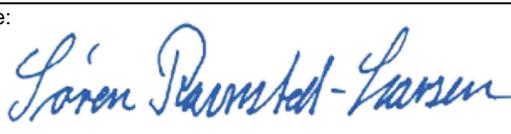
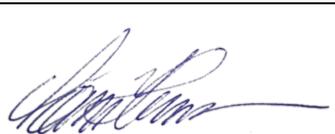


<p>Title:</p> <h2 style="text-align: center;">IWD Software Configuration Setup</h2>	
<p>Released Software Version:</p> <h3 style="text-align: center;">1.18.1</h3>	
<p>Location / Department:</p> <p>KEN Brobyværk / Development Department</p>	<p>Products:</p> <p>IQ3, IQ4, IQ5, IQ6</p>
<p>Document ID:</p> <p>IWD_Software configuration setup.docx</p>	<p>Document Template Revision:</p> <p>008</p>

Approval	
<p>Author: SRL</p>	<p>Approved by: SHH</p>
<p>Date (yyyy-mm-dd):</p> <p style="text-align: center;">2022-04-01</p>	<p>Date (yyyy-mm-dd):</p> <p style="text-align: center;">2022-04-01</p>
<p>Signature:</p> 	<p>Signature:</p> 

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# 1 Change Log

Not change log is for software configuration setup template and not for each software release-

Version	Date	Sign.	Description
001a	2015-06-29	SRL	Document changed i to use the C15 controller. Section 2 list expanded. Section 3 corrected. Section 5 corrected. Section 6.2 deleted and replaced by old section 6.3. Section 6.4 added.
001	2016-03-18	SRL	Ready for official release.
002a	2016-10-26	UBJ	Section 5.2 list expanded.
002	2016-10-26	SRL	Review done with no changes. Document released to be signed.
003a	2017-12-07	SRL	Expanded table with dfu file for C15 controller and RFID reader configuration file.
003	2017-12-07	UBJ	Review done with no changes. Document released to be signed.
004a	2017-12-15	SRL	Section 5.2.1 updated with options supported by each machine.
004	2017-01-25	UBJ	Review done with no changes. Document released to be signed.
005a	2018-10-04	SRL	Added software version to header on each page. Section 5.1 Added extra file for Engicam displays. Section 5.3 Added extra row for Engicam displays. Section 5.4 Added extra rows for Engicam displays. Translated to English.
005	2018-10-04	UBJ	Review done with no changes. Document released to be signed.
006a	2019-02-20	SRL	Section 3 Added building procedure for the C15 Display software. Section 5.1 Added extra files for C15 HMI displays. Section 5.2.1 Added IQ4 in table. Section 5.3 Added extra row for C15 displays displays.
006	2019-02-20	UBJ	Review done with no changes. Document released to be signed.
007a	2020-03-09	SRL	Added IQ3 and IQ10 to machines this release support Section 3 Added building procedure for the C15 PRES software. Section 5.1 Added extra file for C15 PRES.
007	2020-03-09	UBJ	Review done with no changes. Document released to be used.
008a	2021-11-02	SRL	Section 5.1 Added description to each of all the firmware and configuration files on customer request.
008	2021-11-02	UBJ	Review done with no changes. Document released to be used.

Table 1 Change log.

# 2 Terms and Definitions

Term	Description
ASM	Assembly.
PLC	Programmable Logic Controller.
HMI	Human Machine Interface
IWD	Instrument Washer and Disinfector
C15	Washer Controller, Version 15

Table 2 Terms and definitions.

## 3 References

Reference	Document	Version
1	KEN_Building IWD software	003
2	KEN_Building C15 desinfektionsovervågning software	003
3	KEN_Building IWD HMI software	004
4	KEN_Building C15 Display software	004
5	KEN_Building C15 VARD software	002
6	KEN_Building C15 PRES software	002

Table 3 References.

## 4 Introduction

For the front page stated software version this document defines, which software module versions and hardware module versions which all together form a complete KEN IWD controller software release.

Versions of development tools used to build and link software is given.

Versions of documents for this software release are given.

Release notes for this software version are given.

## 5 Released Software

The overall software version number for this software release is:

Software Version
1.18.1

### 5.1 Files Released

Released file	Description	Language	MD5
C15_IWD_1_18_1_and_Bootloader_1_00_0.dfu	Complete firmware to program into C15 master and slave using DfuSeDemo software	All	a99438e32d8d721b04b13db00d528cdf
C15_IWD_1_18_1.hex	Application firmware to program into C15 master and slave using washer web-interface	All	f23697a40bcb85a1e4da0c45aaf64dbf
IWDGui_dlogic	Graphical user interface application for dlogic displays with custom cable. Updated with SDCard kupgrade folder	All	c20ff2d7d059dd88a006568b487a4a63
IWDGui_engicam	Graphical user interface application for engicam displays. Updated with USB pen or SDCard kupgrade folder	All	bccd6a01dc8f3f6d38ac90cea2c5d0c9
C15_DIS_V3-00-0.hex	Application firmware to program into C15 disinfection monitor CPU with JFlashLite	All	f0d2fa0ca91ef0c0ec05138c339e6cc8
C15_HMI_V1-02-3.hex	Application firmware to program into C15 display (small OLED) using washer web-interface	All	853f71aece5fc678cac4935228897100
C15_HMI_V1-02-3_and_Bootloader_V1-03-0.hex	Complete firmware to program into C15 display (small OLED) using STM32 ST-LINK software	All	2efa17c228475198db48cbf9f812030e
bism400.in	Setup file for RFID reader device setup using BIS Configuration Software	All	2cc7c78d90ed11b24fc1ebe36eeb9c56
C15_VARD_1_00_1_and_Bootloader_1_00_0.dfu	Complete firmware to program into C15 VARD (wash arm rotation detection) using DfuSeDemo software	All	5a784191bd79438f5db5357ca6aad9ff
C15_VARD_V1_00_1.hex	Application firmware to program into C15 VARD using washer web-interface	All	167e741c59fa0202d5e4a83b242e51f4
C15_PRES_1_00_2_and_Bootloader_V1_00_1.hex	Complete firmware to program into C15 PRES (pressure board) using STM32 ST-LINK software	All	370ea1b6a0cb80f90d192fac28c6c145
C15_PRES_V1_00_2.hex	Application firmware to program into C15 PRES (pressure board) using washer web-interface	All	276b416b8e12f510fca3c2536539f278

## 5.2 Release Notes

Version includes the following new features and bug fixes.

- Added extra door tightening step on washers with sliding door.
- User log in requirement at Matachana HMI now work with delayed start.
- Delayed start feature now requires a license. Contact KEN to get a license for customers who has purchased this feature already.
- KEN HMI graph view now shows all batch number digits for large batch numbers.
- Calibrations can now only be done in service mode to ensure washer is not calibrated while running as this might confuse the disinfection monitor CPU.
- IQ3 and IQ4 can now be set in service mode from an entry in their menu to set washer in service mode. Hold “C” button to enter menu and scroll to service mode entry.
- IQ4, IQ5, IQ6 printer drying graph now show temperature.
- LD100, LD500, LD1000 door open close icon is now hidden on alarm acknowledge / reset page.
- Washers with automatic loading table now do not falsely report error 137.
- Possibility to run a chemical disinfection phase added.
- IQ6 now report “low level sensor disconnected” if no low level is detected which is more logical.
- Washer needs service alarm added.
- Manual advance mode for validation purpose added.
- One degree compensation in A0 value calculation added.
- Conductivity calibration water valve button is now valve 2 which by default is RO water.
- Machine number and type can now only be changed in diagnostics mode.
- 24V short circuit alarm added.
- Support for 3 dry contacts on IQ4 added.
- Possible to delete an RFID tag number from washer list of known RFID tags added.
- Wash arm rotation detection software improved to detect wash rotating with more than 60 RPM.
- TCP Stack improved to in order to have more stable client connections.
- C15 HMI OLED display Russian small ‘o’ character corrected.
- Made support for C15 PCB’s without water conductivity measurement IC.

### 5.2.1 Usage

Version is released to be used on all the products using the C15 controller shown on front page.

Version requires the correct hardware module versions and software module versions as stated in section 5.3.

The manual advance mode is entered by technicians in their service menu. When technician has set washer in manual advance mode he can at cycle start select which fases in a cycle to run and he can set washer to pause prior to phase draining. In manual advance mode unclean door may be opened and therefore a water sample can be taken during washer validation. This helps the validation technician.

Due to component supply shortage software now supports digital chemistry level detection (DI) for all four chemistries on selected washers as described below. Original the software use water conductivity sensor input (AI) to detect chemistry level. Now this can be setup using machine setting: “Digital chemistry X level detection”

Software now support:

- IQ3 - LD100BM : Default support AI, AI, DI – **not support DI, DI, DI**
- IQ4 – LD100: Default support AI, AI, AI – now supported DI, DI, DI
- IQ5 – LD500: Default support AI, AI, AI, AI – now supported DI, DI, DI, DI
- IQ6 – LD1000: Default support AI, AI, AI, AI – now supported DI, DI, DI, DI

Washer with IMS sensors which are updated to this or a newer version support setups below. Note washers with the default setup should after upgrade still use default setup otherwise chemistry level detection will not work.

- IQ5 – LD500: Default support AI, AI, DI, DI – now supported DI, DI, DI, DI
- IQ6 – LD1000: Default support AI, AI, DI, DI – now supported DI, DI, DI, DI

This all sums up to machine settings only needs to be changed for IMS washers with chemistry 3 or 4 and IQ3 – LD100BM washers with chemistry 3.

Washer software now includes the possibility to setup a washer needs service alarm. The alarm # 91 Service needed alarm can be triggered by either a time interval is elapsed or by a predefined number of cycle has been run or by a combination.

IQ4 / LD100 washers now have mechanical support for the wash arm rotation detection system and software now also support this.

The following options are supported in the software on the different products.

Options	IQ3	IQ4	IQ5	IQ6
Automatic loader and unloader.	N/A	N/A	N/A	OK
Automatic program selection using RFID tag reader.	N/A	N/A	OK	OK
Valves for cold, hot and RO water.	OK	OK	OK	OK
Support of condenser.	N/A	OK	OK	OK
Flowmeters to measure water consumption.	N/A	OK	OK	OK
Conductivity measurement of final rinse water.	OK	OK	OK	OK
Chemistry dosing of up to 4 chemistry pumps.	Max 3	Max 3.	OK	OK
Signal to external exhaust system.	N/A	OK	OK	OK
Control of drain pump.	OK	OK	OK	OK
Control of valve to cool drain water.	OK	OK	OK	OK
Intelligent steam heating.	N/A	N/A	OK	OK
7 tommer touch display on unloading side of machine.	N/A	OK	OK	OK
Remote access and support using machine web interface.	OK	OK	OK	OK
XML process data to external data collection systems.	OK	OK	OK	OK
Printer.	OK	OK	OK	OK
Buzzer to indicate washer errors and cycle completed.	OK	OK	OK	OK

## 5.2.2 Version of Interface to External Equipment

Communication to external process data collection systems use the KEN XML protocol in the version defined in section 5.5.

## 5.2.3 Bug Fixes

Consult section 5.2.

## 5.2.4 Known Issues

- It is not possible to skip drain between two phases if water in first phase is filled from a tank.

## 5.2.5 Known Bugs

None

### 5.3 Software Component Configuration

Software Component	Software Version	Development Tool	Hardware Component	Hardware Revision	KEN #
IWD SW	1.18.1 (check sum section 5.1)	GNU ARM environment	C15	Ver 4.0	7606987
C15 Disinfection monitor	3.00.0 (check sum section 5.1)	GNU ARM environment	C15	Ver 4.0	7606987
IWDGui_dlogic	1.18.1 (check sum section 5.1)	QT4 environment	HMI panel	Part No 101084	7606989
IWDGui_engicam	1.18.1 (check sum section 5.1)	QT5 environment	HMI panel	LOCO 7" CAP Custom KEN	7609106
C15 Display	1.02.3 (check sum section 5.1)	GNU ARM environment	C15 Display	Ver 2.0	2548338
C15 Display bootloader	1.03.0 (check sum section 5.1)	GNU ARM environment	C15 Display	Ver 2.0	2548338
Printer	SCODE rel 2.04, FCODE rel 1.13	N/A	Custom Printer	PLUS2	7602968
RFID Reader	2.6 (reader configuration file bism400.in check sum section 5.1)	N/A	Balluf RFID Reader	Ver 2.1	7607110
C15 VARD	1.00.1 (check sum section 5.1)	GNU ARM environment	C15 VARD	Ver 2.0 Ver 2.0	7609963 7609964
C15 PRES	1.00.2 (check sum section 5.1)	GNU ARM environment	C15 PRES	Ver 2.0	7610803 7610899

## 5.4 Development Tools

Development Tool	Tools	Version
GNU ARM environment	GNU Tools for ARM Embedded C/C++ Cross Compiler	gcc-arm-none-eabi-10-2020-q4-major
QT4 environment DLogic	QT Creator	2.6.0
	QT	4.8.3
	Cross gcc linux arm gnueabi	4.6.1
QT5 environment Engicam	QT Creator	3.6.1
	QT	5.6.0
	Cross gcc linux arm gnueabi	4.9.2

## 5.5 Documentation

Table 5 below show a complete list of the documents delivered in the project. The table show document name, document version, purpose of document, document audience, document responsible, document reviewer and document maintainer. Software team is defined in Table 4:

KEN initials	Name	Position / Role
SHH	Søren Herholdt Hartmann	Development manager / Project manager
SRL	Søren Ravnsted-Larsen	SW Developer / Software project manager and SW team member.
UBJ	Uffe Bak Jensen	SW Developer / SW team member
SJA	Steen Jansdal	SW Developer / SW team member
MTJ	Mads Tilgaard Jensen	SW Developer / SW team member
JKA	Jonatan Kondrup Andersen	SW Developer / SW team member
TGJ	Thor G. Jensen	SW Developer / SW team member
CAA	Christian Albin Andersen	SW Developer / SW team member

Table 4 Project Team

Document	Information	
IWD Software udviklingsplan	Document name	IWD_Software udviklingsplan.pdf
	Version	3
	Purpose	The purpose of the document is to document a software development plan for IWD in accordance with DS/EN 62304 regarding software for medical devices.
	Audience	Development Department
	Responsible	Software manager
	Approval	Development manager
	Verification/Review	Development manager
Risk Management File IWD	Maintenance	Software manager
	Document name	IQ Risk Management File V1.12.xlsx
	Version	1.12
	Purpose	Documentation of the ongoing risc analysis.
	Audience	Development Department
	Responsible	Project manager
Approval	Development manager	
Verification/Review	Development manager	

Document	Information	
IWD Software kravspecifikation	Maintenance	Project manager
	Document name	IWD_Software kravspecifikation.pdf
	Version	012
	Purpose	The purpose of this document is to define requirements for the IWD software.
	Audience	Development Department
	Responsible	Software team
	Approval	Development manager
	Verification/Review	Software team
KEN Software kodestandard	Maintenance	Software team
	Document name	IWD_Software kodestandard.pdf
	Version	003
	Purpose	The purpose of this document is to define coding guidelines on how do all program coding.
	Audience	Development Department
	Responsible	Software team
	Approval	Development manager
	Verification/Review	Software team
IWD Software arkitekturspecifikation	Maintenance	Software team
	Document name	IWD_Software arkitekturspecifikation.pdf
	Version	011
	Purpose	The purpose of this document is: <ul style="list-style-type: none"> <li>• General system description.</li> <li>• Description of architecture for software layers and components.</li> <li>• Description of physical architecture of the hardware on which the software is executed.</li> <li>• Description of design selections..</li> <li>• Traceability between software architecture and software requirements.</li> </ul>
	Audience	Development Department
	Responsible	Software team
	Approval	Development manager
	Verification/Review	Software team
IWD Software configuration setup	Maintenance	Software team
	Document name	IWD_Software konfigurationssskema.pdf
	Version	008
	Purpose	The purpose of this document is to state which documents, tools, configurations and setting used in current software release.
	Audience	Development Department
	Responsible	Software team
	Approval	Development manager
	Verification/Review	Software team
IWD Software fabriksindstillinger	Maintenance	Software team
	Document name	IWD_Software fabriksindstillinger.pdf
	Version	015
	Purpose	The purpose of this document is to state the factory setting for this software release.
	Approval	Development manager

Document	Information	
	Verification/Review	Software team
	Maintenance	Software team
KEN_NO_DISINFECTION_correctly_translated	Document name	KEN_NO_DISINFECTION_correctly_translated.pdf
	Version	001
	Purpose	The purpose of this document is to document correct "No Disinfection" text for this software release translations.
	Audience	Development Department
	Responsible	Software team
	Approval	None
	Verification/Review	Software team
	Maintenance	Software team
KEN Building C15 desinfektionsovervågning software	Document name	KEN_Building C15 desinfektionsovervågning software.pdf
	Version	003
	Purpose	The purpose of this document is to describe building procedures for the disinfection monitor.
	Audience	Development Department
	Responsible	Software team
	Approval	Development manager
	Verification/Review	Software team
	Maintenance	Software team
KEN Building IWD HMI software	Document name	KEN_Building IWD HMI software.pdf
	Version	004
	Purpose	The purpose of this document is to describe building procedures for the HMI.
	Audience	Development Department
	Responsible	Software team
	Approval	Development manager
	Verification/Review	Software team
	Maintenance	Software team
KEN Building IWD software	Document name	KEN_Building IWD software.pdf
	Version	003
	Purpose	The purpose of this document is to describe building procedures for the IWD software.
	Audience	Development Department
	Responsible	Software team
	Approval	Development manager
	Verification/Review	Software team
	Maintenance	Software team
KEN_Building C15 Display HMI Software	Document name	KEN_Building C15 Display HMI Software.pdf
	Version	004
	Purpose	The purpose of this document is to describe building procedures for the C15 Display HMI software.
	Audience	Development Department
	Responsible	Software team
	Approval	Development manager
	Verification/Review	Software team
	Maintenance	Software team
KEN_Building C15 VARD software	Document name	KEN_Building C15 VARD software.pdf
	Version	002
	Purpose	The purpose of this document is to describe building procedures for the C15 VARD software.

Document	Information	
	Audience	Development Department
	Responsible	Software team
	Approval	Development manager
	Verification/Review	Software team
	Maintenance	Software team
KEN_Building C15 PRES software	Document name	KEN_Building C15 PRES software.pdf
	Version	002
	Purpose	The purpose of this document is to describe building procedures for the C15 PRES software.
	Audience	Development Department
	Responsible	Software team
	Approval	Development manager
	Verification/Review	Software team
	Maintenance	Software team
IWD Software designspecifikation	Document name	IWD_Software designspecifikation/html/index.html
	Version	011
	Purpose	The purpose of this document is to describe the design of the software executed on the C15 controller. <ul style="list-style-type: none"> <li>• Module design and their interfaces.</li> </ul>
	Audience	Development Department
	Responsible	Software team
	Approval	Development manager
	Verification/Review	Software team
	Maintenance	Software team
KEN XML Protocol	Document name	KEN_XML_Protocol.pdf
	Version	011
	Purpose	The purpose of this document is to describe the KEN XML protocol.
	Audience	Development Department
	Responsible	Software team
	Approval	Development manager
	Verification/Review	Software team
	Maintenance	Software team
IWD HMI Software designspecifikation	Document name	IWD HMI Software designspecifikation.pdf
	Version	006
	Purpose	The purpose of this document is to describe the design of the graphical user interface.
	Audience	Development Department
	Responsible	Software team
	Approval	Development manager
	Verification/Review	Software team
	Maintenance	Software team
C15 Software Desinfektion designspecifikation	Document name	C15_Software Desinfektion designspecifikation/html/index.html
	Version	002
	Purpose	The purpose of this document is to describe the design of the software executed on the C15 disinfection monitor CPU. <ul style="list-style-type: none"> <li>• Module design and their interfaces.</li> </ul>
	Audience	Development Department
	Responsible	Software team
	Approval	Development manager
	Verification/Review	Software team
	Maintenance	Software team

Document	Information	
	Maintenance	Software team
C15 Pressure designspecifikation	Document name	C15_Pressure designspecifikation/html/index.html
	Version	001
	Purpose	The purpose of this document is to describe the design of the software executed on the C15 Pressure CPU. <ul style="list-style-type: none"> <li>• Module design and their interfaces.</li> </ul>
	Audience	Development Department
	Responsible	Software team
	Approval	Development manager
	Verification/Review	Software team
	Maintenance	Software team
IWD Software modul testrapport	Document name	IWD_Software modul testrapport/html/index.html
	Version	011
	Purpose	The purpose of this document is to document the unit testing of the IWD software and the results generated.
	Audience	Development Department
	Responsible	Software team
	Approval	Development manager
	Verification/Review	Software team
	Maintenance	Software team
C15 Software Desinfektion modul testrapport	Document name	C15 Software Desinfektion modul testrapport.pdf
	Version	002
	Purpose	The purpose of this document is to document the unit testing of the C15 disinfection monitor CPU software and the results generated.
	Audience	Development Department
	Responsible	Software team
	Approval	Development manager
	Verification/Review	Software team
	Maintenance	Software team
C15 Pressure modul testrapport	Document name	C15_PRES modul testrapport/html/index.html
	Version	001
	Purpose	The purpose of this document is to document the unit testing of the C15 Pressure software and the results generated.
	Audience	Development Department
	Responsible	Software team
	Approval	Development manager
	Verification/Review	Software team
	Maintenance	Software team
IWD system testrapport	Document name	IWD system testrapport.pdf
	Version	012
	Purpose	The purpose of this document is to describe and document the integration and system testing done on the complete IWD software.
	Audience	Development Department
	Responsible	Software team
	Approval	Development manager
	Verification/Review	Software team
	Maintenance	Software team
IWD Software valideringsrapport	Document name:	IWD valideringsrapport.pdf
	Version	003

Document	Information	
	Purpose	The purpose of this document is to document the result of the integration and system testing handling all test results in a test log, deviations and actions taken on deviations.
	Audience	Development Department
	Responsible	Software team
	Approval	Development manager
	Verification/Review	Software team
	Maintenance	Software team
KEN Leveringsprocedure software	Document name	KEN_Leveringsprocedure software.pdf
	Version	009
	Purpose	The purpose of this document is to describe the software delivery procedure which must be used.
	Audience	Development Department
	Responsible	Software team
	Approval	Development manager
	Verification/Review	Software team
Maintenance	Software team	
Software problem og modifikations rapport	Document name	Software problem og modifikations rapport.pdf
	Version	006
	Purpose	The purpose of this document is to give a template to handle software bugs and new features implemented in the software and how they are documented and software is revalidated.
	Audience	Development Department
	Responsible	Software team
	Approval	Development manager
	Verification/Review	Software team
	Maintenance	Software team

Table 5 Documents for this software version.

## 6 Building Procedures

To build all KEN software components defined in this document building procedures must be defined. All other software is built by sub suppliers.

### 6.1 Building IWD Software

Use procedure stated in [1].

### 6.2 Building C15 Disinfection Monitor Software

Use procedure stated in [2].

### 6.3 Building IWD HMI Software

Use procedure stated in [3].

### 6.4 Building C15 Display HMI Software

Use procedure stated in [4].

### 6.5 Building C15 VARD Software

Use procedure stated in [5].

### 6.6 Building C15 PRES Software

Use procedure stated in [6].