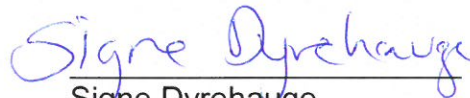


User Requirement Specification (URS)

Electronical medicine-cabinet (E-cabinet)

Prepared by:

Sygehusapotek Fyn

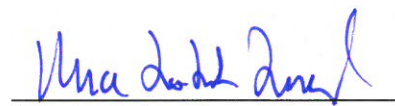


Signe Dyrehauge

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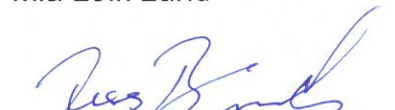
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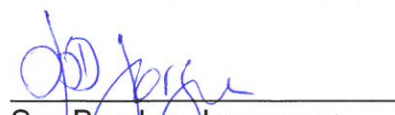
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1 Introduction

1.1 Purpose

Odense University Hospital (OUH) performs a pilot test with an e-cabinet for medicine as a part of preparing for the New OUH.

1.2 Delivery

This URS describes the requirements for delivery, installation, function and performance for an e-cabinet, for one ward at OUH.

2 Regulatory requirements

- CE-marking
- EU machinery directive

3 Responsibilities

The list of responsibilities is not fulfilling, but as add on to the contract. If there is a contradiction in requirements between the URS and other documents in the contract, the URS is prioritized.

SAF is responsible for preparing and approving this URS.

The supplier has the responsibilities to perform a Site Acceptance Test (SAT) and to deliver a timetable for the project. The supplier should carry out commissioning (SAT protocol and SAT report).

The supplier must provide a fully functional system.

The supplier is responsible for compatibility between the delivery and this URS.

4 Definitions

URS – User Requirement Specification

E-cabinet – electronical medicine cabinet

SAF – Sygehusapotek Fyn (the hospital pharmacy)

OUH – Odense University Hospital

CTS-system – a central system where temperature and other parameters can be monitored and to some extent controlled

SAT- Site Acceptance Test

5 Limitation

The URS only requires delivery of an e-cabinet, as standalone equipment. There will be no CPR (social security numbers) numbers in the system. Even though it is standalone equipment, the supplier must be able to access the system using the Internet, in order to update the system or correcting the set up e.g.

6 Installation

6.1 Area

The E-cabinet is to be placed in a medicine-room on a ward at OUH, Odense. The medicine-room is temperature CTS monitored. All refrigerators at OUH are also CTS monitored.

6.2 Facilities

- Electricity
- Internet – R syd, Wi-Fi/cable

7 Requirements

All requirements below should be fulfilled (minimum requirements) unless there is a mark **CR** (Competition Requirements)

Req. no.	Requirement	Acceptance criteria
7.1 Generally requirements		
R1	The offer must include <ul style="list-style-type: none"> - a Danish user interface - an E-cabinet with computer and software to control the cabinet - room for approximately 200 unique drugs - a touch-screen (CR) - a label printer (CR) - a refrigerator with sensor technology – see 7.2.3 - shelves and drawers with sensor technology – see 7.2.4 - card reader which read access cards for the staff at OUH - scanner which can read both EAN barcodes and 2D matrix codes 	The delivery is complete
R2	The delivered equipment must be the supplier's recently developed top model	Top model is delivered
R3	The E-cabinet is to be delivered at: Sygehusapotek Fyn Solfaldsvej 38, Indgang 209 5000 Odense C Denmark	The equipment is delivered at correct site
R4	The equipment must be able to have remote connection between supplier and e-cabinet for support and update purposes, using a restricted corporate network	A test of remote connection, using the guest network, is made

R5	The pharmacy staff must be able to have remote access to the cabinet with access to the full software package using the same network as the E-cabinet is connected to.	A test of remote connection, using the OUH network is performed
R6	User, cleaning and service manual in English or Danish are delivered before SAT	Manual is present
R7	A one page quick guide for the nurses how to pick up medicine in Danish	The one page quick guide is present
R8	A one page quick guide for the pharmacy staff how to fill medicine to the cabinet in Danish	The one page quick guide is present
R9	The offer must include appropriate training for a technical employee Showing basic functionalities, daily service and maintenance features	Training is made on site
R10	The offer must include appropriate training for super and normal users	Training is made on site
R11	Quality requirements <ul style="list-style-type: none"> - The e-cabinet must be easy to clean with smooth surfaces (CR) - The e-cabinet must be solidly constructed (CR) - It must be mandatory to scan when removing the medicine from the e-cabinet. 	The three quality requirements are present
R12	SAT protocol and report shall be prepared and executed by the supplier and the protocol should be approved by SAF	SAT protocol and report are present and accepted by SAF

7.2 Hardware requirements

7.2.1 Touch-screen/Keyboard

R13	If the equipment is delivered with a touch-screen it should be possible to operate with nitrile gloves. If a keyboard is necessary it should be medical grade.	Nitrile gloves can be used at the touch-screen Keyboard should be medical grade
R14	Materials must be easy to clean i.e. touch-screen and keyboard must be waterproof and washable	Touch-screen /keyboard waterproof and washable

7.2.2 Label printer

R15	A label printer, which can print in colors must be installed	Label printer can print (in colors)
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7.2.3 Smart refrigerator

R16	The refrigerator must have internal monitoring and be prepared for external central monitoring (CTS). The temperature setting should comply with GMP demands of 2 and 8 degrees Celsius	Refrigerator is with internal monitoring
R17	Refrigerator must be with sensor technology, that lights up the place	Light and sensor

	where the medicine should be placed/are placed	technology present
7.2.4 Smart shelves and drawers		
R18	All shelves and drawers should be with sensor technology, that lights up the place where the medicine should be placed/are placed	Light and sensor technology present
7.2.5 Tabletop		
R19	Tabletop should be in stainless steel (CR)	Tabletop is in stainless steel
7.3 Software performance requirements		
R20	The E-cabinet must have a computer with a software that can identify the medicine-packages	Computer and software are present
R21	The software must continually be able to be updated, so it will never be "end of life" – according to the service agreement	Software updates possible
R22	The supplier should give a quote for an annual service and update agreement (CR)	Quote is present
R23	It must be possible to add new medicine data by <ul style="list-style-type: none"> - scan - tap in manually - using a USB stick 	Reading in new medicine can happen in three suggested ways
R24	The E-cabinet must be fitted with software and sensor technology that lights up the place/shelves, where the medicine is to be/is placed	Light and sensor technology present
R25	The supplier must be able to access the system using remote access using the internet connection at OUH, through Dameware remote access system (CR)	Remote access is obtained using internet connection
R26	Up-time during the operational lifetime of the IT solution must be 99.5%, calculated pr. month except dedicated service windows (CR)	Up-time is 99,5% calculated (pr. month) 6 months after installation (report)
R27	Manuel override should be possible in case of power shut down or software updates, that cannot be performed in a limited service window	Test of the manuel override function is performed
7.3.1 User set up		
R28	There should be 2 different kinds of users. A normal user who is able to take out medicine from the cabinet and a super-user, who both can put in medicine and take out medicine.	2 different kinds of users are possible
R29	The super-user must be able to change <ul style="list-style-type: none"> - the assortment of medicine - the period of time before the cabinet locks if nobody is using it - settings for the users - settings for automatic reports regarding alarms 	It is possible to adjust the suggested parameters
7.3.2 Alarm		
R30	The E-cabinet refrigerator must be able to connect to the OUH CTS-	Functionality

	system by using internal sensors or by the possibility of applying external sensors.	tested
R31	The E-cabinet must give an alarm if a nurse tries to pick another medicine than the one searched at the panel	Alarm is present
R32	The E-cabinet must give an alarm if the nurse try to scan another medicine than the one searched at the panel	Alarm is present
R33	Picking medicine should not be possible to override the scanning process but simply clicking OK. If the manual override is performed it should be by tapping the barcode number	Functionality tested
7.3.3 Closing function		
R34	E-cabinet must be with a closing function, so the cabinet will lock when the user logs out	Lock out function is present
R35	E-cabinet must be with a closing function, so the cabinet will lock itself when the cabinet has not been used for X minutes. It must be possible for the super user to choose a period of time	Adjustable lock function is present
7.3.4 Access/ log in to the cabinet		
R36	There must be a card reader installed which can read Mifare 1K chips, which is the chip used by OUH staff access cards. Access should be granted by holding the card to the scanner. The needed coding of the cards should be described.	Card reader Mifare system is present
R37	It should be possible to log into the E-cabinet by maximum 3 clicks/touch including tapping one password at the touch screen (CR)	Log in can be done ≤ 3 clicks/touch
R38	The E-cabinet should have a restricted access function for narcotics (CR)	Restricted access functionality is present
7.3.5 Data logging/mapping/transferring		
R39	All activity in the E-cabinet must be logged for each user.	Log is established
R40	Data should be saved for at least one year (CR)	Technical specification is present
R41	Log activity must be able to be generated in a report	Report is generated
R42	Data must be stored in such a way that it is possible to generate new types for reports, if necessary	Database view is possible
R43	It must be possible to transfer process and log data to Excel for further processing	It is possible to transfer process data to Excel for further processing

8 Change log

Date	Ver.	Change	Initials
2017-06-26	0a	New document	SID
2017-08-08	1	Signed tender version	SID