Iscus.resources.dll	3.0.11.53
ru\Loader_Iscus.resources.dll	3.0.11.53
ru\UserGUI.resources.dll	3.0.11.53

Item	Version
Language files (continued)	
sl\Common_Iscus.resources.dll	3.0.11.53
sl\Loader_Iscus.resources.dll	3.0.11.53
sl\UserGUI.resources.dll	3.0.11.53
sv\Common_Iscus.resources.dll	3.0.11.53
sv\Loader_Iscus.resources.dll	3.0.11.53
sv\UserGUI.resources.dll	3.0.11.53
tr\Common_Iscus.resources.dll	3.0.11.53
tr\Loader_Iscus.resources.dll	3.0.11.53
tr\UserGUI.resources.dll	3.0.11.53
CLIA Module	
CLIAModule\CLIAModule.exe	3.0.11.53
CLIAModule\ CMASeriesLib.dll	3.0.11.53
CLIAModule\ CMAWinCEControls.dll	3.0.11.53
CLIAModule\ Common_Iscus.dll	3.0.11.53
CLIAModule\ OSAccess.dll	3.0.11.53
Bootup Application (REF 8050258)	
C:\MDIA\Bootup\Bootup.exe	3.0.11.53
PowerMonitor application	
C:\MDIA\Bootup\PowerMonitor.exe	3.0.11.53
PowerMonitor languages files	
cs\Common_FORSCUS.resources.dll	3.0.11.53
cs\PowerMonitor.resources.dll	3.0.11.53
da\Common_FORSCUS.resources.dll	3.0.11.53
da\PowerMonitor.resources.dll	3.0.11.53
de\Common_FORSCUS.resources.dll	3.0.11.53
de\PowerMonitor.resources.dll	3.0.11.53
es\Common_FORSCUS.resources.dll	3.0.11.53
es\PowerMonitor.resources.dll	3.0.11.53
fr\Common_FORSCUS.resources.dll	3.0.11.53
fr\PowerMonitor.resources.dll	3.0.11.53
it\Common_FORSCUS.resources.dll	3.0.11.53
it\PowerMonitor.resources.dll	3.0.11.53
nl\Common_FORSCUS.resources.dll	3.0.11.53
nl\PowerMonitor.resources.dll	3.0.11.53
no\Common_FORSCUS.resources.dll	3.0.11.53
no\PowerMonitor.resources.dll	3.0.11.53
ro\Common_FORSCUS.resources.dll	3.0.11.53

Item	Version
PowerMonitor languages files (continued)	
ro\PowerMonitor.resources.dll	3.0.11.53
ru\Common_FORSCUS.resources.dll	3.0.11.53
ru\PowerMonitor.resources.dll	3.0.11.53
sl\Common_FORSCUS.resources.dll	3.0.11.53
sl\PowerMonitor.resources.dll	3.0.11.53
sv\Common_FORSCUS.resources.dll	3.0.11.53
sv\PowerMonitor.resources.dll	3.0.11.53
sv\UserGUI.resources.dll	3.0.11.53
tr\Common_FORSCUS.resources.dll	3.0.11.53
tr\PowerMonitor.resources.dll	3.0.11.53
Main Board Firmware	
Internal version (readable using the GetVersion button in IscusTest):	
MSP Stepper Motor Version	3.4
MSP Controller Version	3.4

2.4. Helpers

Item	Version	Comment
OnlineLogDisplay.exe	2026-02-20	Software for saving log data (DEBUG)
DebugFileScannerForIscusFlex.exe	1.8	Software for analyzing log data (DEBUG SCANNER)
ICUpilot	2.4	Software for exploring data
IscusCollect	3.9.0.1	Software for saving data in ICUpilot and relay data to PDMS/ER systems
IscusFlexInstallation.exe	3.0.11.53	Software for compiling files to a release folder
CMAPreUpdate.exe	1.0.0.0	Installation pre phase
CMAPostUpdate.exe	3.0.11.53	Installation post phase
VNCRegistrySettings.exe	3.0.11.53	Update registry settings (REGISTRY)
UpdateDB_ISCUSflex.exe	3.0.11.53	Update database settings
ViewLogs.exe	3.0.11.53	View log files and trends (VIEWLOGS)

3. Related documents

Formal software verification has been finalized. Practical testing has been made and no new anomalies have been found. All known residual anomalies are documented and evaluated in release 3.0.11.53. The anomalies were found not to contribute to an unacceptable risk.

D9164-01 P192 ISCUSflex WinCE 5 V&V Summary Report (2.1.0.447, Rev L).
D9164-02 P192 ISCUSflex WinCE 5 V&V Summary Report (2.1.0.449, Rev L).
D9164-03 P192 ISCUSflex WinCE 5 V&V Summary Report (2.1.0.459, Rev L).
D9164-04 P192 ISCUSflex WinCE 5 V&V Summary Report (2.1.0.465, Rev L).
D9164-05 P192 ISCUSflex WinCE 5 V&V Summary Report (2.1.0.468, Rev L).
D9164-06 P192 ISCUSflex WinCE 5 V&V Summary Report (2.1.0.470, Rev L).
D9164-07 P192 ISCUSflex WinCE 5 V&V Summary Report (2.1.0.471, Rev L).
D9164-08 P192 ISCUSflex WinCE 5 V&V Summary Report (2.1.0.472, Rev L).
D9164-09 P192 ISCUSflex WinCE 5 V&V Summary Report (2.1.0.475, Rev L).
D9164-10 P192 ISCUSflex WinCE 5 V&V Summary Report (2.1.0.477, Rev L).
D9164-11 P192 ISCUSflex WinCE 5 V&V Summary Report (2.1.0.478, Rev L).
D9164-12 P192 ISCUSflex WinCE 5 V&V Summary Report (2.1.0.485, Rev L).
D9164-13 P192 ISCUSflex WinCE 5 V&V Summary Report (2.1.0.494, Rev L).
D9163-14 P192 SW Release report for ISCUSflex software rev M (3.0.11).
D10721-00 P192 Verification Report ISCUSflex NG Software (8050256M 3.0.10)
D10721-01 P192 Verification Report ISCUSflex NG Software (8050256M 3.0.11.0)
D10721-02 P192 Verification Report ISCUSflex NG Software (8050256M 3.0.11.3)
D10721-03 P192 Verification Report ISCUSflex NG Software (8050256M 3.0.11.4)
D10721-04 P192 Verification Report ISCUSflex NG Software (8050256M 3.0.11.15)
D10721-05 P192 Verification Report ISCUSflex NG Software (8050256M 3.0.11.16)
D10721-06 P192 Verification Report ISCUSflex NG Software (8050256M 3.0.11.28)
D10721-07 P192 Verification Report ISCUSflex NG Software (8050256M 3.0.11.44)
D10721-08 P192 Verification Report ISCUSflex NG Software (8050256M 3.0.11.53)

IEC 62304:2006 and IEC 60601-1-6

4. 8050256 ISCUSflex Win Application Software Release notes

See D9163-16 P192 SW Release report for ISCUSflex software rev M (3.0.11.28) for earlier releases.

Rev M (3.0.10.1, December 2024)

See D10723-00 P192 ISCUSflex NG Software Change History

Rev M (3.0.11.4, April 2025)

See D10723-01 P192 ISCUSflex NG Software Change History

New functionality:

PowerMonitor – Separate helper application which gives the possibility to close the system when needed.

New service codes:

SHOW PACKLOGS – Show packlogs folder in explorer

PACKLOGS – Packs log files for trouble shooting

PACKLOGS CLEAR - Clears the packlogs files, only the latest logs are packed

CLOSE – Closes the running application (ServiceGUI/UserGUI)

RESTART – Restarts the application

Remedied Defects:

TT #340 New Service Code ICUPILOT to start or show ICUpilot

TT #341 Extend the RunWastePumpCommand timeout to 5000 ms

TT #342 D10692-01 SSR 14.125 & 14.125 SHOW/HIDE AIRGAP

TT #343 Reportable Range misfunction when running ordinary samples

TT #344 PowerMonitor

TT #345 Internal communication issues

TT #346 Database defaults updated (including TT #339)

TT #347 Several service codes added

TT #348 CPL files may be run (Control Panel files)

TT #349 Brightness Control

Rev M (3.0.11.16, June 2024)

See D10723-02 P192 ISCUSflex NG Software Change History

New functionality:

Cleaning now works

PowerMonitor translated to all supported languages

Taskbar icon for status messages (Click to open or hide)

New service codes:

SETTINGS – Open the system settings

SHOW STATUS – Shows the StatusMessages dialog

Remedied Defects:

TT #350 Timeout when cleaning is made (Sterilize procedure)

TT #351 SW crashes when registry lacks the HKCU\System\Ident settings

TT #352 RETURNPUMP CYCLES default is too large

TT #353 VialID editing not always possible

TT #354 Batch analyses operators are recorded as UNKNOWN in the CLIA log (still failing)

Rev M (3.0.11.28, October 2025)**See D10723-03 P192 ISCUSflex NG Software Change History****New functionality:**

Service code input is now simplified. A help text is displayed for each service code.

On-Screen Keyboard (OSK) is activated as required in all dialogs where the ISCUSflex keyboard is not available.

An Autosize dialog has been implemented.

Internal communication has been updated to almost 100% stability.

See also remedied defects.

New service codes:

SHUTDOWNTIMESTAMP – Get/Set number of times per day during a session to save ShutdownTimeStamp

LOG INVOKE ERROR YES/NO – Log invoke error in service log

Remedied defects:

TT #354 Batch analyses operators are recorded as UNKNOWN in the CLIA log (still failing)

TT #355 An autosize dialog is desirable

TT #356 Possibility to keep Anydesk running at start up

TT #357 When a path for Network store contains invalid characters the software crashes at startup

TT #358 Sometimes the software crashes due to internal communication flaws

TT #359 Combobox dropdown is misplaced in the batch dialog.

TT #360 Too many super washes, should be decreased in number

TT #361 ControlSamples - When clicking on an item, details are only shown for 30 ms

TT #362 At shutdown the final message is shown extremely short

TT #363 An On-Screen Keyboard is necessary for ServiceGUI (and more)

TT #364 Analysis dialog does not update Status bar sample vial icons properly

TT #365 Factory reset function requested

TT #366 Pronounced message at RackIn and RackOut

TT #367 An On-Screen Keyboard is missing for CLIA dialogs

TT #368 A better service code dialog would be nice (with help texts)

Rev M (3.0.11.44, March 2026)

New functionality:

Message text is always copied to clipboard to support trouble shooting.

Support for Glucose units other than mg/dL added.

If the Brightness control fails, it is handled. User is given the choice to restart the system. Until the system is restarted the brightness controls are hidden.

Service log also get entries when closing the system.

Loopback networking (localhost/127.0.0.1 and localhost2/127.0.0.2) may be used for logging and patient data.

Help texts for service codes implemented

DNS names can now be used in network connections

OnlineLogger debugging is highly automated, including automatic restart and removing older log files

PACKLOGS include document log files and OnlineLogger log files

DebugFileScannerForIscusflex always installed and available

IscusCollect always installed and available

Easier to find old data in Graph screen

Print functionality is improved. A4/Letter adaption, option to print to CSV file, option to change default printer

Control samples default values corrected

New service codes:

SHOW CODE HELP – When entering a service code, the service code help is always shown

HIDE CODE HELP – When entering a service code, the service code help is not shown

DEBUG – Starts OnlineLogger for general logging of commands. Automatic restart according to restart interval

DEBUG <hours> – Sets restart interval to <hours>. Default 24 hours.

DEBUG STOP – Stops OnlineLogger

DEBUG CLEAN – Delete log files older than clean interval days. Automatic or manual.

DEBUG CLEAN <days> – Sets clean interval to <days>. Default 90 days.

DEBUG SCANNER – Starts the DebugFileScannerForIscusFlex application for analyses of OnlineLogger log files

ISCUSCOLLECT – Start IscusCollect application to store data locally and optionally pass data to hospital database

Remedied defects:

TT #369 Sometimes sw crashes during servo state (reagent cassette holder is out)

TT #370 Service code for the label showing help text for selected service code would be nice

TT #371 When editing Y-scaling in Settings a clearer header would be nice

TT #372 BatchDialog, when the rack is out, it should stay out until OK

TT #373 BatchDialog - Missing label for vial nr 2

TT #374 See #379. Graph window cannot display data properly (big red cross)

TT #375 When changing unit, control samples are not presented properly directly

TT #376 The CLIA units should be handled correctly

TT #377 Messages dialog should copy text to ClipBoard

TT #378 If GetBrightness doesn't work the software locks on showing messages

TT #379 Red cross over a graph window issue

TT #380 Service log entries shall be created when closing the application

TT #381 Network connection issues shall not flood the Service log

TT #382 DNS names can't be used for network connections

TT #383 Loopback network shall be possible

TT #384 Using localhost in Settings/Data shall be possible

TT #385 Possibility to run batch files in update software

TT #386 New service codes DEBUG, DEBUG STOP and DEBUG CLEAN

TT #387 New service code DEBUG SCANNER

TT #388 New service code ISCUSCOLLECT

TT #389 A simple method to find old data in graphs

TT #390 Printout for A4/Letter format with CSV option

TT #391 Printout dialog should have printer icon for printer selection access

TT #392 New default control samples values (set at installation)

TT #393 Printout of service log duplicates calibration data

Rev M (3.0.11.53, August 2026)**New functionality:**

Number of decimal places can be set manually for any analyte/catheter combination. Automatic scaling is still available.

Reagent cassette status is now properly updated at startup, also the Pyruvate dot, showing that Low calibration interval, is updated correctly.

General dialog cleanup for all languages.

Possibility to easily connect/disconnect a network share using the External media icon in the status bar.

New service codes (obsolete sic!):

CASSETTE STATUS MANUAL – Cassette status has to be manually detected at startup

CASSETTE STATUS AUTOMATIC – Cassette status is detected at startup

Remedied defects:

TT #394 QCData.txt has erroneous List separator after Date-Time

TT #395 Reagent cassette status is not properly updated after restart

TT #396 Please wait text not translated when opening reagent cassette

TT #397 Confusing sample batch setup

TT #398 Number of decimals shall be selectable

TT #399 Application shall be locked to use the SIP (on screen keyboard)

TT #400 General layout assessment

TT #401 Exceptions in Settings/Scaling when selecting <All> catheters

TT #402 When selecting Elevated Control an Exception occurs

TT #403 Editing a single vial in a batch sequence is not possible

TT #404 Clicking on microvials in the status bar shall not lock it

TT #405 Clicking on the External Device icon shall give options to connect or disconnect network share

Verification:

D10721-08 P192 Verification Report ISCUSflex NG Software (8050256M 3.0.11.53)

D10954 P192 ISCUSflex NG Software (8050256M 3.0.11.53) Release Review (R4)