

## Software Release Report

|  |                |                     |
|--|----------------|---------------------|
| Title  |                |                     |
| <b>SW Release report for ISCUS software rev I (WinCE5)</b> |                |                     |
| Document number  | Project number | Unique ID           |
| 7930   | 169            |                     |
| Approved: Date/Sign  |                | Approved: Date/Sign |
| _____<br>Author  |                | _____<br>Approver   |

### 1. Article

This document specifies the configuration items for the following software product

| CMA reference number<br>(Article number) | Revision | Name                                  |
|--|----------|---------------------------------------|
| <b>8003826</b>                           | <b>I</b> | <b>ISCUS CE5 Application Software</b> |

### 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               | SQL CE Server 3.5          | 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 1.0.0.65

#### 2.3. Software System

| Item                  | Version                    |
|-----------------------|----------------------------|
| AdapterLib_Iscus.dll  | 1.0.0.65                   |
| CFSerialClass.dll     | 1.0.0.65                   |
| CMASeriesLib.dll      | 1.0.0.65                   |
| CMAWinCEControls.dll  | 1.0.0.65                   |
| Common_Iscus.dll      | 1.0.0.65                   |
| Core_Iscus.dll        | 1.0.0.65                   |
| DBAdmin_Iscus.dll     | 1.0.0.65                   |
| DBLib_Iscus.dll       | 1.0.0.65                   |
| FPGABoot.bin          | 2009-11-12 17:23           |
| ISCUSClassLibrary.dll | 1.0.0.65                   |
| Iscus.dll             | 1.0.0.2 (2009-11-12 17:23) |
| IscusSimulatorAdapter | 1.0.0.65                   |
| IscusTest.exe         | 1.0.0.65                   |
| Loader_Iscus.exe      | 1.0.0.65                   |

|                               |                  |
|-------------------------------|------------------|
| MCUApi.dll                    | 2009-11-12 17:23 |
| MCUDriver.dll                 | 2009-11-12 17:23 |
| OSAccess.dll                  | 1.0.0.65         |
| RemoteHWAdapter_Iscus.dll     | 1.0.0.65         |
| SerialCommunication.dll       | 1.0.0.65         |
| ServiceGUI_Iscus.dll          | 1.0.0.65         |
| UserGUI.dll                   | 1.0.0.65         |
| ViewLib_Iscus.dll             | 1.0.0.65         |
| XE-50.dll                     | 1.0.0.65         |
|                               |                  |
| <b>Language files</b>         |                  |
| cs\Common_Iscus.resources.dll | 1.0.0.65         |
| cs\UserGUI.resources.dll      | 1.0.0.65         |
| da\Common_Iscus.resources.dll | 1.0.0.65         |
| da\UserGUI.resources.dll      | 1.0.0.65         |
| de\Common_Iscus.resources.dll | 1.0.0.65         |
| de\UserGUI.resources.dll      | 1.0.0.65         |
| es\Common_Iscus.resources.dll | 1.0.0.65         |
| es\UserGUI.resources.dll      | 1.0.0.65         |
| fr\Common_Iscus.resources.dll | 1.0.0.65         |
| fr\UserGUI.resources.dll      | 1.0.0.65         |
| it\Common_Iscus.resources.dll | 1.0.0.65         |
| it\UserGUI.resources.dll      | 1.0.0.65         |
| nl\Common_Iscus.resources.dll | 1.0.0.65         |
| nl\UserGUI.resources.dll      | 1.0.0.65         |
| sv\Common_Iscus.resources.dll | 1.0.0.65         |
| sv\UserGUI.resources.dll      | 1.0.0.65         |
| tr\Common_Iscus.resources.dll | 1.0.0.65         |
| tr\UserGUI.resources.dll      | 1.0.0.65         |

### 3. Related documents

Software verification has been completed and the results evaluated. All known residual anomalies have been documented and evaluated. The anomalies were found not to contribute to an unacceptable risk.

See D7932 P169 ISCUS WinCE 5 Rev I Design verification Review (R3)

**8003826 ISCUS CE5 Application Software Release notes****Rev G (Apr 2010)**

Calibrations and sample injections calculations now work with actual slope and detect also strange negative slopes.  
Calibrations now handle blanks correctly (min/max slope comparisons).

**Rev H (May 2010) – Not officially released**

Noise measurement in ISCUStest implemented  
Language corrections

**Rev I (June 2011)**

Miscellaneous bug fixes.

New service codes:

CELSIUS and FAHRENHEIT to switch temperature unit.

COPYDB to copy database to a file on SD card or USB memory

DELAY <seconds> to define automatic scroll

DELETE SDMEM to delete faulty folder on SMC

DELETE USB to delete faulty folder on SMC

GLTA to specify smaller capacity in Glutamate bottle

GLTB to specify larger capacity in Glutamate bottle

LIFE x to modify reagent life in days

LOCAL to disable remote control

REMOTE to enable remote control

RESTART to restart ISCUS. Also in Service mode.

STARTFTP improved, e.g. STARTFTP \SDMEM\DATA

STOPFTP to stop FTP server

Glutamate volume increase

Cannula change at middle position

MainBoard, Detector, IP-number and MAC-address in log file printout.

Extra evacuation of wash bin introduced

Possibility to reset calibration history when re-calibrating

Automatic reset of calibration history at needle change

Remote access activated by default (for service mode too)

Patient ID is always folder compatible

Manual control, Service graphs and Calibration interval added in Service mode. Possibility to override sensors added.

When using the XML protocol the latest patient admission will also be transmitted.

Glycerol and Glutamate included in US mode.

Automatic removal of unwanted SDMEM and USB folders now removes the entire structure.

Possibility to print the latest 3 productions tests.