Software Release Report

Title		
SW Release report for ISCUSflex software rev L (2.1.0.494)		
Document number: 9163-12	Project number: 192	Unique ID:
Approved: Date/Sign: 2022-03-14 Magnus Hedberg, Author		Approved: Date/Sign: 20220314, Approver

1. Article

This document specifies the configuration items for the following software product

Reference number (Article number)	Revision	Name
8003726	**L**	**ISCUSflex CE5 Application Software**
8003931	**T**	**ISCUSflex CE5 Appl SW component**

2. Configuration Items

2.1. SOUP

Item	the title	the manufacturer	the unique SOUP designator
Operating System	Windows CE 5.0	Microsoft	WinCE 5.0 Teleca platform
.Net Compact Framework	.NET Compact Framework 2.0	Microsoft	Ver 2.0.7045.0
Database	SLQ CE Server	Microsoft	Ver 3.5

2.2. Configuration Documentation

The system has been built using Visual Studio 2008 (version 9.0.21022.8 RTM).

MS Visual C# 2008 91605-270-0790165-60396

Source code from SVN, version 2.1.0.494

2.3. Software System

Item	Version
AdapterLib_Iscus.dll	2.1.0.494
CFSerialClass.dll	2.1.0.494
CMASeriesLib.dll	2.1.0.494
CMAWinCEControls.dll	2.1.0.494
Common_Iscus.dll	2.1.0.494
Core_Iscus.dll	2.1.0.494
DBAdmin_Iscus.dll	2.1.0.494
DBLib_Iscus.dll	2.1.0.494
FPGABoot.bin	2009-09-02 15:26. See also page 3.
ISCUSClassLibrary.dll	2.1.0.494
Iscus.dll	1.0.0.2 (File Version), 1.0.0.4 (Product Version). See also page 3.
IscusSimulatorAdapter	2.1.0.494

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Item	Version
IscusTest.exe	2.1.0.494
Loader_Iscus exe	2.1.0.494
MCUApi.dll	2009-09-02 15:26. See also page 3.
MCUDriver.dll	2009-09-02 15:26. See also page 3.
OSAccess.dll	2.1.0.494
RemoteHWAdapter_Iscus.dll	2.1.0.494
SerialCommunication.dll	2.1.0.494
ServiceGUI_Iscus.dll	2.1.0.494
StatusBar_FORSCUS.dll	2.1.0.494
UserGUI.dll	2.1.0.494
ViewLib_Iscus.dll	2.1.0.494
ViewLogFiles.exe	2.1.0.494
XE-50.dll	2.1.0.494
Language files	
cs\Common_Iscus.resources.dll	2.1.0.494
cs\UserGUI.resources.dll	2.1.0.494
da\Common_Iscus.resources.dll	2.1.0.494
da\UserGUI.resources.dll	2.1.0.494
de\Common_Iscus.resources.dll	2.1.0.494
de\UserGUI.resources.dll	2.1.0.494
el\Common_Iscus.resources.dll	2.1.0.494
el\UserGUI.resources.dll	2.1.0.494
es\Common_Iscus.resources.dll	2.1.0.494
es\UserGUI.resources.dll	2.1.0.494
fr\Common_Iscus.resources.dll	2.1.0.494
fr\UserGUI.resources.dll	2.1.0.494
it\Common_Iscus.resources.dll	2.1.0.494
it\UserGUI.resources.dll	2.1.0.494
nl\Common_Iscus.resources.dll	2.1.0.494
nl\UserGUI.resources.dll	2.1.0.494
no\Common_Iscus.resources.dll	2.1.0.494
no\UserGUI.resources.dll	2.1.0.494
ro\Common_Iscus.resources.dll	2.1.0.494
ro\UserGUI.resources.dll	2.1.0.494
ru\Common_Iscus.resources.dll	2.1.0.494
ru\UserGUI.resources.dll	2.1.0.494
sv\Common_Iscus.resources.dll	2.1.0.494
sv\UserGUI.resources.dll	2.1.0.494
tr\Common_Iscus.resources.dll	2.1.0.494
tr\UserGUI.resources.dll	2.1.0.494
sl\Common_Iscus.resources.dll	2.1.0.494
sl\UserGUI.resources.dll	2.1.0.494

Item	Version
CLIA Module	
CLIAModule\CLIAModule.exe	2.1.0.494
CLIAModule\ CMASeriesLib.dll	2.1.0.494
CLIAModule\ CMAWinCEControls.dll	2.1.0.494
CLIAModule\ Common_Iscus.dll	2.1.0.494
CLIAModule\ OSAccess.dll	2.1.0.494
Driver files	
Internal versions (readable using the GetVersion button in IscusTest) of the following files: Iscus.dll 1.0.0.5 MCUApi.dll 1.0.0.7 MCUDriver.dll 1.0.0.3 FPGABoot.bin 1.0.0.6	

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 2.1.0.494. 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).

IEC 62304:2006 and IEC 60601-1-6

4. 8003726 ISCUSflex CE5 Application Software Release notes

Rev D (Oct 2009)	**Rev E (R3 Dec 2009) – Selected customers only**
Remote control and file transfer Nominal controls levels for CLIA changed. Glucose in mg/dL Water values now correctly sorted CLIA fixes for Low and Elevated control levels WinCE 5.0 Spanish language Italian language Dutch language Russian language Turkish language	New improved input panel (SIP) Hatch motor set to idle when hatch is closed Russian language When using multiple injections (more than three) a warning is issued German string error fixed Patient data Final attribute fixed
Rev F – not released but formally verified	**Rev G (May 2010)**
Some memory problems solved Calibration approval improved (allows more deviation) Custom reagents together with a reagent cassette now works Printer exception fixed	Urea parameters now printed when printing from the settings dialog Some more memory problems solved Database copy utility added to ISCUS tools Urea reagent handling bugs removed Control samples dialog crashed when opened. Fixed. Calibrations now handle blanks correctly (min/max slope comparisons) Initial absorbance Min value modified for all reagents except Urea to accept new reagents better
Rev H (Aug 2010)	**Rev I (Nov 2010)**
Extra evacuation of wash bin introduced Noise measurement in ISCUStest implemented	CLIA enhancements – extended controls and logging Possibility to change calibration interval HL7 protocol adapted to Telcor requirements

Rev J (Jan 2011)	Rev K (March 2011)
Possibility to reset calibration history when re-calibrating Automatic reset of calibration history at needle change Empty error dialog fixed Auto control results sorted after type also CLIA activated (if used) directly at start up A control question is asked before shut down Calibrator lot and expire date is saved in CLIA Expiry date is stored in the same format as labeled on the reagent, calibrator and auto control bottles Events are sent to any external host (HL7 and XML). Requires IscusCollect version 3.0.0.0 and ICUpilot 2.2.3.30 Bug when loading parameters fixed Remote access activated by default (for service mode too) New service code - COPYDB - to copy database to any external media Patient ID is always folder compatible Z-position 1 mm shallower (wash bin & reagents) Extended logfile including main board number, detector number, IP number and MAC address	Glutamate sample/reagent volumes changed to 1.5/7.5 ul => total amount of 9 ul to increase center volume error tolerance. Glutamate capacity changed to 2700 ul default (total of 4 ml in bottle). New Service Codes: LIFE x is used to set reagent life for all reagents to the specified number of days. Entering LIFE only will return the actual number of days already set. GLTA sets Glutamate capacity to 1700 ul after restart (Glutamate reagent rev A). GLTB sets Glutamate capacity to 2700 ul after restart (Glutamate reagent rev B). CLIA module: Default selection for the approval interval fills in levels as stated on control samples sheet. Nominal auto control levels slightly adjusted for Glucose (< 0.1 %). Extra log file information included in paper print out.
Rev L (May 2011)	**Rev L (2.0.0.292, June 2011)**
Miscellaneous bug fixes New Service codes: - MOVECLIA to move/copy CLIA-logs to the SD card - CELSIUS and FAHRENHEIT to switch temperature unit. - RESTART to restart ISCUS*flex*. Works also in Service mode. - STARTFTP now accepts an argument, e.g. STARTFTP \SDMEM\DATA. Start application also activates the VNC server which makes it possible to update ISCUS*flex* remotely. Start application checks that it is run under WinCE5 and on the proper machine, i.e. ISCUS update for ISCUS and ISCUS*flex* update for ISCUS*flex*. Improved remote control. Easy to copy files from the SD card to another computer. New CLIA file which can be easily imported in Excel (using MOVECLIA). HL7 issues fixed – date/time format in some messages and number of decimal points in message.	Miscellaneous bug fixes. Important bug fix: Saving data to SD card and sending XML last admission to remote host only worked for the first registered patient and not for the following patients. The display unit is now used in XML and HL7 exports. Operator identity included in the HL7 output (CLIA only). Vial ID included in sample results in log file. New service code SEND P<x> which sends all data for the specified patient position (e.g. SEND P2), works only in XML mode.

Rev L (2.0.0.298, September 2011)	Rev L (2.0.0.336, May 2012)
Miscellaneous bug fixes: Service GUI clock format corrected. Multiple entries in HL7 output removed. Reset of calibration history causing exception corrected. Faulty event message formatting in CLIA log file corrected. Errors in CLIA handling of Glucose unit of measurement corrected. Reagent dialog suddenly appearing when using CLIA functionality corrected. Failing calibration reporting Success corrected.	Production test reverted to rev K type. Vial nr included in HL7 messages and XML messages for ICUpilot compatibility. HL7 messages packed and sent (for non-completed messages) when vial is removed or ISCUSflex is switched off. CannulaType included; Screw (new one) or Snap (old one) type. A Registry setting that is shown in log file and cannula change dialog. Measurement cell included in registry settings and shown in log file. New Bootup application (ver 2.0) which allows USB upgrade and maintenance. Requires U01390C software tool. TestTrack bug #156 fixed; Controls&Settings dialog suddenly appearing without obvious reason. Possible to use a network location as primary storage device. Settings/Network tab changed name to Settings/Data. When using network storage the SD Card/USB tab is renamed to Network. Owner settings must be made in Control Panel/Owner. **CLIA:** Rinsing Fluid Lot number and Expire date included in CLIA logging. Input panel jumping around less when entering Lot numbers and Expire dates. Default Min/Max values for CLIA control limits updated. Reportable ranges introduced. Analytes units are shown in appropriate forms. **New service codes:** BOOT SD – Disable USB sw upgrade and maintenance. SD card used for sw upgrade and maintenance. BOOT USB – Enable USB sw upgrade and maintenance. DELETE AMPM – Delete the AM/PM files on the SMC card for easy reset of AM/PM handling. Must be combined with Regional Settings and a restart. DELETE MIGRATE – Remove migrate folder from external media HELP or ? - Present a help screen with all available service codes HIDE ABOVE LL – Hide the values above the linearity interval (linearity limit) HIDE OUTSIDE RR – Hide values outside the reportable range HIDE TOOLS – Disable the Tools folder (Service) HIDE UNDER DL – Hide values under detection limit HIDE UPDATE – Disable the sw update folder MIGRATE – Migrate database and user settings to an external media (for automatic migration at next start up) PRINT ON – Print directly PRINT OFF – Disable printer PRINT ASK – Confirmation question before print out SHOW ABOVE LL – Show the values above the linearity interval (linearity limit) SHOW OUTSIDE RR – Show values outside the reportable range SHOW UNDER DL – Show values under detection limit UNHIDE TOOLS – Enable the Tools folder (Service) UNHIDE UPDATE – Enable the sw update folder

Rev L (2.0.0.339, August 2012)

Events saved to and retrieved from external media.
Change needle form does not crash application when out of memory.
CMA changed to M Dialysis in Service mode.
Glutamate issue resolved

Rev L (2.0.0.346, October 2012)

Romanian translation
Event.xml deleted when patient is deleted from external media.
CLIA log files moved to selected medium (Network and USB now work)

Rev L (2.1.0.374, November 2013)

External media handling improved (specifically for the MIGRATE command)

Temperature log added. Every hour to service log, every ten minutes to TemperatureLog.txt.

Measurement Cell temperature readings added (log file and optional display in status bar)

Default cell temperature measurements display is disabled.

N**ew service codes**
ADDTOLOGFILE ALWAYS
ADDTOLOGFILE CLIA
ADDTOLOGFILE NEVER
CELLTEMP OFFSET <value>
CELLTEMP LOWLIMIT <value>
CELLTEMP HIGHLIMIT <value>
CONTROL PANEL
DATA STRUCTURE [LABPILOT][ICUPILOT]
FAN <value> - -1 default behavior, 0-100 fan speed in %
FTP ADDUSER <username> <password>
FTP DELETEUSER <username>
FTP LISTUSER
HIDE CELLTEMP
MOVECLIAAT DAILY
MOVECLIAAT MON/TUE/WED/THU/FRI/SAT/SUN
MOVECLIAAT MONTHLY
MOVECLIAAT NEVER
NOISE <value>
RESETCALIBHISTORY ALWAYS
RESETCALIBHISTORY ASK
RESETCALIBHISTORY NEVER
SHOW CELLTEMP <value>
SUPPRESSTIME <value>

Provisions for handling the new geared XZ module have been implemented in the service GUI.

A possibility to lock the sample positions in the patient dialog has been introduced in the Misc. tab in Settings.
This will disable the catheter selection for an analysis position in the patient dialog.
This to avoid unwanted changes of the catheter assignment for an analysis position.

When using preclinical sample vials, i.e. Glass or plastic vials a symbol is shown of the vial shape when trying to analyze (Batch and normal analysis).
This to remind the user that the automatic vial sensing is not activated.

Changes to PostUpdate routine to facilitate updates in US (Install English only option).
Possibility to access the control panel directly from the user interface.
Two different data storage structure modes for LABpilot and ICUpilot compatibility.

Solvent blanks older than 24 hours are not included in average calculations in displays and printouts (in UserGUI).
Batch dialog now initializes reagent indicators according to what reagents are inserted.
Date/time check at start up before load of database and GUI. User given opportunity to use the Control Panel to set date/time. Software accepts dates from 2012-01-01 to 2099-01-01.

First time usage of Network location now creates the ISCUSflex folder and subfolders as expected.
If a Network storage location is defined for a non existing computer, after a timeout longer than 15 seconds, the network storage will be temporarily disabled and a message displayed.

On screen keyboard shown in CLIA dialog when changing date.
Multiple service log entries minimized.
Patient samples and control samples info not saved in service log when CLIA is active.
Status messages suppressed when working in the CLIA module.

When doing detector measurements the Cell temperature measurements will be suspended to avoid duplicate calls in case of hardware errors.

NoReagentException and NoReagentError defined to handle the situation where a reagent is removed even though a auto control sample is being processed.

A StoreResult with null values will no longer cause an exception.

When clearing all patient positions this is remembered when system is restarted.

Improved errors and warnings handling.
Events dialog allows all types of characters in entered text.

Temperature is displayed in messages when temperature and cell temperature are outside allowed interval.
First time after cell temperature recover, a message is displayed and logged.
Printing and copying of patient data is always logged in the CLIA log.
No authorization to see or copy the CLIA log as no patient data is included.
The CLIA log contains empty fields for patient names and results. It is possible to get actual values in those fields by setting the IscusParameters parameter IncludeResultsInCLIALog to true.
No need for CLIA authorization for the Printing Tab.
When patient data is copied in the database dialog it is recorded in the CLIA log.
Possibility to add password protected FTP users added.
Possibility to force the fan.
Clear patient position freezes analyzer bug (TT#196) has been remedied.
FormActions disabled when Show CLIA log button has been pressed. Enabled again when CLIA log is closed.
Remote Control Settings now allow ISCUS to be configured to use FTP password (block Anonymous login).
Failing auto control will cause icon to turn red.
Fixed defect #198 wrong unit displayed when viewing control levels from reagent dialog (CLIA)

Rev L (2.1.0.396, July 2014)

TT #208 In batch and normal analyses, if no reagents are selected any inserted vial status is set to ready avoiding a non-ready (white) vial never becoming ready.

TT #209 GetInsertedAnalytes returns only reagents inserted in order to preset only those reagents that are available.

TT #210 Statusbar-IscusParameters has now been extended to include all parameters to avoid errors when switching e.g. reagents in ServiceGUI thus causing a faulty WriteXML (several settings lost, e.g. network storage).

TT #211 When Clear Patient Position is clicked there are try-catch around the save action (could previously give a software crash when a faulty SD card was inserted).

TT #212 Sterilize method working with 130 µL (instead of 100 µL) to include the measurement cell too.

TT #213 Recalibration after 40 minutes to allow for controls to run.

TT #214 Recalibration of blocked reagents after 6 hours (in fact after calibration interval, default 6 hours).

TT #215 When cleaning system messages are disappearing after 5 seconds so it is difficult to know when the system is ready. Changed to require user intervention (or new message).

TT #216 Glutamate volumes updated automatically at startup. All low volume Glutamate reagents have expired thus service codes GLTB and GLTA are obsolete and have been removed.

TT #217 Remedied defect. If issuing the service code FAN x without a working SD card gave a system crash in ver. 2.1.0.393 and earlier.

TT #218 Remedied defect. Nominal control levels were not handled correctly for locales using comma as the decimal point. System crash or missing functionality.

Rev L (2.1.0.445, August 2015)

New functionality:

Configurable recalibration delay to allow for auto controls to run.
Service codes are protected with an access code
New log file – AirGapLog.txt
Production test logs stored electronically when printing
New application ViewLogFiles
VIEWLOGS service code for viewing internal log files
UpdateDB used to install fixes; Glutamate, Glycerol and aspirate speed fixes
Air gap issues are detected
Configurable whether to handle air gap issues
Configurable whether to report air gap issues
CLIA Users possible to migrate to other systems
Bar code scan option (labels changed on all products)
QCData log file for complete recording of calibrations and auto control samples
Pyruvate low linearity interval is default
Archive possibility implemented
Pyruvate low linearity interval is increased to include up to 900 µmol/L

New service codes:

USE BARCODE SCANNER YES/NO – Determines whether a barcode scanner shall be possible to use. Opens up some fields and dialogs for scanning.
NOMINAL CL SCAN –Opens a new window for scanning the nominal control levels from the control samples insert sheet.
SECOND CALIBRATION DELAY <minutes> –Defines when a recalibration shall occur after inserting new reagents. Default is 40 minutes, 0 means no automatic recalibration.
AIRGAP SHOW/HIDE – Defines whether air gap issues shall be shown in the log file and/or as error messages or not.

AIRGAP PROCESS/NOPROCESS – Defines whether the system shall rerun an analysis that has an air gap issue (No air gap or double air gap).
SYRINGE SPEED [NORMAL/LOW] <value> –Defines the aspirate speed for the pipetting syringe. E.g. SYRINGE SPEED 576 sets the speed to 1200 µL/min.
VIEWLOGS – Starts the internal application ViewLogFiles.exe to display and copy the different log files in ISCUSflex.
COPYCLIA – Copies all CLIA log files to SD-card, USB stick or Network shared folder.
The file CLIALog.txt is copied.
The file CLIAControls.txt is copied.
The archived CLIALog files are copied (files with format CLIALog <Date> <Time>.txt).
COPYCLIA ALL – Works like the COPYCLIA service code but also copies the files Users.dat and AdministratorSettings.dat to allow for CLIA users backup and migration of CLIA configuration to other analyzers.
MOVECLIA ALL – Works like the MOVECLIA service code but also copies the files Users.dat and AdministratorSettings.dat to allow for CLIA users backup and migration of CLIA configuration to other analyzers
QCDATA LOG – Sets the analyzer in a log mode in which calibrations and auto control samples are logged in a Excel friendly format in the file QCData.txt. This file can be moved/copied with the commands MOVECLIA and COPYCLIA.
QCDATA NOLOG – Sets the analyzer in a non log mode which ensures that the QCData.txt log file is NOT updated.
LI PYR LOW – Sets the low linearity interval for Pyruvate (2 – 900 µmol/L) as default.
LI PYR NORMAL – Sets the normal linearity interval for Pyruvate (10 – 1500 µmol/L) as default.
REGISTRY – Starts the VNCRegistrySettings application for detailed registry settings.
ARCHIVE <months> - Sets the archive limit when archiving patient data using the database dialog.
ARCHIVE COPYSD – Copies the entire archive from the SD card to active media (icon in status bar).
ARCHIVE DELETESD – Deletes the entire archive on the SD card. **Ensure that archive is backed up**.

Remedied defects:

TT #219 Database maintenance doesn't work for patients having events defined
TT #220 Network storage not automatically restored
TT #221 A faulty return pump can cause strange analyses results
TT #222 Network data storage recover does not work as intended
TT #223 Message box not working correctly in Service mode when cleaning of measurement cell has been performed
TT #224 Bar code reader support desired
TT #225 A possibility to export/import CLIA users would be nice
TT #226 A possibility to detect double air gap issues is desirable
TT #227 It is desirable to be able to save the service mode production logs to log files and having printing as an option
TT #228 A viewer for internal log files is desirable
TT #229 A possibility to start the log file viewer from ServiceGUI and UserGUI would be nice
TT #230 A possibility to set the second calibration delay would be nice
TT #231 A way to start in service mode or normal mode would be nice
TT #232 Service codes shall be protected by an access code
TT #233 Pipetting syringe aspirate speed too high
TT #234 If the MOVECLIA service code is used erroneously the device looses log data
TT #235 QC data shall be logged
TT #236 Glutamate Fix needed for Blank Slope Max
TT #237 Glycerol Fix needed for Blank Slope Max
TT #238 Setting am/pm time doesn't work perfectly
TT #239 A possibility to set default linearity interval for Pyruvate is desirable (default = LOW)
TT #240 AM/PM radio buttons shall not be displayed when setting the interval in the batch dialog
TT #241 A way to do the registry settings from within the UserGUI & ServiceGUI would be nice
TT #242 The CLIA Administrator doesn't have privileges to open QA tab and handle patient data
TT #243 It would be nice to directly display test reports on screen when testing a machine
TT #244 Accessed by CNS Monitor bad performance caused by too many patients on the SD card

TT #245 A sort function would be nice in the database dialog
TT #246 Database dialog - Ability to change the scope for the external media list box would be nice
TT #247 A possibility to copy the SD card archive tree would be nice
TT #248 A possibility to delete the SD card Archive would be nice
TT #249 The Pyruvate linearity limit for PreClinical (Low) calibrations shall be 900
TT #250 The Pyruvate calibrator response for PreClinical (Low) calibrations shall be adjusted
TT #251 Low controls acceptance limits for PreClinial (Low) calibrations incorrectly set
TT #252 Database dialog. Disable the Archive button when listbox is updating
TT #253 Database dialog. True archive date is used and displayed beneath the archive button
TT #254 Low controls to be updated properly at startup
TT #255 The PatientDataScanner gets exceptions trying to read files/folders where access is denied
TT #256 Scanning reagent, calibrator and control sample bottles with a barcode reader does not work
TT #257 If Pyruvate Normal calibration is selected the system cannot be restarted

Rev L (2.1.0.449, February 2016)

New functionality:
Possible to send QC data (Calibrations and auto control results) to external server
Service codes presented in a list box
Improved sample preparation (slow speed passing the cannula tip). Configurable.
Return pump warnings possible to suppress
Bad blanks handling improved for better low concentration results

New service codes:
ASTM NOQC - Will deactivate the QC data export
ASTM QC - Will activate the QC data export
HIDE RETURNPUMP - Will suppress return pump warnings (always logged)
NOMINAL CL RELOAD – Loads new nominal control samples values from SD card, USB or Network regardless of previous loaded nominal controls. Compare with **NOMINAL CL LOAD** that loads only if LOT number is different.
RINSING FLUID WARNING <times> where times can be 0-20
SHOW RETURNPUMP - Enables return pump warnings
TIP VOLUME <vol> - Causes the system to move the sample/reagent mixture slowly pass the cannula tip. Vol in 1/10 µL

Remedied defects:
TT #238 Setting am/pm time doesn't work perfectly
TT #256 Scanning reagent, calibrator and control sample bottles with a barcode reader does not work
TT #258 QC data shall be sent to the network port
TT #259 Return pump warnings not possible to turn off
TT #260 Exceptions at first start up due to attempt to connect to network, even though no network has been defined
TT #261 System freezing due to missing NominalControlLevels.ini
TT #262 Cell temperature OK message at start up disturbing when shown on screen
TT #263 Bad blanks handling defect
TT #264 New functionality - Pass the narrow part of the cannula at low speed
TT #265 Stop analyzing immediately when Rinsing Fluid container is empty
TT #266 Service codes could be presented in a list box for easier access
TT #267 When reading nominal control levels the parsing fails if the NumberDecimalSeparator is different from the one in the file.
TT #268 SW Exception during calibration if ASTM QC and protocol is XML or CMAExt

Rev L (2.1.0.458, August 2016)

New functionality:
QC data (Calibrations and auto control results) to external server now contains LOT numbers
Cleaning cassette can be run in normal mode giving the cassette code STE-RIL-IZE or CLE-AN
Possibility to suppress the service code protection
Possible to change patient ID
Possibility to set patient data to final
Return pump performance improved
Possibility to wash the system from normal user mode
Service log time and serial no stamped
Control samples log time and serial no stamped
Possibility to extend the service (PM) interval to 15 months

New service codes:
ADMISSION CHANGE ALLOW – Enables the possibility to change patient data status to final (possible to load)
ADMISSION CHANGE DENY – Disables the possibility to change patient data status to final
NOMINAL CL SCAN AND RELOAD – Loads new nominal control samples when scanning regardless of previously loaded nominal controls. Compare with NOMINAL CL SCAN that loads only if LOT number is different.
RETURNPUMP CYCLES <value> – Sets the number of return pump cycles at shutdown (default 50)
RETURNPUMP SPEED <speed> – Sets the maximum return pump speed in %. Valid values are 80 – 100
SERVICE CODE OPEN – Gives unlimited access to service codes
SERVICE CODE PROTECT – Ensures that a password is needed to access the service codes (password is 151224, 1A2B3 works as well but if typed as a service code the system will restart in service mode. If CLIA is active the Administrator CLIA authorization is used)
WASH <cycles> – Washes the system, cycles = 1 – 10

Remedied defects:
#256 Scanning Calibrator and Rinsing Fluid bottles now works
#260 Remaining exceptions with network errors remedied
#261 Redundant MessageBox removed
#265 Stop analyzing immediately when Rinsing Fluid container is empty (lost setting)
#269 QC data shall contain the lot numbers
#270 When scanning control lot numbers the confirmation dialog box is confusing
#271 ISCUSflex does not remember how many cleanings racks that has been run
#272 No messages when running a cleaning cassette in normal user mode
#273 FormYesNo sometimes gives unrecoverable errors
#274 Service code - When selecting the same drop down list box item again the text box is not filled in
#275 When changing patient ID data is "lost“
#276 Sometimes batch runs get the date 2007
#277 Possibility to use 250 µL syringe
#278 ViewLogs crashes at start up if the airgap logfile (default) is missing
#279 Possibility to get a cleaning cassette code in UserGUI
#280 Possibility to set patient data to final
#281 It shall be possible to control whether it shall be possible to set patient data to final
#282 Possibility to disable password requirement for service code access
#283 Glutamate BlankSlopeMin changed to -0.10 (from -0.047) to handle latest reagent (T25316)
#284 Possibility to control the number of return pump cycles at shutdown
#285 Possibility to wash the system from UserGUI
#287 A non available network causes database dialog storage of patient data to USB to fail
#288 Service log and control samples shall be time stamped
#289 Database dialog external media list box does not update properly
#290 Activity log shall be updated when VIEWLOGS is issued
#291 It shall be possible to extend the service interval to 456 days (15 months)

Rev L (2.1.0.459, September 2016)

New functionality:
None, same as 2.1.0.458

New service codes:
None

Remedied defects:
#292 The service code NOMINAL CL SCAN AND RELOAD shall work.

Rev L (2.1.0.465, September 2017)

New functionality:
Improved handling of remote control (for service only, TT #294)
Improved handling of failing battery (TT #295)
Handle high Pyruvate concentrations properly (TT#300)
Possibility to handle patient data archiving (TT #301 & #302)
Improved handling of badly shaped polynomials (TT #304)
Possibility to handle min/max ratio issues (TT #306)

New service codes:

RUN <value> - Possibility to run external commands. E.g. RUN CMD to open a command window.
BATCH INTERVAL <minutes> - Sets the default batch interval in minutes for the batch dialog.
MMRC <value> - Sets the Min/Max Ratio value important for sample approval. Default 0.5, allowed 0.5-10. For allowing high Pyruvate concentrations especially in production testing, e.g. MMRC 3.
MINMAXCHECK [ON/OFF] - Sets the maximally allowed value for the Min/Max ratio to approve a sample. Default is 0.5, max is 10. Use e.g. MMRC 3 when elevated Pyruvate auto control won't get analyzed.

Remedied defects:
TT #293 When changing the network store it is not permanently stored in the registry
TT #294 Impossible to handle migration and CLIA copying remotely (WinVNC server not started)
TT #295 Missing or bad battery give such strange dates that dialogs can't be displayed (compare with #178)
TT #296 Pyruvate AC interval fails first time entered
(TT #297 SD cards patient not possible to deregister if patient data removed from database (See TT #280))
TT #298 New services codes:
RUN <exe-file> <command line> (exe-file within quotes if necessary) (extension .exe automatically added)
BATCH INTERVAL <minutes>
TT #299 Default values changes
TT #300 The Min/Max ratio gives problems with high Pyruvate concentrations.
New Service code: MMRC <value>. Default is 0.5, allowed 0.5 - 10.
TT #301 Archive shall be possible to do to other media
TT #302 It shall be possible to copy the SD card archive to USB and Network
TT #303 When archiving patient data, latest EndDate isn't always correct
TT #304 Badly shaped polynomial fits may be accepted
(TT #305 Entering service mode when reagents are in causes inconveniences)
TT #306 Min/max ratio issues may fail auto controls without explanation
TT #307 Some settings are not guaranteed to be retained when entering service mode

Rev L (2.1.0.468, May 2018)

New functionality:

Possibility to add a comment in the service log using a service code.
Possibility to set the low calibration linearity limit for Pyruvate to 300.

New service codes:

LOG <text> - New entry in the service log with the text specified.

PYRUVATEFIX <level> - Sets the Pyruvate low calibration linearity limit to <limit>. Allowed values are 300 – 1500. The preferred level is 300.

Remedied defects:
TT #308 Possibility to add service log comments

TT #309 Possibility to adjust database for Pyruvate preclinical linearity interval to 300 (or back to 900)

Rev L (2.1.0.470, September 2018)

New functionality:

Possibility to LOAD Nominal Control Levels from the CLIA Control Levels dialog.
A reminder about Nominal Control values not being consistent with entered auto control lot.
Slovenian language implemented.

New service codes:

LOT CHECK/NOCHECK – Enables (default)/disables check of auto control lot numbers in the CLIA module.

NETWORK LOG/NOLOG – Enables/disables logging of failing/successful network connections.

CLIA NOMINAL CL MANUAL CALC/NOCALC – Enable/disable a button for calculations of Nominal CL from CLIA Limits in the CLIA control levels dialog.
Primarily used when no scanner is installed and CLIA control levels are activated. This allows manual input of CLIA levels and LOT number, after which the calculation button determines the Nominal Control Levels and store them internally.

CLIA NOMINAL CL CALC/NOCALC – Enable/Disable Nominal CL to be calculated from CLIA limits in the CLIA control levels dialog.
Primarily used when a scanner is installed and CLIA control levels are activated. This allows a simple scan of the CLIA levels, the LOT number and Nominal Control Levels will automatically be determined and stored internally. Primary method of scanning CLIA levels and Nominal Control Levels.

CLIA LIMITS CALC/NOCALC – Enable/disable CLIA Limits to be calculated from Nominal Control Levels in the CLIA control levels dialog.
Primarily used when a scanner is installed and CLIA control levels are activated. This allows a simple scan of the nominal control levels, which will be stored internally. The CLIA levels will be automatically determined.

CLIA CALC – Shows state of parameters for control of Nominal CL/CLIA Limits.

Remedied defects:
TT #310 A reminder about Nominal Control Values would be nice
TT #311 Unable to connect to <IP> :<port>
TT #312 A possibility to load Nominal Control Levels in the CLIA module
TT #313 If PRINT ASK is combined with daily printing an indefinite loop is entered
TT #314 In CLIA mode, start-up always initiates a calibration
TT #315 Slovenian language added to software

Rev L (2.1.0.471, September 2018)

New functionality: None

New service codes: None

Remedied defects:

TT #316 Scanning Nominal Control Levels in the CLIA module requires double scans
TT #317 Custom reagent setup is not automatically re-loaded

Rev L (2.1.0.472, April 2019)

New functionality: None

New service codes: None

Remedied defects:

TT #318 Scanning Nominal Control Levels from Service code causes exception

Rev L (2.1.0.475, August 2019)

New functionality: None

New service codes:

AUTOSAVE LOGS YES/NO – Will automatically save log files when changing the reagents to keep information about previous set up. Default YES.

Remedied defects:

TT #319 Urea LOT T26386 difficult to calibrate on some instruments
TT #320 When changing reagents it would be nice with an automatic save of the service log
TT #321 Barcode scanner field shall have the focus when opening Control Levels from the reagent lot numbers and expiry dates dialog
TT #322 When the NominalControlLevels file is lacking the LOT number an unrecoverable error may occur
TT#323 When changing reagent cassette and pressing Return before the cassette is ejected, a dead lock situation arises

Rev L (2.1.0.477, September 2019)

New functionality: None

New service codes: None

Remedied defects:

TT #324 When changing reagent cassette, a dead lock focusing of controls occur freezing the software

TT #325 The Rinsing Fluid LOT and expiry date vanishes from the CLIA registration when restarting the analyzer

Rev L (2.1.0.478, November 2019)

New functionality: None

New service codes: None

Remedied defects:

TT #326 Change of Pyruvate Response Limits to handle Low Sensitivity Pyruvate Lots

Rev L (2.1.0.485, September 2021)

New functionality: See remedied defects

New service codes:

ANALYTEDL <Reagent> <Interval> - Show the detection limit for the given reagent and interval, e.g. ANALYTEDL PYR LOW.
ANALYTEDL <Reagent> <Interval> <value> - Set the detection limit for the given reagent and interval, e.g. ANALYTEDL PYR LOW 10.
ANALYTEDL - Show the settings for all reagents and both intervals
ANALYTEDL <Reagent> - Show the settings for the reagent and both intervals, e.g. ANALYTEDL PYR.
ANALYTEDL <Interval> - Show the settings for all reagents and selected interval, e.g. ANALYTEDL LOW.

SAMPLEVOL ORIGINAL - All volumes will be set to original volumes before this version, confirmation required.

	GLU*	GLU	LAC*	LAC	PYR*	PYR	GLY*	GLY	GLT
Sample volume	2.0	0.5	0.8	0.2	2.0	0.5	1.5	0.5	1.5
Reagent volume	13.0	14.5	14.2	14.8	13.0	14.5	13.5	14.5	7.5

SAMPLEVOL OPTION - All volumes will be set, confirmation required, according to:

	GLU*	GLU	LAC*	LAC	PYR*	PYR	GLY*	GLY	GLT
Sample volume	2.0	0.5	0.8	0.4	2.0	0.5	1.5	0.4	1.3
Reagent volume	13.0	14.5	14.2	14.6	13.0	14.5	13.5	14.6	7.7

SAMPLEVOL - Show the settings for all reagents and both intervals

Remedied defects:

TT#327 Change of Lactate Initial Blank Max level to handle reagents with increasing initial blank level

TT #328 TimeZeroOffset interval for Glycerol too tight

TT #329 Decrease sample volume for increased linearity for Glutamate and Glycerol

TT #330 Increase sample volume for increased stability for Lactate

TT #331 Service code SAMPLEVOL introduced to set sample volume and reagent volume for any combination of reagent and linearity interval.

TT #332 MinMaxSlopeRatio calculations do not work properly.

TT #333 Calibrator B introduced in full (also in CLIA)

TT #334 Possibility to change detection level for all analytes and interval.

Rev L (2.1.0.491, March 2022)

New functionality: See remedied defects

New service codes: None

Remedied Defects:

TT #335 Lactate calibrator response too high. Implemented as an ISCUS tools fix.
TT #336 Difficult to measure Glucose blank. Fixed, notice in service log.

DBUpdate Fix for nominalcontrollevels.ini being ReadOnly showing result

Rev L (2.1.0.493 and 2.1.0.494, March 2022)

New functionality: See remedied defects

New service codes: None

Remedied Defects:

TT #337 Default values for sample and reagent volumes are according to SAMPLEVOL OPTION

TT #338 Faulty sample volumes for preclinical Glucose. Fixed.