



The Functional Interoperability Framework for Automated Systems Integration in Electronic Medication Management Processes

Association « Réseau Phast »

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- 5 Correction of the table of primary repacking and over-wrapping automated systems

v1.2.1

Translation in English. Several sources have been used as a reference such as HL7, IHE, IRDES, BDSP glossaries. When no translation was identified in these sources, PHAST proposed its own translations.

- 10 *v1.2.2*

Review of the English translation, text integrity.

Translator's Note:

- 15 Our best efforts were made to ensure an accurate representation of the terms and concepts specific to Hospital Pharmacy and the terminology associated with Automated Systems. However, inaccuracies may occur. We would like to ensure that the current document is up-to-date and correctly translated.

If you identify any errors, have comments or would like to contribute otherwise with your experience please contact us at: **contact@phast.fr**.

- 20

Introduction

25 Electronic patient drug management software must integrate the growing presence of the automated systems in the hospital setting. This is a key component to achieve interoperability in healthcare informatics. Many national French projects are geared toward encouraging interoperability:

- the national electronic health record (DMP) is based on the The Health Information Systems (HIS) Interoperability Framework (IF) published by the shared healthcare information systems agency (ASIP Santé)
- the Interoperability Chart from LESSIS
- 30 • the Hospital Interoperability Guidelines of Interop'Santé

Within this context, hospital project owners (AP-HP*, RESAH Ile de France*) and Order Entry software vendors identified the need for an interoperability framework addressing the presence of automated systems in electronic medication management process, starting at very early stages such as the tender.

35 Phast Association was central to the production of such an Interoperability Framework due to several factors such as:

- The extensive expertise in the standardization of electronic medication processes (the national standard PN13-SIPh2), and its role in IHE Pharmacy.
- 40 • The ability to mobilize hospital professional experts and industry stakeholders, Order Entry Software vendors, as well as Automated Systems vendors.

Phast organized, led and supported the working group which led to the creation and publication of the present Functional Interoperability Framework for automation integration in an electronic medication process.

45

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200

1 Objective

205 The continuous advancement of the healthcare data exchange needs to follow certain rules so that interoperability is possible. This document lists the key functional aspects needed when dealing with the integration of automated systems in the electronic medication management processes so that interoperability can be achieved. The classification of automated systems as well as the sequence diagrams illustrating the hospital pharmacy workflow is shown. The use cases described in this document are meant to result in technical specifications in the PN13SIPh2 standard, and can also be used to enrich the development of certain IHE Pharmacy profiles.

210

1.1 Project Owners

Hospital project owners should refer to the current Interoperability Framework when making a request for tender in order to ensure compatibility of the existing and future patient drug management systems and the automated systems.

215

1.2 Order Entry Software Vendors

220 Order Entry software vendors should take into account the specifications present in this Interoperability Framework when the developing their software and the associated components (data models, messages, business logic, Graphical User Interfaces) in order to assure as wide of a functionality as possible.

1.3 Relationship to Current Standards

225 This document describes the role of automated systems as related to the patient drug management process and aims to contribute with functional recommendations to the PN13-SIPh2 standard, certain IHE Hospital Pharmacy profiles (HL7v2) and HL7v3 storyboards.

The 2012 release of the PN13-SIPh2 standard will incorporate the functionalities in the present document and extend the already-existing standard.

230 As PHAST had contributed extensively to the early stages of the Hospital Medication Workflow profile, the underlying use cases and workflow present in this profile are not far from those used in the PN13SIPh2 standard. The present Functional Interoperability Framework can enhance significantly the existing IHE model and the underlying standards such as HL7 and contribute to their further development.

It is with this intention that PHAST decided to communicate the present English translation of this document to the IHE Pharmacy Domain as well as to the HL7 Pharmacy Working Group.

235

2 Automated Systems Study

2.1 Scope of Study

240 This document addresses the presence of automated systems in a patient drug management
processes that are already modeled. It is based on the integration model of patient drug
management process which served as functional basis for both the standard PN13-SIPh2 and
certain IHE profiles concerning the Hospital Medication Workflow. With this in mind, the
pre-requisites are listed but they are not specified in detail. For example, the prescription
messages between the prescriber, pharmacist, and nurse, the pharmaceutical validation, the
care plan of an Electronic Medical Record (EMR) or other messages related to synchronizing
245 the common registries used in such messages are not described in this document.

2.2 Automated Systems

2.2.1 Automated Dispensing Machine (ADM)

250 The Automated Dispensing Machine manages a decentralized inventory at the Care Unit level
and dispenses medication based on prescription or on orders present in the care plan.



Fig 1 – Automated Dispensing Machines

2.2.2 Nominative Dispensing Robot

255 The Nominative Dispensing Robot manages a certain stock and may repack medication as
individual doses according to the schedule, time of administration or the length of the time
period according to the prescription or care plan orders. The unitary packaging is dependent
on the existing medication delivery configuration. The robot does not cover all medication in
the formulary. The dispensing is supplemented by manual nominative dispensing, re-
260 globalized dispensing and / or local picking in the ward cupboard. A use case will further
describe the situation.



265

Fig 2– Nominative Dispensing Robot

2.2.3 Global Dispensing Robot

270 The Global Dispensing Robot manages a stock and packs and dispenses medication based on a multiple of a defined Unit of Dispense (UD) (blister, box, or bottle) according to the prescription or the care plan. The medication is packaged or released per Care Unit and at intervals based on local needs. The Global Dispensing Robot can also distribute medication to replenish the care units cabinets based on the same parameters (UD, Care Unit, frequency). Not all the medication in the formulary is covered. The dispensing is supplemented by complementary picking in the central stock and / or local picking in the ward cupboard.

275 Robots can work without operators as the loading and dispensing can be done automatically without supervision. The work can be programmed to be done in order of priority. Robots can also automatically prepare the refilling of standard stock cabinets.

2.2.4 Carousels

280 Carousels store medication as multiples of UCD¹ in the original packaging supplied by the laboratory (box, bottle) or in the primary packaging of the manufacturer (blister, bag). This type of robot informs the human operator of the particular location where the medication is stored. The robot software associates the brand medication with its location and with the Unit of Dispense.

285 There are two main types of carousels:

¹ Translator's Note (TN): UCD or *L'Unité Commune de Dispensation* is a French codification used for medication dispensed within a healthcare facility and it refers to the smallest unit dispensed of that medication.

Vertical Rotary Carousels:

- Computer-driven motorized shelves
- Picking assistance

290 Horizontal Rotary Carousels:

- Same principles
- Horizontal motion
- Less frequent in central pharmacies

295



300

Figure 3 – A Vertical Rotary Carousel (A) and a Horizontal Rotary Carousel (B).

305

2.2.5 Smart Pillbox

A Smart Pillbox releases the individual doses supplied by the pharmacy and is comparable to a secured cabinet dedicated to the patient. The Smart Pillbox is used in community medicine.

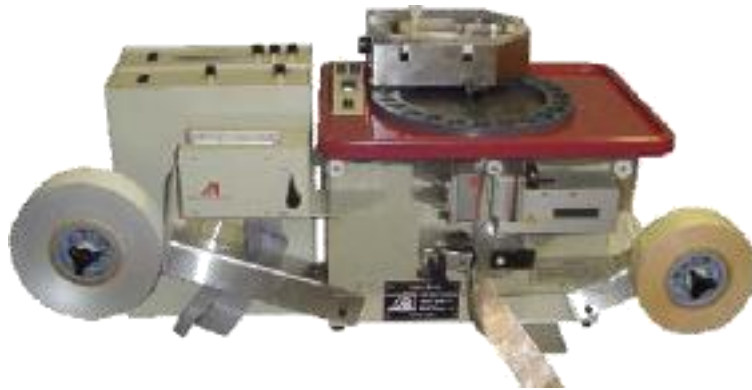
310 2.2.6 Smart Cart

The Smart Cart is similar to a small mobile secured cabinet containing only the individual doses supplied by the pharmacy or prepared in the ward.

2.2.7 Primary Repacking Machine

315 The Primary Repackaging Machine repackages the drug that has been previously removed
from its original packaging. The repackaged product is relabeled so that it is perfectly
identifiable and it also carries an expiration date and batch number. The correspondence with
the expiry date and batch number of the original industrial packaging must be kept and
audited.

320



325

Figure 4 – Primary Repacking Machine

2.2.8 Overwrapping Machine

330 The overwrapping machine overwraps the medication already wrapped in its original primary
package. The overwrapping machine transposes the package that it manufactures the
information attached to the original secondary package (for example the box with the Market
Authorization). It does not modify the indication of the expiration date of the medication.

The overwrapping machine may be an integrated part of a Nominative or Globalized
Dispensing Robot.

335



340

Figure 5 – Overwrapping Machine

2.2.9 Inventory and Warehouse Management Systems

345 The Inventory and Warehouse Management Systems provides control functions and/or
supervision of warehouses, locations, inventories, and medication flows. The *control* mode
can drive the robots and assists the operator in filling the Pillbox, indicating the medication
location. The *monitoring* mode compiles all the information issued by the driving software
and the robots so that it can offer a consolidated view to the operator. Further illustrations of
350 these two modes which sometimes can be mixed are shown in the use cases.

2.2.10 List of the Studied Automated Systems

The following types of automated systems were studied:

- Automated Dispensing Machine
- 355 • Nominative Dispensing Robot
- Global Dispensing Robot
- Carousels
- Overwrapping machine

360 The Pillboxes and Smart Carts are excluded because of the lack of specificity in relation to the
Automated Dispensing Machine.

2.3 Workflow Considerations

2.3.1 Medication Identification and Logistics Objects

365 The medication identification as used in medication management processes is not the same as
the logistics objects that are managed. The medication is identified by its UCD code which
does have some limitations such as medication that for various reasons does not have a code
or phasic preparation (for example ATCIFIED day/night or biphasic birth control pills).

370 The logistic objects are produced locally in the supply chain by the automated systems and/or
by human actors. This production must take into account the local equipment and workflow,
and thus the identification and description of the logistic objects are specific to each
healthcare facility.

375 The logistic objects are considered to be *containers*, which can be multiply packaged (nested)
starting from the primary packaging of the medication, which is considered as the *content*. A
DOLIPRANE® tablet, *content*, is identified by its UCD code and thus receives all the
qualifying attributes present in its CIOsp² sheet. This *content* is overwrapped (primary

² TN: CIOsp - The Phast CIOsp (*Codification Interoperable des Spécialités Pharmaceutiques*)- or the Medication Interoperable Coding) is a standardized medication terminology describing various medication attributes, leading to having a common understandable vocabulary requested by and addressed to all vendors and users wishing to produce and respectively use pharmacy management and medication knowledge base software.

repackaged) by the Nominative Dispensing Robot, and the bag, the *container*, is further packaged in strip that will be delivered in a box which will contain other medication in various packaging, sometimes not handled by the automated system.

380 In the medication management processes messages containing logistic objects must describe them in an accurate and exhaustive fashion (for example repacking bags, strips of individual dispenses, pill boxes, boxes or transport containers to the care units and pharmacy). Some examples are present in *Figure 6* and *7*, below.



390 **Figure 6** – Various logistics objects: A) Primary repackaging B) Unit Dose Overwrapping C) Packaging of an individual dose according to the schedule D) Secondary Packaging of a ring of individual doses. Note that on the packing of individual doses one can see an identifying barcode and a description of its contents. On the label identifying the ring one can see the identifying barcode and the list of individual doses.



Figure 7 – Pillbox morning/noon/evening/bedtime.

395 These logistics objects are not captured in the care plan software as often supports only an *ad hoc* representation of the drug from a pharmaco-clinical viewpoint. Sometimes this includes information which can be used for traceability in epidemiological and financial studies (the quantity of UCD with a particular lot number).

400 Care must be applied while validating the administration of individual doses which involves barcode scanning of a primary packaging labeled by the pharmacy as the information transmitted is that of the identifier of the container or the primary packaging. This identifier (*of the container*) is used to populate the medication administration module in the EMR with information about the *content* (a UCD code) as well as the quantity present. This information might be further sent to billing and used to monitor the financial activity (T2A in France). Mixing information concerning the *container* and its *contents* may be acceptable as long as the EMR is not used for managing the logistics of the containers involved in the automated

405 systems integration to the electronic medication management processes. Unfortunately, this is the current state of most prescribing and EMR software interfaced with a pharmacy management system.

2.3.2 Labeling the Smallest Unit of Repacking

410 One should not equate the label with the outgoing message from the robot: the label is aligned with the message but is not a true copy. The layout of the label is a function of the robot whose configuration is not included in the production messages. The label may be part of a centralized function using a common registry.

415 2.4 Primary Repackaging

The primary repackaging of a medication by an automated system is different from its primary industry packaging as it contains important information for traceability:

- the expiration date is changed by the repackaging process.
- the original laboratory lot number is different than the one generated from repackaging.

420 Both sets of this information are kept in a registry for traceability purposes and samples are kept at pharmacy for control purpose. Their meaning should be clearly identified in the exchanged messages and in product labeling. The repackaging software must be able to clearly identify and store these attributes so that it can be easily retrieved by the pharmacist in case he or she has to promptly act when inquiries are made, especially those concerning
425 ANSM³ batch recalls.

2.5 Fractional Doses

A packaged fractional unit dose is considered a logistics unit that cannot be superposed with a UCD. The expiration date is defined by the fractionation process and its labeling follows the
430 same rules as applied to the repackaging process.

2.6 Conditional Prescription

Their dose regimen is based on the clinical situation and as a consequence it is challenging to determine what individual doses are made available at different levels in the supply chain and
435 in the individual dispensing process.

Some EMR care plans can generate a floating task that can shift hourly, and that can be accomplished, abandoned or carried over. For example in the conditional prescription: “*if pain then give DOLIPRANE®*” one cannot know in advance at what precise time

³ TN : ANSM - L'Agence nationale de sécurité du médicament et des produits de santé. The French equivalent of FDA.

440 DOLIPRANE® should be administered. The only information available is the maximal dose that can be administered to the patient over a given period.

445 Managing conditional prescriptions is challenging when using centralized automated systems. Decentralized automated systems, especially the "*secure cabinets*," are used as needed in the process of care and the uncertainties introduced by the conditional prescription are less likely to have an impact on volume optimization and inventory management. Nevertheless, these uncertainties must not be neglected otherwise they generate local overstock (stocking more than the maximal possible administrable dose) or local understock (doses are not available to administer when needed clinically).

2.7 Synchronization of Common Registries

450 Sharing local registries within an institution is a prerequisite for the successful integration of software and automated systems. The registries used by different applications must be synchronized so that the information can flow seamlessly. For example, the structures within the healthcare facility, the drug formulary, the attributes used in the automated systems (threshold capacities), and the workflow organization should be shared. Patient identification
455 is shared through the ADT messages arriving in the HIS.

Sharing common registries is achieved according to the healthcare facilities' internal policies.

In order to ensure smooth integration of the automated systems in the hospital workflow, the following functional recommendations are made:

- 460 • Conduct an inventory of needed common registries and build a shared matrix (the registries are needed by both the software and the automated systems).
- Specify the structure and content of each registry and ensure that it is integrated with the same meaning by all applications and automated systems using it.
- 465 • Indicate the lifecycle of the registry as well as its source of truth (i.e. – external or identifying their life cycle of framework: what is its source of truth (external or local) and means of update?
- Specify the implementation life cycle of each registry, the type of management (centralized or distributed), and the means of sharing the framework according to the common registries matrix (manual or computerized) and according to the sharing protocol fit for each software and relevant automated system.

470 2.8 Use Cases

The use cases presented in this document describe real-life scenarios and accompanied by sequence diagrams.

In order to claim compliance with the present Functional Interoperability Framework one must comply with the functionality present in the sequencing.

475 Use Cases

1. Automated Dispensing Machine
2. Computerized DJIN^{4*} with barcode management, and both centralized and decentralized automated dispensing.
3. Nominative Dispensing Robot (re/overwrap) Packager, and Unit Doses Storer + Re-globalized Dispensing by carousel (blisters and boxes storer)
- 480 4. Nominative Dispensing Robot + Weekly supply + Ward cupboard
5. Nominative Dispensing of oral liquid forms + Ward cupboard
6. Dynamic Storage in Logistic Area of Pharmacy

These use cases are presented in the Appendix.

⁴ NT: *Dispensation journalière individuelle nominative* - Individual Daily Nominative Dispensing.

485 3 Data Model

3.1 Composition and Management of Stock

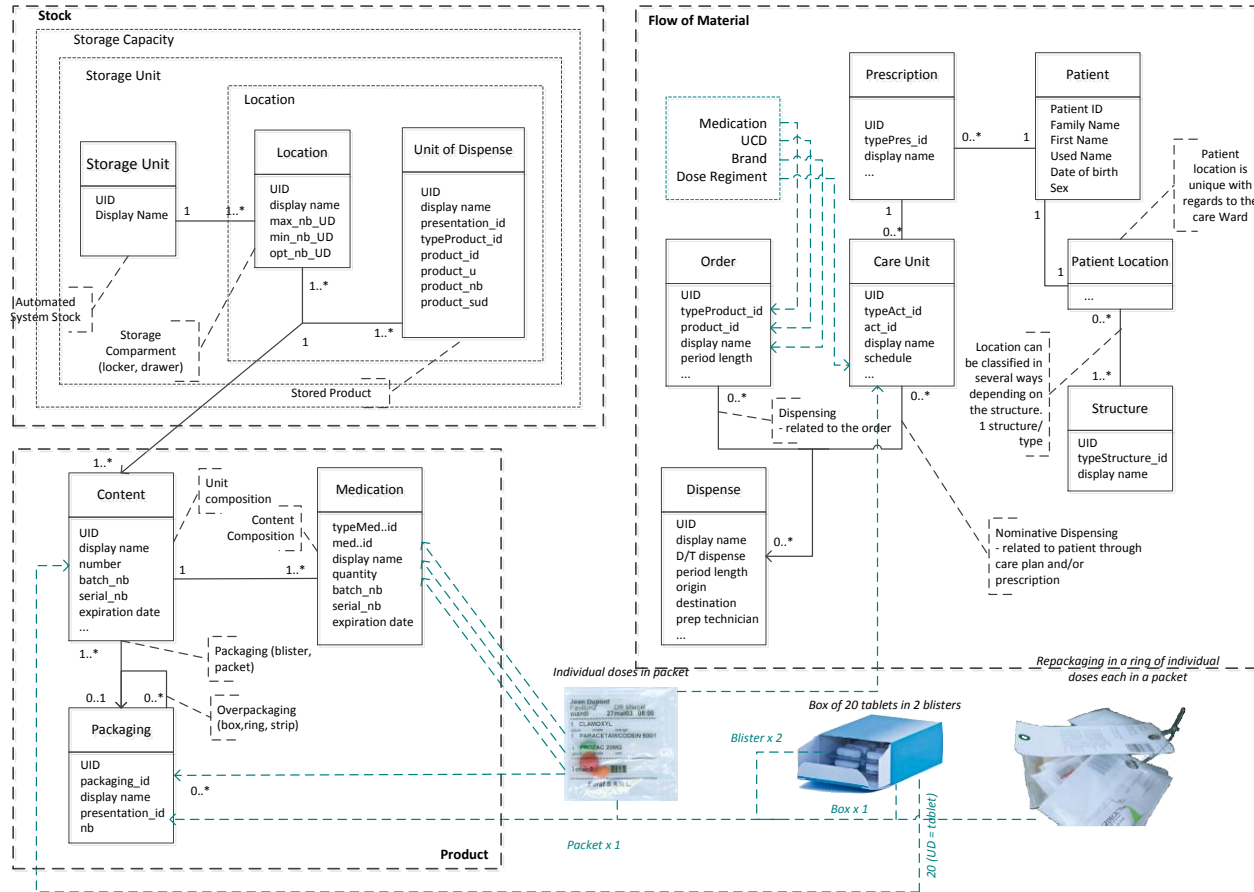


Figure 8 – The composition and management of stock

3.2 The Stock

490 The stock can be described in terms of the *container* (storage capacity), and the *content* (stored products).

3.2.1 Storage Capacity

495 The object *Storage Capacity* represents all the storage units (cupboard, carousels, etc.) as part of the electronic patient drug management process. Each *Storage Unit* is a set of locations (shelve, locker, drawer, etc). The products stored in each location are characterized by *Units of Dispense*. Among those storable products the *Medication* is the only one which is detailed in the present Interoperability Framework.

500 The object *Storage Capacity* is stable over the period between two configurations. It can be considered as a reference file whose update process must be carefully defined by the stakeholders concerned by the automated system integration in the healthcare facility.

505 The information contained in the *Storage Capacity* is shared between the automated systems and the software according to mechanisms meant to share common directories. The automated systems do not contribute themselves to this common directory update; they can only be negatively influenced if the information is not shared correctly.

Two use cases must be considered when updating the common directory:

- Adding / deleting a storage unit (can a storage unit be removed when not empty?).
- Updating a storage unit, the only rule applicable is that its identifier cannot be changed. There are no restrictions on its label.

510

3.2.2 Storage Unit

The object *Storage Unit* represents a set of locations which are homogeneous in terms of the stored products and stock management. Each robot having a local stock in order to participate to the materials flow represents a *Storage Unit*. Not all *Storage Units* are automated.

515 Some examples of *Storage Units* are: cupboard, carousel, or Nominative Dispensing Robots.

Key attributes of the object *Storage Unit*:

- *UID* : unique identifier of the object instance *Storage Unit*
- *Display name*: local description of the *Storage Unit* object instance, a priori hierarchical (eg. ward.care unit.standard of stock.cabinet)
- *A collection of UID* (unique identifiers) of its *Locations*

520

3.2.3 Location

The *Location* is defined as the smallest differentiable subunit in a *Storage Unit* such as a tray, bin or a drawer.

525 **Key attributes** of the object *Location*

- *UID* : unique identifier of the object instance *Location*.
- *Display name*: local description of the *Location* object instance, a priori hierarchical (eg, cabinet.drawer.locker)
- *max_nb_UD* : maximal number of *Units of Dispense* (integer, no units)
- *min_nb_UD* : minimal number of *Units of Dispense* (integer, no units)
- *opt_nb_UD* : optimal number of *Units of Dispense* (integer, no units)
- UID collection (unique identifiers) of its *Units of Dispense*.

530

3.2.4 Unit of Dispense (UD)

535 The *Unit of Dispense* object (UD) represents the smallest quantity of product that can be handled at a *Location*. The Unit of Dispense can take different values depending on the configurations.

For example, a cabinet can receive blisters as supply and distribute UCD either by taking the UCD out of the blister as part of the picking process or by cutting the blister into UCDs before to storing them in its locker. The UD_{in} is however not different than the UD_{out} as they are identical (both are equal to 1 UCD in this case). The only difference is the *unit of refill* (UR), i.e. the blister.

540

The supply management function should support the transition UR / UD delivered. The conversion UR/UD uses information which is part of the common automated system registry that is shared between the medication management software and the automated systems. The present Interoperability Framework requests that the automated system must be aware of the UD (whole or fractional), which can be set according to the particular drug. The handling of UR versus UD and the matching algorithms between these two units are outside the scope of this Interoperability Framework.

545

550 **3.2.4.1 UD and Location**

When a brand drug (eg *Lexomil*) is distributed automatically by a robot in $\frac{1}{4}$, $\frac{1}{2}$ or 1 tablet then corresponds to three different *Locations* in this robot, each with its respective UD as the $\frac{1}{4}$ of UCD, $\frac{1}{2}$ of UCD and an entire UCD of this brand.

555 If the same brand is available in an Automated Dispensing Machine, the nurse will break the tablets as necessary at the time of obtaining it. The UD corresponding to this specific *Location* for this brand is a divisible UCD.

560 If the Automatic Dispensing Machine has a medication brand as a liquid form in a multi-dose vial, the nurse will take the volumes as needed. The UD from the specific *Location* in this case is the smallest deliverable volume (1 ml, 1 dose, 10 ml, etc.. depending on the measuring device provided for dispensing this medication).

Key attributes of the object *Unit of Dispense*

- *UID*: unique identifier of the UD object instance.
- *display name*: local description of the UD object instance.
- 565 • *presentation_id*: packing identifier of UD object instance according to the common automated systems registry (tablet, blister, ampoule, vial, box,...)
- *typeProduct_id*: product type identifier, according to common automated systems registry whose value indicates a medication brand. Note: a stock may not be exclusively consisting of brand medication.
- 570 • *product_id*: product identifier as per common medication registry. This is the UCD code if the product is a brand medication.
- *product_u*: product reference unit for the product identified by *product_id*. *Product_u* can have values based on the common automated systems registry. eg. capsule, tablet, ml or $\frac{1}{4}$, $\frac{1}{2}$ tablet.
- 575 • *product_nb*: quantity reference unit for the product contained in the UD. This number is an integer without units of measure. For example, *product_nb* is 8 if UD is a blister (*packing_id*) of 8 tablets, with *u_product*= tablet.
- *sud_product*: the *smallest unit of deliverable* product. This is represented as an integer, possibly decimal, without units of measure.

580 Example:

	1	2	3	4	5	6
product_id	UCD in blister of 8 tablets quad-breakable			UCD in vial	UCD in 250 ml vial 10 ml/dose	
packing	blister_id	tablet_id	$\frac{1}{4}$ tablet_id	vial_id	vial_id	
product_nb	8	1	0,25	250	250	25
product_u	tablet	tablet	$\frac{1}{4}$ tablet	ml	ml	dose
product_sud	0,25	0,25	1	1	10	1

Table 1 - Examples of possible values of Unit of Dispense

- **1, 2 and 3**: the UCD is *tablet* ; it could be dispense as $\frac{1}{4}$ *tablet*
- **1** : the UD is a *blister of 8 tablets*
- **2** : the UD is a *tablet*
- **3** : the UD is a $\frac{1}{4}$ *tablet*
- **4, 5, 6** : the UCD is a *vial of 250 ml*
- **4**: the UD is a *vial of 250 ml* ; UCD could be dispensed as *ml*
- **5**: the UD is a *vial of 250 ml* ; UCD could be dispensed as a multiple of *10 ml*
- **6**: the UD is a *vial of 25 doses*; UCD could be dispensed as a *dose*.

585

590

3.2.5 Stored Products

The *Stored Products* are represented as products in relation to the *Storage Capacity* for each *Location* according to its *Unit of Dispense*.

595 A *Stored Product* shares a common representation, *Product*, with products being supplied or dispensed.

3.3 Stock Workflow

600 This Interoperability Framework is limited to the supply and dispense of medication involved in the automated systems circuit.

3.3.1 Dispense

A *Dispense* object represents a flow of delivered or dispensed medication and it is composed of a collection of *Products*.

605 In Nominative Dispensing *Dispense* is associated with the prescription order through the dose to be administered to the patient located in the healthcare facility.

When delivering of dispensing, *Dispense* is associated with the order.

Key attributes of the object *Dispense*

- *UID*: unique identifier of the *Dispense* object instance.
- 610 • *display name*: local description of the *Dispense* object instance.
- *D/T_dispense*: time stamp of dispense or delivery.
- *period length*: time period indicated by the dispense or delivery.
- *origin*: origin of the dispensed or delivered medication.
- *destination*: destination of dispensed or delivered medications.
- 615 • *technician*: pharmacy technician providing the delivery or the dispense.

3.3.2 Delivered or Dispensed Products

Delivered or Dispensed Products are linked to Order via Dispense.

620 Dispensed products are represented by products corresponding to *Prescription* and/or the *Medication Administration Record* in the EMR by *Dispense*.

A dispensed or delivered product shares a common representation with the stored products, namely *Product*.

3.4 Medication Product

Medication Product is a representation for both in store and circulating medication.

625 The *Medication Product* can be thought of in terms of *Content* for *Medication* and in quantities for *Packaging*.

3.4.1 Content

630 The object *Content* represents the content of a delivered or dispensed unitary container. It is composed of a collection of *Medications*.

In Nominative Dispensing, *Content* is associated with the doses to be administered to the patient through *Medication* objects corresponding to the doses planned.

Key attributes of the object *Content*

- *UID*: unique identifier of the *Content* object instance.
- 635 • *display name*: local description of the *Content* object instance.
- *nb*: quantity of *Content* in its possible *Packaging* in its *Location* - if it is in stock - or its *Dispense* if it is in a delivery or nominative dispensing workflow.
- *batch_num*: batch number assigned by the process of packaging (can be local).
- *serial_num*: serial number assigned by the process of packaging (can be local).
- 640 • *expiry_date*: expiry date assigned by the process of packaging (can be local).
- collection of *Medication* which compose it.
- its *Packaging* (if present).

3.4.2 Medication

645 The *Medication* object is the unitary content of the *Content* object. In nominative dispensing this composition corresponds to doses to be administered as indicated by the prescription or by the care plan in an EMR. When dispensing or refilling, this composition is in relation to the dispensing or the delivery order.

Key attributes of the *Medication* object

- 650
- *typeMed _id* : Medication type (brand of medication, hospital pharmacy preparation, etc.)
 - *Med_id* : identifier, UCD code for a brand medication.
 - *display_name*: local description of the *Dispense* object instance. In this case we see the benefit of the *CIOsp* structured labeling which allows in this context building an
- 655
- *ad hoc* label of the brand name.
 - *quantity*: quantity of medication.
 - *batch_num* : original batch number, assigned by manufacturer.
 - *serial_num* : original serial number, assigned by manufacturer.
 - *expiry_date*: original expiry date, assigned by manufacturer.
- 660

3.5 Packaging

Packaging is another attribute of the medication stored or involved in a delivery or dispensing workflow which can take different values according to these states.

3.5.1 Packaging Attributes

665 The *Packaging* object describes the container of the *Content* object of a medication in stock or involved in delivery or dispensing workflow.

Figure 9 shows different packaging.



A



B



C

670

Figure 9 – Different Packaging. A) Bag. B) Ring C) Box

- The *Packaging* object in *A* is the bag. Its identifier is present in a barcode and its *Presentation* attribute takes the value *bag*.
- The content is represented by 1 *Content* object, itself composed of 3 *Medication* objects, each corresponding to a brand in the bag (CLAMOXYL, PARACETAMOL CODEINE and PROZAC).

675

The *Packaging* object can also describe the container of a content composed of *Packaging* objects (nested packaging).

- In image *B*, each bag is a *Packaging* object with printed identification details. Just like in the previous picture, the content of each bag is represented by a *Content* object which in its turn may be composed by as many *Medication* objects as there are medications.
- The ring is represented by a *Packaging* object, whose identifiers appear on the label (including a barcode), and the container is represented by the collection of the *Packaging* objects corresponding to each bag on the ring. The *Presentation* attribute of this *Packaging* object has the identifier value *ring*.

680

685

Image C shows a box of 2 blisters, each with 10 tablets.

- If this box is considered **in stock**, the *Content* object is represented by the 20 tablets stored in an ad hoc *Location*, the *Packaging* object is represented by the 2 blisters and the content of this object is *Content*. The *Packaging* object is represented by the box whose content in turn is represented by the *Packaging* object (the 2 blisters).
- If this box is considered in the **material flow** (medication workflow within the automated systems), the *Content* object is unitary and composed by the 20 tablets that are delivered or dispensed together and considered indistinguishable. This unitary content has its first level of packaging represented by the *Packaging* object (the 2 blisters). The box over-wrapping represents a second *Packaging* object whose content is the first *Packaging* object (the 2 blisters).

690

695

Key attributes of the object *Packaging*

- *UID*: unique identifier of the *Packaging* object instance. This UID is used in the traceability of packaging.

700

This identifier is optional because if the packaging is not traced individually, then this UID does not exist. For example, a blister does not receive an individual label hence no available UID can exist for it.

705

***NOTE:** Packaging can also be considered an abstract concept of the quantity of the product: one blister means 10 tablets and a box means 20 tablets. If in a box with 2 10 tablets are removed and the removal of each blister is not tracked, one cannot know if 10 tablets have been removed from the same blister (which would then be empty) and the total quantity of the product will then be reduced to one blister, or if the tables have been removed from both blisters randomly and the total remaining quantity is represented by 2 partially filled blisters.*

710

***WARNING:** One must be careful what Packaging carries as information to a software application: a physical reality which is traced and identified by a UID or the equivalent of quantity.*

715

- *packaging_id* : identifier of *Packaging* object instance according to a common shared automatic systems registry. For example, the CIP registry uses the "*CIP code*" to identify the packaging used for sale of a brand medication. This identifier is optional as not all packaging is necessarily referenced. For example, the CIP registry does not reference any blister.
- *display name*: local description of *Packaging* object instance.
- *packing_id*: identifier of the *Packaging* object instance according to the common shared pharmaceutical forms registry (blister, vial, box).
- *nb*: number of items of the *Packaging* object instance. If the *UID* is defined, then *nb* = 1, as the item is unique. For example, two blisters in an over-wrapping box.

720

Note : However if these blisters are each individually represented by a *UID*, then each must be represented by its own *Packaging* object instance whose *nb* = 1.

725

- collection of a *Content* object and potential *Packaging* objects instances of lower level.

730

3.5.2 Labeling Rule

735 The present Interoperability Framework is not a substitute for the rules of best practice of medication packaging. To that effect, the format or the content of a labeling of a package is not defined here.

740 If the prescription or the care plan in an EMR contains posology (dose regiment) information pertinent to the content of packaging (for example PRN), this must be taken into consideration at the point of entry. The same principle applies for the length of a dispense period or the scheduled time of the administration of a medication.

3.6 Barcodes

745 Barcodes are a method of representing alphanumeric information without having to connect to the system that generated them; in that way they can be considered a messaging system in their own. Barcode scanning is a very commonplace procedure; however semantic interoperability challenges are still present. The information carried by the barcodes needs to be defined and structured and tables need to be established. This Interoperability Framework does not address barcodes integration with the management processes in the supply chain.

750 3.7 Relationship with Prescription and Care Plans in EMRs

Nominative Dispensing links the automated systems to the prescription and/or the care plan. The relation to the patient is done through the doses to be administered according to the prescription.

755 3.7.1 Scheduling of Individual Doses

An automated system can schedule individual doses based on and/or a care plan. Routine information such as the medication name, its quantity and the period over which is to be administered is needed.

760

3.7.2 Automatic Substitution

Some automated systems are able to perform automatic substitution. This is necessary when the individual doses or the dispense orders are expressed in a medication brand that is not available among those delivered the automated system

765

3.7.3 Pharmaceutical Validation

Some automated system can also perform pharmaceutical validation in certain cases of nominative dispensing when the prescription is not validated by the pharmacist.

3.7.4 Generic Name Prescription

Certain automated system can transcribe from a prescription and/or care plan order written in a generic medication name (such as the International Nonproprietary Names) to the brand name that it carries.

3.8 Compliance to the Functional Interoperability Framework

Since this Interoperability Framework addresses only the functional aspects of the integration of automated systems with the medication management processes, being compliant means that the automated systems and software support the roles and corresponding actors mentioned above. They need to be able to receive and interpret inbound messages and information (for example Brand Name prescription, Generic Name prescription, and the associated information in care plans), and they also need to be able to respond appropriately (pharmaceutical validation, substitution, Generic Name transcription to Brand Name, populating Medical Administration Records with the correct information).

780

The Functional Interoperability Framework does not include technical specifications for implementers. The use cases present as well as the activity diagrams can be used to further develop the PN13-SIPh2 standard and to contribute to the functional component of IHE Profiles and HL7v3 artifacts.

785

790 **3.9 The Automated Systems**

The automated system has several criteria according to which is can be classified:

- Integration with the electronic information system: receiving/sending information, configuration
- Interaction with the material flow: incoming/outgoing material; can also be local stock.
- Local intelligence – presence of features that:
 - Process the incoming messages related to the material flow and manage the local stock.
 - Generate outgoing material flow messages for stock management and keep track of the local stock.
 - Assist the operator in his or her tasks

805 The Automated systems integrating with electronic medication management processes must follow the model in *Figure 10* that defines, for each type of automated seven parameters listed below.

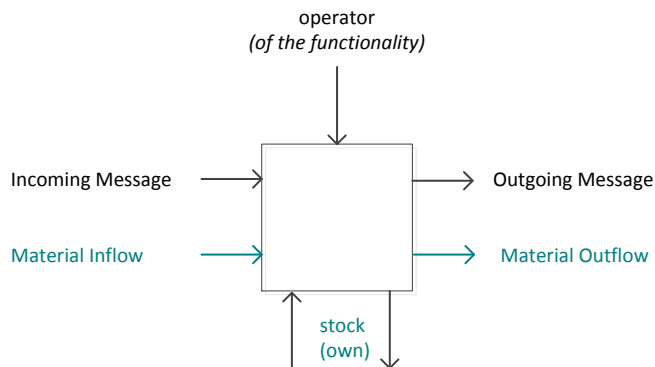


Figure 10 – General Modeling of an Automated System

810 The model defines for each type of automates system:

- All the supported functionalities
- For each supported functionality:
 - *The operator*): the human actor involved in providing the functionality and who is in direct contact with the automated system. If the operator does not act, the operation cannot be executed. The operator's action may be an interaction with the automated system software and/or with the material handled by the system. If the operator interacts with the automated system though another application not part of the system, then he or she is not considered as an operator of the automated system.

815

820

- Inbound message
- Outbound message
- Incoming material flow: material feeding into the automated system.
- Outgoing material flow: material generated by the automated system.

825

Local stock: the stock required for the functioning of the automated system and an integral part of it. This information must be captured in the information system. The stock capacity of the automated system must be described as listed in the present Interoperability Framework and must be shared via the common automated system registry with the other applications and automated systems requiring this information. The common automated system registry is kept up to date by synchronization mechanisms which are out of scope of this Interoperability Framework.

830

This local stock requires to be managed carefully by monitoring the material inflow and outflow. The operator or the inbound message (whichever might be the case) never act directly on the local stock. Only the *ad hoc* features of the automated system operate on local stock. An automated system that does not have a local stock is dependent on the inflow of material for producing what it was requested.

835

The stock capacity of an automated system also includes the attributes necessary to its optimum operation, such as the restocking threshold or the maximum numbers of a UD of a brand that can be stored. Their update is also part of the synchronization of the common automated system shared registry. These parameters are not used in the messages used for the production of the material by the automated system.

840

3.10 Classification of Automated Systems

The automated systems are classified as listed below.

3.10.1 Automated Dispensing Machine

Features	Operator	Incoming Message	Outgoing Message	Material In	Material Out	Stock
Supply	x	Prescriptions Care Plan none	Nominative Dispensing		Dispensed Doses	-
Supply Follow-up	x	Supply Report				
Return of doses	x	Care Plan	x	Dispensed Doses		+
Inventory	x ⁽²⁾ /o ⁽³⁾	o ⁽²⁾ /x ⁽³⁾	Inventory			
Refill Request	x ⁽²⁾ /o ⁽³⁾	o ⁽²⁾ /x ⁽³⁾	Order			
Refill	x	Delivery Slip	Delivery Report	UD ⁽¹⁾		+ ⁽⁴⁾
Removal from storage	x	o ⁽⁵⁾	Delivery Slip		UD ⁽¹⁾	- ⁽⁵⁾

Table 2 – The Automated Dispensing Machine Functionalities

845 x/o: required/optional

(1): Unit of Dispense of medication (UCD, UCD fraction or multiple of UCD -blister, box) according to robot configuration.

(2): Inventory or refill request is triggered by the operator, with or without prior inbound message to his/ her action

850 (3): Inventory or refill request is requested by an inbound message, with or without operator action.

(4): Entering stocks (+), either load or refill, coming from the stock defined in the Delivery Slip of the incoming message.

855 (5): Removal from storage (-), intended for the stock in the Delivery Slip of the outgoing message. This removal can be due to:

- Transfer of medication to another unit, typically in emergency mode with or without a prior order message.
- With a prior order message.
- Outdated, as determined by the automated system operator
- Returns ordered by the pharmacy, with or without a prior order message.

860

Note: A prescription or a care plan from another care unit in the healthcare facility might be re-routed to the Automated Dispensing Machine. In this case, the dispensing is accomplished as usual via the Dispensing functionality.

865

3.10.2 Nominative Dispensing Robot

Features	Operator	Incoming Message	Outgoing Message	Material In	Material Out	Stock
Supply	x	Prescriptions Care Plans none	Nominative Dispensing		Dispensed Doses	-
Supply Follow-up	x	Supply Report				
Inventory	x ⁽²⁾ /o ⁽³⁾	o ⁽²⁾ /x ⁽³⁾	Inventory			
Refill request	x ⁽²⁾ /o ⁽³⁾	o ⁽²⁾ /x ⁽³⁾	Order			
Refill	x	Delivery Slip	Delivery Report	UD ⁽¹⁾		+ ⁽⁴⁾
Removal from storage	x	o ⁽⁵⁾	Delivery Slip		UD ⁽¹⁾	- ⁽⁵⁾

(): see previous notes of Table 2 - *The Automated Dispensing Machine Functionalities*

Table 3 – The Nominative Dispensing Robot Functionalities

870

3.10.3 Global Dispensing Robot

The Global Dispensing Robot can have two modes of operation:

- Nominative re-globalized: accepts prescriptions or care plans orders in addition to potential delivery orders.
- Purely global: accepts only delivery orders.

875

Features	Operator	Incoming Message	Outgoing Message	Material in	Material out	Stock
Supply	x	Prescriptions Care Plans <i>none</i>	Delivery Slip		UD ⁽¹⁾ in boxes /ward & /period /patient ("rétrocession")	-
Supply Follow-up	x	Supply Report				
Inventory	x ⁽²⁾ /o ⁽³⁾	o ⁽²⁾ /x ⁽³⁾	Inventory			
Refill Request	x ⁽²⁾ /o ⁽³⁾	o ⁽²⁾ /x ⁽³⁾	Order			
Refill	x	Delivery Slip	Delivery Report	UD ⁽¹⁾		+ ⁽⁴⁾
Removal from Storage	x	o ⁽⁵⁾	Delivery Slip		UD ⁽¹⁾	- ⁽⁵⁾

(): see previous notes of Table 2 - *The Automated Dispensing Machine Functionalities*

Table 4 – Global Dispensing Robot Functionalities

880

3.10.4 Carousel

Features	Operator	Incoming Message	Outgoing Message	Material in	Material out	Stock
Inventory	x ⁽²⁾ /o ⁽³⁾	o ⁽²⁾ /x ⁽³⁾	Inventory			
Refill Request	x ⁽²⁾ /o ⁽³⁾	o ⁽²⁾ /x ⁽³⁾	Order			
Refill	x	Delivery Slip	Delivery Report	UD ⁽¹⁾		+ ⁽⁴⁾
Removal from Storage	x	o ⁽⁵⁾	Delivery Slip		UD ⁽¹⁾	- ⁽⁵⁾

(): see previous notes of Table 2 - *The Automated Dispensing Machine Functionalities*

Table 5 – Carousel Functionalities

885 3.10.5 Primary Repacking Machine

The Primary Repacking Machine is comparable to the carousel, with manufacturing report.

Features	Operator	Incoming Message	Outgoing Message	Material In	Material Out	Stock
Fabrication	x		Manufacturing Report		UD ⁽¹⁾	- ⁽⁵⁾
Inventory	x ⁽⁶⁾ /o ⁽⁷⁾	o ⁽⁶⁾ /x ⁽⁷⁾	Inventory			
Refill request	x ⁽²⁾ /o ⁽³⁾	o ⁽²⁾ /x ⁽³⁾	Order			
Refill	x	Delivery Slip	Delivery Report	UD ⁽¹⁾		+ ⁽⁴⁾
Removal from storage	x	o ⁽⁵⁾	Delivery Slip		UD ⁽¹⁾	- ⁽⁵⁾

(): see previous notes of Table 2 - *The Automated Dispensing Machine Functionalities*

Table 6 – Carousel Functionalities

890 (6): Request for inventory is triggered by the operator, with or without a prior incoming message to his or her intervention.

(7): Inventory request is triggered by an incoming message, with or without operator intervention.

3.10.6 Over-wrapping Machine

The Over-wrapping Machine is comparable to automated systems for primary repackaging. Over-wrapping does not change the expiry date of the over-wrapped medication.

895

Features	Operator	Incoming Message	Outgoing Message	Material In	Material Out	Stock
Fabrication	x		Manufacturing Report		UD ⁽¹⁾	- ⁽⁵⁾
Inventory	x (6)/o (7)	o (6)/x (7)	Inventory			
Refill Request	x ⁽²⁾ /o ⁽³⁾	o ⁽²⁾ /x ⁽³⁾	Order			
Refill	x	Delivery Slip	Delivery Report	UD ⁽¹⁾		+ ⁽⁴⁾
Removal from Storage	x	o ⁽⁵⁾	Delivery Slip		UD ⁽¹⁾	- ⁽⁵⁾

(): see previous notes of Table 2 - *The Automated Dispensing Machine Functionalities*

Table 7 – Over-wrapping Machine

3.11 Definitions of features Functionalities Performed by Automated Systems – Definitions

900

3.11.1 Nominative Dispensing

Nominative Dispensing is the dispensing of medication for a patient nominally identified in quantities specified by the prescription orders. The medication is supplied from identified stock present in the automated system. If the dispensing robots are also re-packaging or over-wrapping the medications, the traceability of the manufacturing process must be assured. Also, if re-packaging, the batch number of the manufacturing process and the expiry date that is given to the re-packaged medication must be provided. This information must be linked with the batch number and the expiry date from the original industry primary packaging.

905

Note: the batch number of the manufacturing process can be the time stamp (date/time).

910

The length of the period during which Nominative Dispensing takes place can be determined in two ways:

- The period covered by the dispensing is set in the automated system software (or the third party software driving it) as listed in the prescription.
- The period covered corresponds to the scheduled doses administration activities as indicated in the patient care plan in the EMR.

915

Dispensing can be individualized or re-globalized, according to the material flow management and packaging.

Note that it is possible to have re-globalized dispensing from an Automated Dispensing Machine if the medications removed individually from the automated system are not placed in an individualized packaging for patient use until the time of administration.

920

Dispensing must not be confused with the functionality *Removal from Storage*, which also involves medication being removed from the stock, but this removal is not in relation to a specific patient. It is possible to locally dispense using the automated system software (or the piloting software) without having a prior prescription or care plan order for the dose dispensed. In these conditions the dose dispensed must be explicitly associated with a patient nominally identified and the time of drug administration should be documented. If this is not performed, this action will be considered as a *Removal from Storage*.

925

WARNING: The information concerning the dose dispensed from the automated system without a prior prescription order must be reconciled as soon as it is possible with the patient prescription or the care plan as part of the compliance to the present Functional Interoperability Framework. If the standard used for the technical implementation or the software itself do not support this use case (commonly called "prescription à posteriori"⁵), then the dispensing shall be considered as Removal from Storage and the reconciliation will be treated as a separate step after a prescription or a care plan order has been placed.

930

935

⁵ Prescribing *à posteriori* is to be understood from an information system standpoint and not as a prescription written after the dose is administered to the patient. There is always a prescription upstream to the medication administration to the patient. Carrying conditional prescription orders depends on the nurses' expertise and responsibility and it is based on a pre-existing prescription.

3.11.2 Return of Doses

The Return of Doses is an identified Entry in the automated system inventory dispensed by patient name. The stock management system is aware of the prescriptions or care plan orders corresponding to the quantities of medication returned.

940 This must not be confused with the functionality *Refill*, which also creates an entry in the inventory but does not have its information related to a patient.

3.11.3 Manufacturing of Re-packaging and Over-wrapping

945 This is defined as manufacturing of primary repackaging or over-wrapping of medications, except in cases when delivering or dispensing. Repackaging or over-wrapping is a pure transformation process without any material flow. It is characterized by the production of a manufacturing report including the traceability information. The batch number of the manufacturing process and the expiry date that is given to the repackaged medication must be provided, as well as a correspondence with the batch number and the expiry date attached to
950 the original industry primary packaging.

Note: The batch number of the manufacturing process can take the form of a manufacturing time stamp (date/time).

3.11.4 Inventory (current)

955 This functionality provides the actual state of the stock in the automated system and allows for physical control of the automated system (if the storage device is automated and presents locations) or provides access to the operator who then counts the number of Units of Dispense (UD) present in stock. This information is then entered in the Inventory. A summary report of the stock is produced entitled: “inventory “. The feature of theoretical inventory is not
960 addressed in this document.

3.11.5 Refill Request

The Refill Request produces a medication delivery order based on the identified automated system inventory needing to be refilled.

965 Synonym: Load request (considered as a refill request based on initial quantity = 0 when medication is stocked for the first time).

3.11.6 Refill

970 This functionality supplies medications for an identified automated system stock in order to replenish it.

 Synonym: Replenish, Resupply. Restock.

 This functionality must not be confused with the functionality *Return of Doses*, which also involves an entry into the medications stock but is related to the patients via their prescriptions and/or their scheduled doses administration.

975

3.11.7 Removal from Stock

 Removal from Stock involves withdrawal of medications from an identified automated system stock in order to supply another identified stock or to be discarded.

980 This functionality must not be confused with *Dispensing*, which also involves removal of medications from stock, but in relation to specific patients according to their prescriptions or care plans. If the automated system is not able to associate the medication removal from stock to a patient, even if the stock removal is performed with the intention to administer it to a patient, from the automated system perspective this is considered as *Removal from Stock*. In this case, the *Dispensing* as a relationship between the medication/patient/prescription or care plan must be accomplished by another software application.

985

3.11.8 Configuration

990 All parameters required for the operation of the automated system must be properly configured. Most of these parameters are part of common automated systems registries shared and synchronized between applications and the automated systems integrated into the electronic medication management process.

3.12 Definition of Incoming and Outgoing Entities in Automated Systems

3.12.1 Dispensed Doses

995 Dispensed Doses are a collection of units of medication as per the granularity managed by the automated system. This may be the UCD, a fraction or a multiple of a UCD, a blister, or box, just to name a few possibilities, all depending on the capacity of the automated system and the predefined organization for dispensing.

The dispensed doses are related to patients through the scheduled individual doses determined from their respective drug prescriptions.

1000

3.12.2 Units of Dispense (UD)

The Units of Dispense (UD) are a collection of units of medication as per the granularity managed by the automated system. This may be the UCD, a fraction or a multiple of a UCD, a blister, or box, just to name a few possibilities, all depending to the capacity of the automated system and the predefined organization for dispensing.

1005

The Units of Dispense are not related to patients.

3.13 Definitions of Messages Supported by the Automated Systems

These messages are defined at functional level with no bearing on the standard used. Their definition must be taken into account when developing technical implementation guides based on this Functional Interoperability Framework.

1010

3.13.1 Prescription (validated by the pharmacist)

1015 The Prescription is a collection of prescription orders identifying the patient, the prescribed medication and its posology (dose regiment). This prescription must be validated by the pharmacist in order to be filled. The prescribed medication is identified according to the shared common medication registry.

The automated system calculates the individual doses to be dispensed and how the dispensation is to be accomplished, including the packaging if applicable.

1020 **3.13.2 Care Plan**

The Care Plan is a collection of scheduled administration activities of single doses of medication identified according to the shared common medication registry. All these scheduled doses are related to their “*parent*” prescription order with each individual dose having the patient name associated with it.

1025 The automated system subtracts the individual doses as needed from this collection and calculates the modality of its dispensing, including packaging if necessary.

3.13.3 Dispensing

1030 Dispensing is a collection of individual doses dispensed by patient name in their dispensing packaging. These doses are associated with the scheduled drug administration activities in the care plan and/or to the “*parent*” prescription, hence each contains the patient identification.

The dispensed medication is identified using the shared common medication registry.

3.13.4 Order

1035 The Order is a collection of quantities of medication to be dispensed from a stock to other stocks as per defined in the shared common automated systems registry. These ordered quantities are not associated with a prescription order or with a patient.

The medication is identified according to the shared common medication registry.

1040 **3.13.5 Delivery Slip**

The Delivery Slip is a collection of doses delivered in their respective dispense packaging from a certain stock outbound for other identified stocks as per the shared common automated systems registry. These supplied quantities are not associated with a prescription or with a patient.

1045 The medication is identified according to the shared common drug registry.

3.13.6 Delivery Report

1050 The Delivery Report is receiving a collection of doses delivered in their respective dispense packaging from a stock bound for other identified stocks as per the common automated system registry. The received quantities are not associated with a prescription order or with a patient.

The medication is identified according to the common drug registry.

3.13.7 Manufacturing Report

1055 The Manufacturing Report accompanies the collection of UD (Units of Dispense) which are repackaged and/or over-wrapped. Attributes such as lot numbers and expiry dates, both from the original manufacturing laboratory as well as and those received during the packaging process are logged for traceability purposes. The medication is identified using the common local drug registry.

3.13.8 Inventory Request

1060 The Inventory Request is a command to perform an inventory of one or more identified stocks registered in the common local automated systems registry. This command does not take place without being triggered and steered by a human operator.

3.13.9 Inventory Report

1065 The Inventory Report is a report counting the content of a group of locations corresponding to one or more identified stocks according to the common local automated systems registry.

3.14 Sequence Diagrams

1070 The following sequence diagrams along with the automated systems classification constitute the building block of the present Functional Interoperability Framework.

The Sequence Diagrams examined are the following:

1. Supplying an ADM from a Central Carousel
2. Supplying an ADM from a Central Carousel with supply management software
 - 1075 a. Supervised mode: the automated systems have remote abilities.
 - b. Centralized management: centralized abilities directly driving the automated systems.

The two modes of operation can be mixed in real life.

- 1080 3. Dispense of daily doses using a re-packaging robot and supplements from the ward ADM
4. Inventory

The sequence diagrams of these typical scenarios are present in appendix.

3.14.1 Modeling an Automated System in a Sequence Diagram

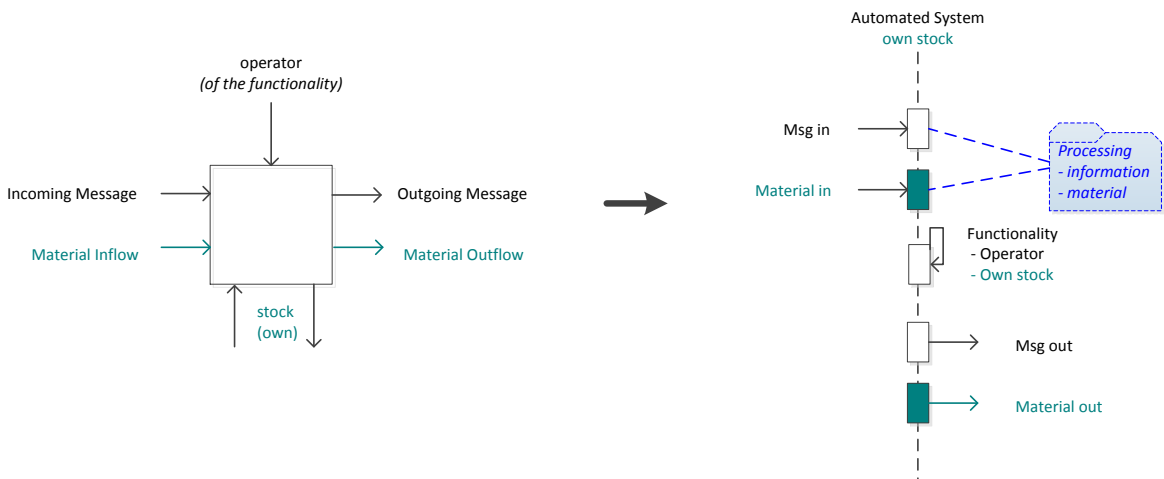


Figure 11 – Representing the activities of an automated system in a sequence diagram

3.14.2 Supplying an ADM from a Central Carousel

1090 The refill request is usually automatic depending on ADM settings.

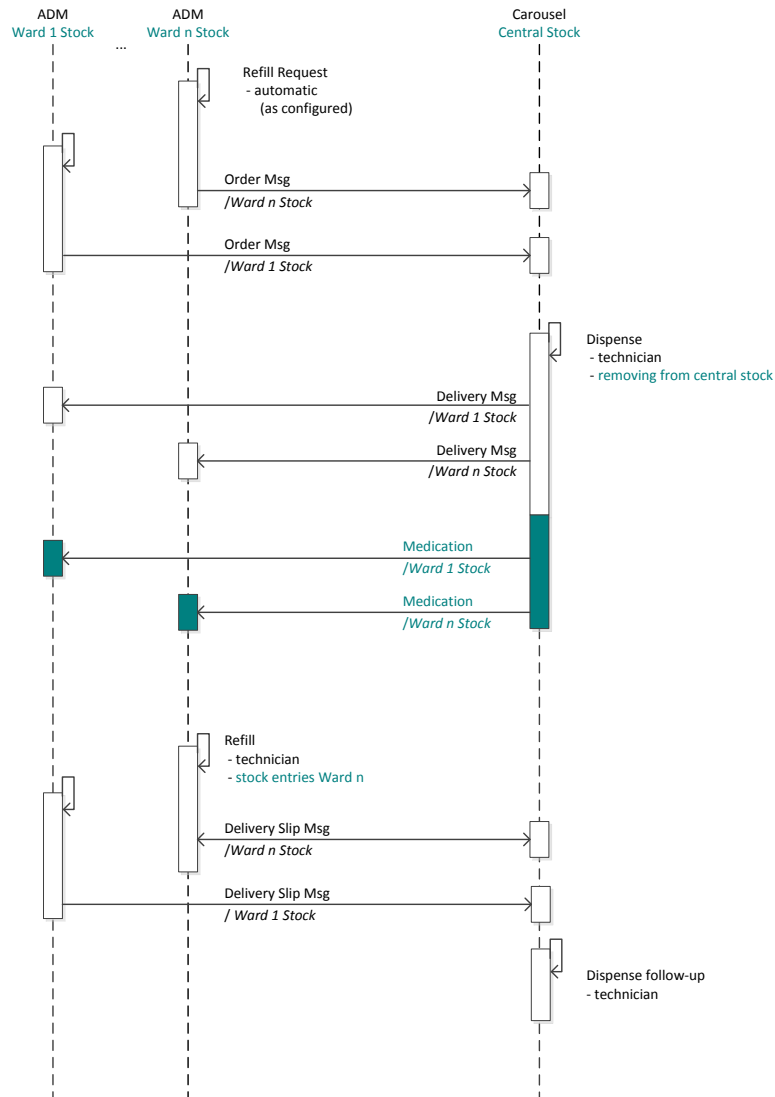


Figure 12

3.14.3 Supplying the Automated Dispensing Machine from a Central Carousel with Supply Management Software

3.14.3.1 Supervised Mode

1095

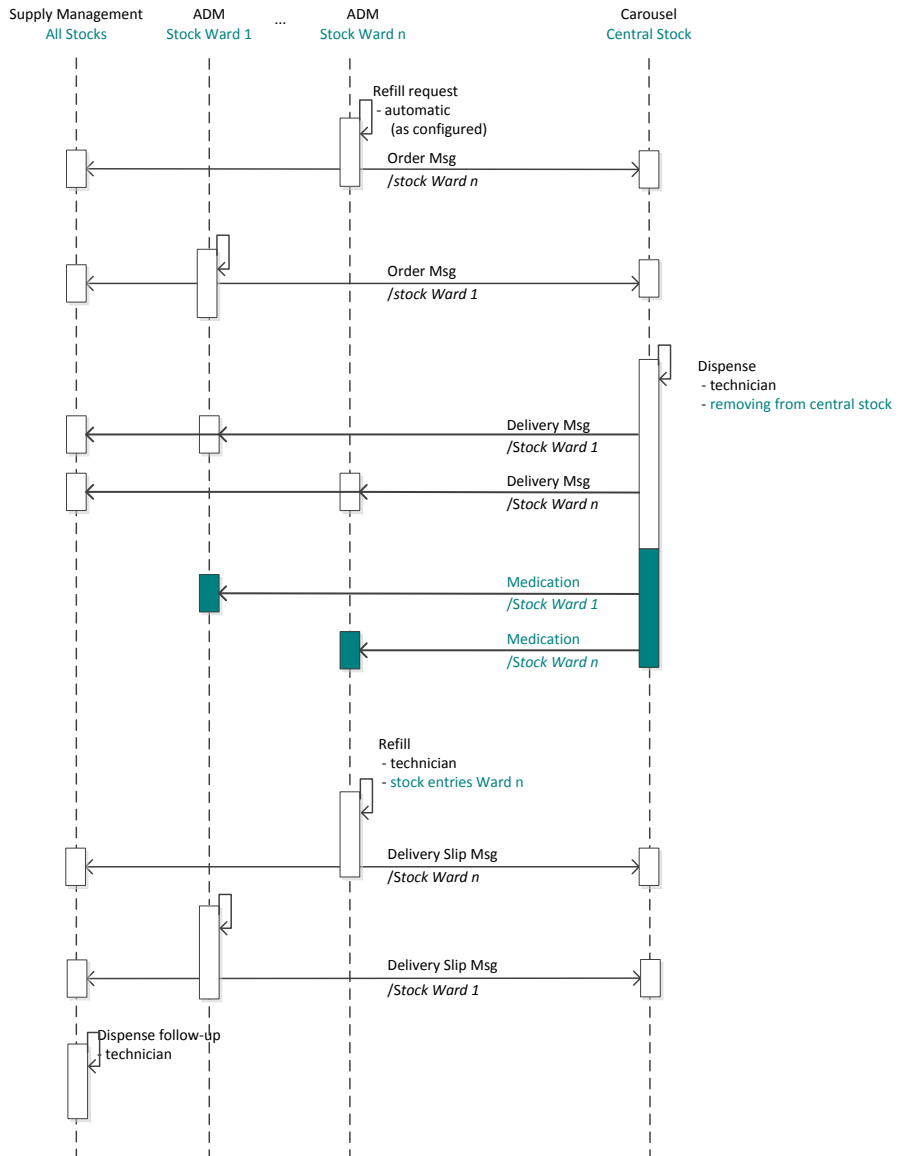
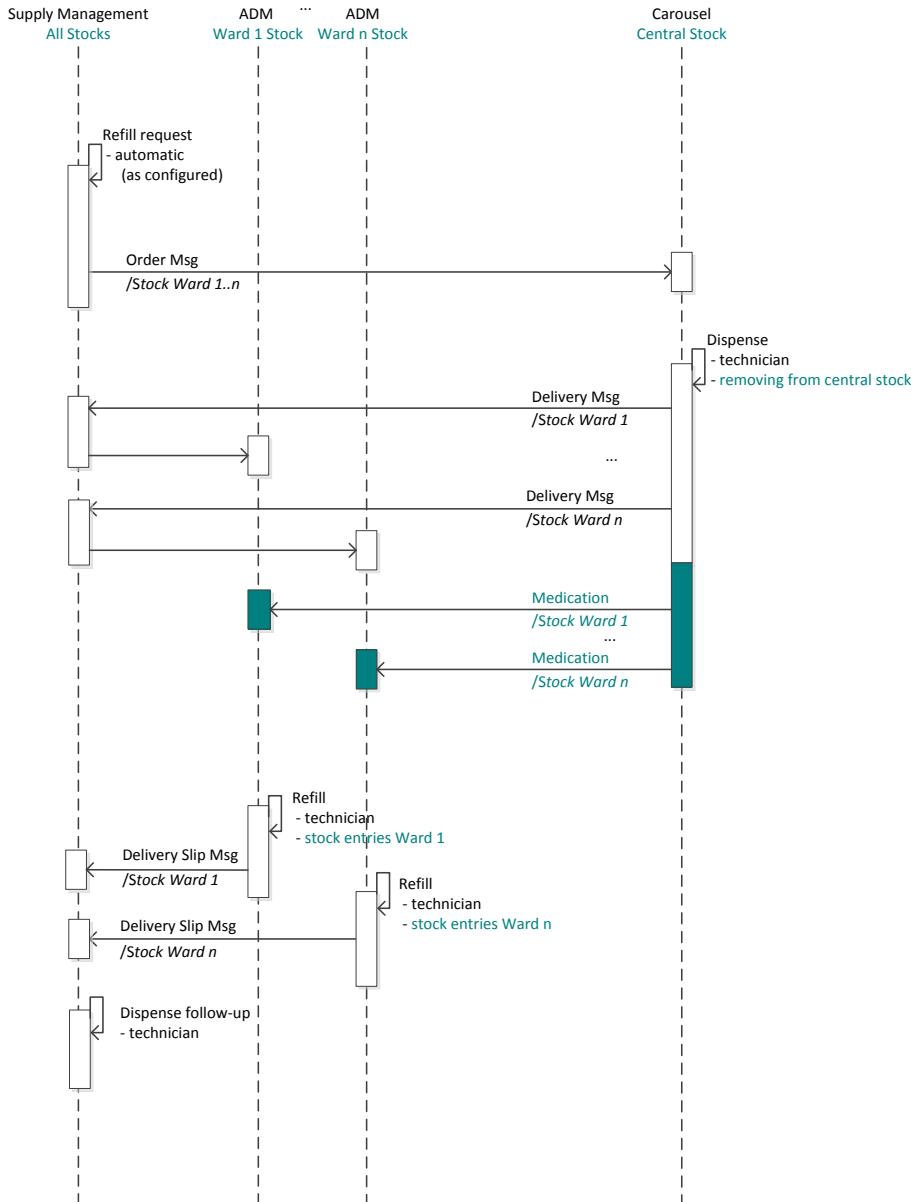


Figure 13

3.14.3.2 Centralized Management Mode



1100

Figure 14

3.14.4 Dispense of daily doses using a re-packer robot and complements from the ward ADM, with return of doses not administered to the ward cabinet

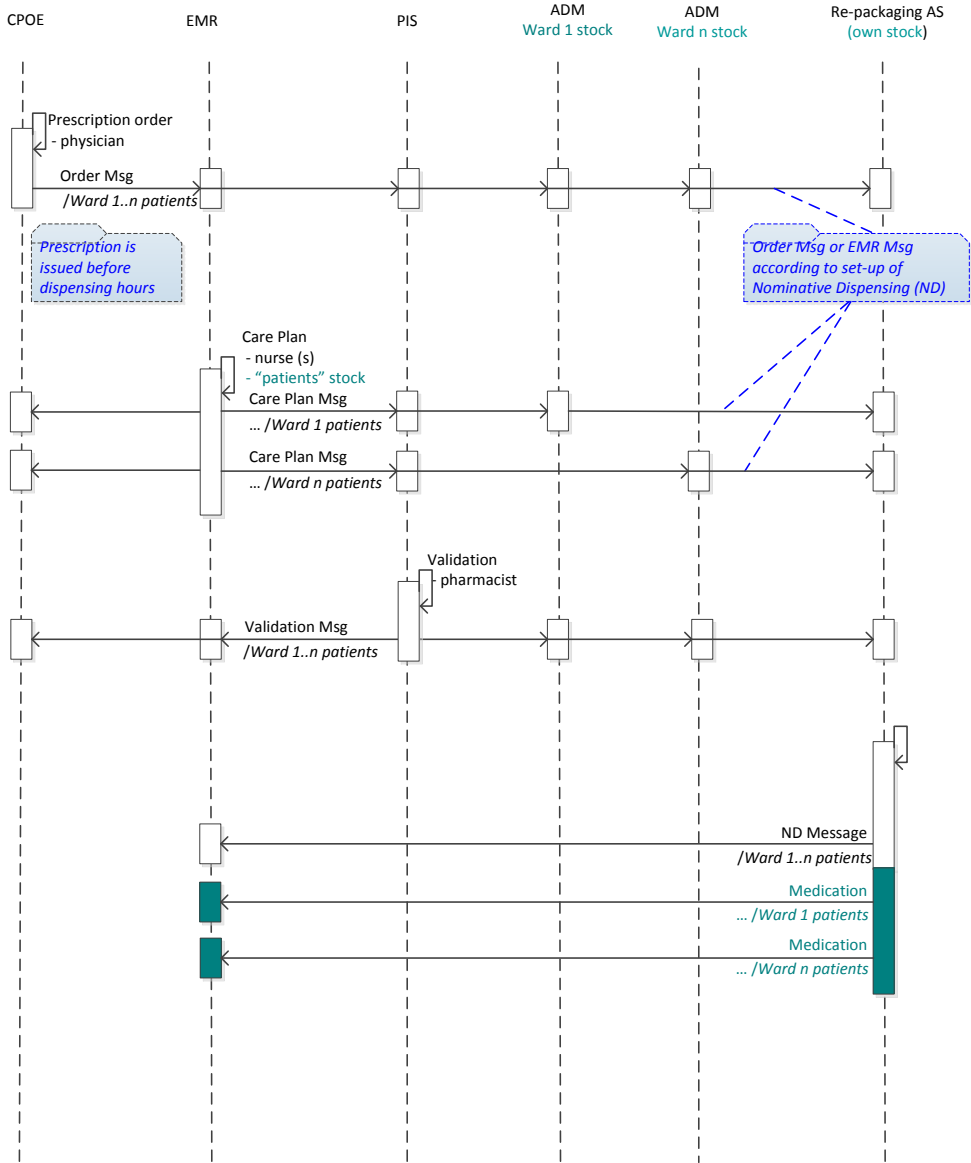


Figure 15

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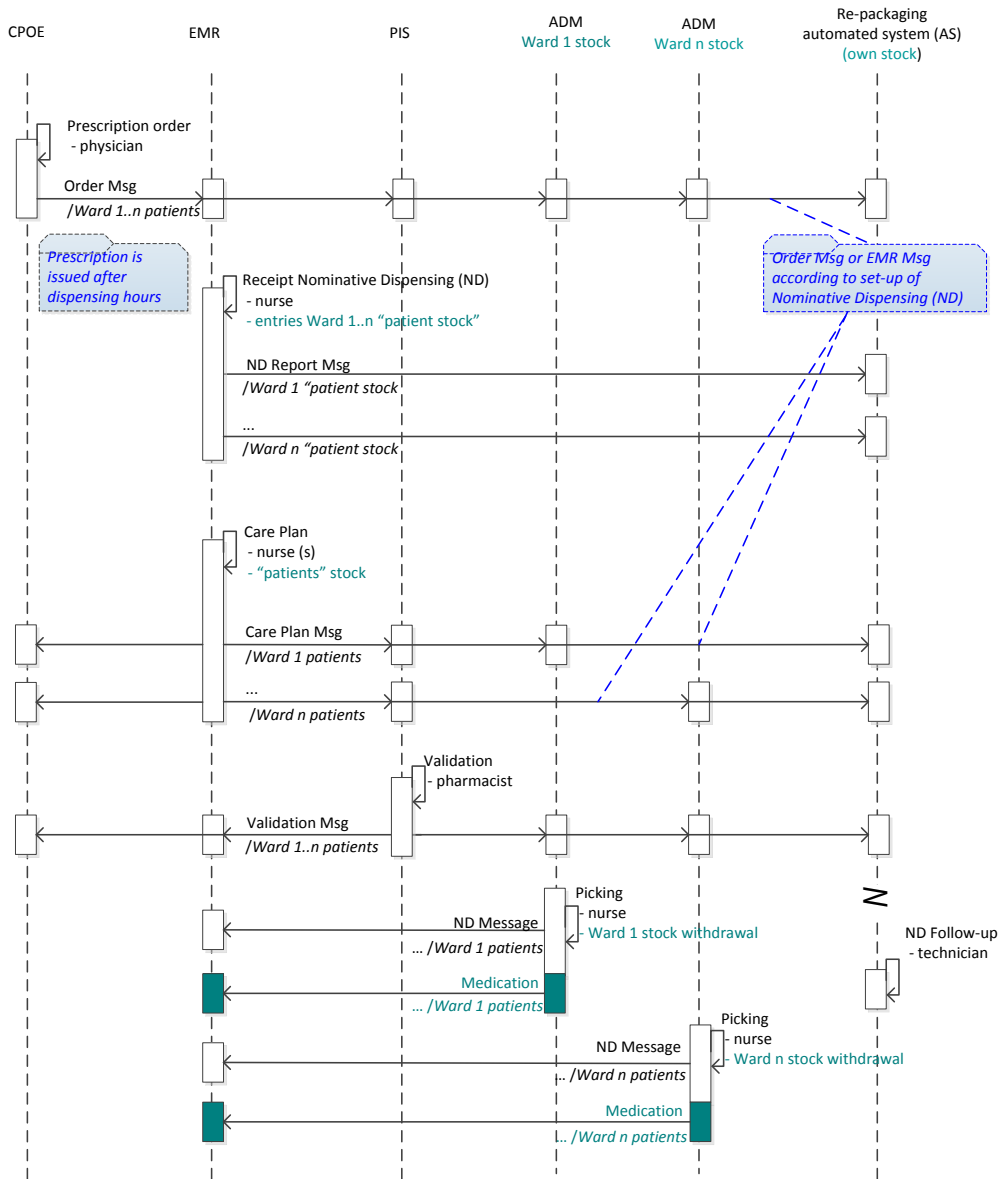


Figure 16

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1110 *continued from previous page*

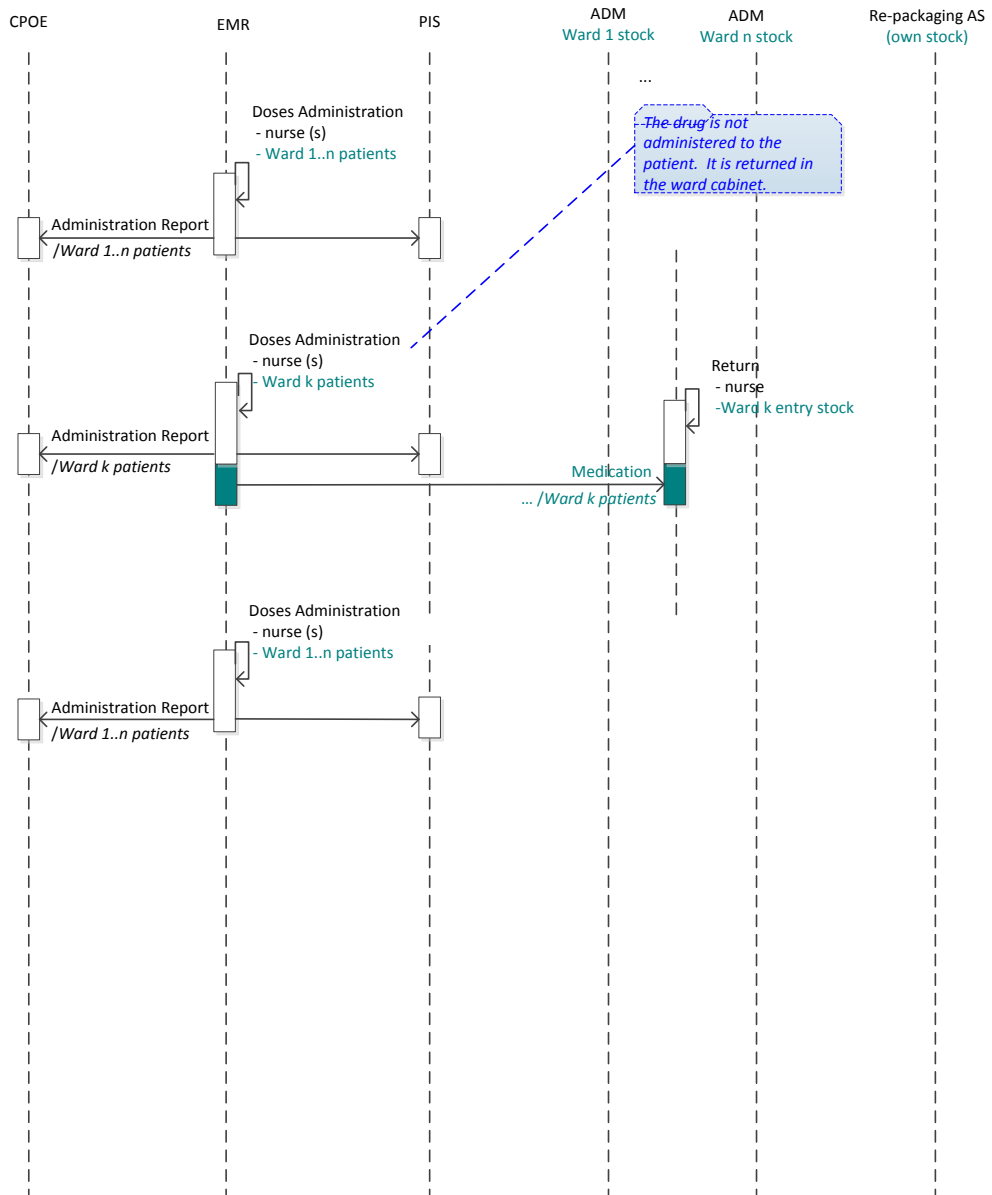
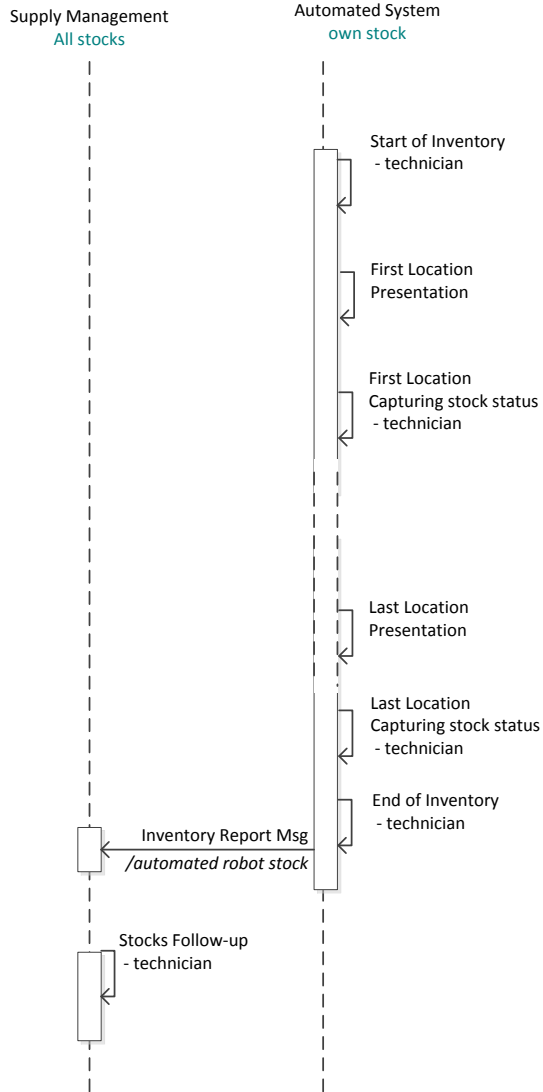


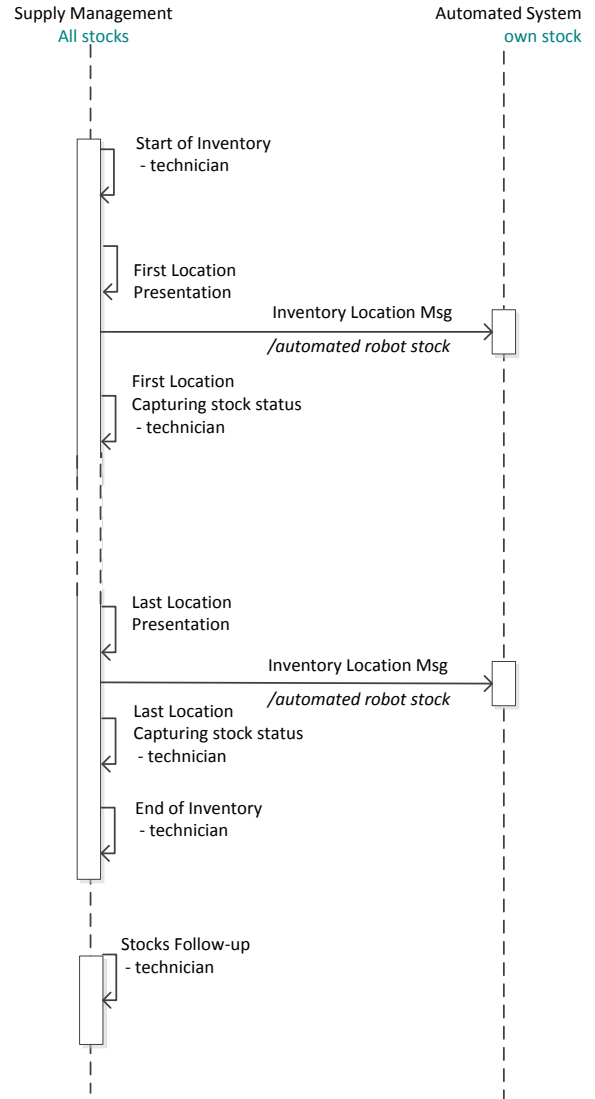
Figure 17

3.14.5 Stock

Supervised Mode



Centralized Management Mode



1115

Figure 18

Appendix I – Typical Use Cases

1. Automated Dispensing Machine
- 1120 2. Computerized Daily Nominative Individual Dispensing (*dispensation journalière individuelle nominative – DJIN*) with Barcode Management, and Both Centralized and Decentralized Automated Dispensing
3. Nominative Dispensing Robot (re /over-wrap) Packager, and Unit Doses Storer + Re-globalized Dispensing by Carousel (Blisters and Boxes Storer)
4. Nominative Dispensing Robot + Weekly Supply + Ward Cupboard
- 1125 5. Nominative Dispensing of Oral Liquid Forms + Ward Cupboard
6. Dynamic Storage in Pharmacy Logistic Area

1 Automated Dispensing Machine

1.1 Structure of the Information System

1130

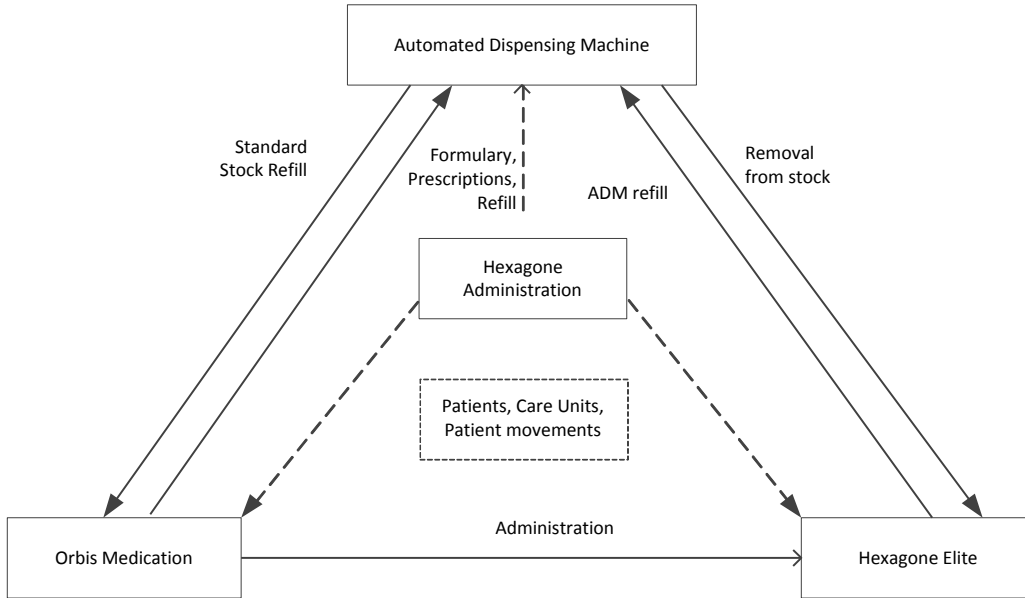


Figure 19 – The Components of the Automated Dispensing Machine Use Case

1.2 Configuration

1135

The Orbis Medication Module can be configured in several ways which can coexist in a healthcare facility:

<p>Care Unit A :</p> <ul style="list-style-type: none"> • Hexagone Administration • Elite 	<p>Care Unit C :</p> <ul style="list-style-type: none"> • Hexagone Administration • Elite • Orbis Medication
<p>Care Unit B :</p> <ul style="list-style-type: none"> • Hexagone Administration • Elite • Automated Dispensing Machine 	<p>Care Unit D :</p> <ul style="list-style-type: none"> • Hexagone Administration • Elite • Orbis Medication • Automated Dispensing Machine

1.3 Use Case

Care Unit A:

- 1140
 - Hexagone administration
 - Elite
- Patient identities and movements are managed in Hexagone Administration.
- Prescription orders are paper-based.
- Nurses order medications through Hexagone Elite.
- 1145
 - Orders supplies are prepared at the pharmacy by pharmacy technicians and billed through Hexagone Elite.
 - Global Dispense.
 - Treatment administrations are tracked manually and are paper-based.

Care Unit B:

- 1150
 - Hexagone Administration
 - Elite
 - Automated Dispensing Machine
- Patient identities and movements are managed in Hexagone Administration.
- Prescription orders are paper-based.
- 1155
 - Nurses have a standard stock of medications stored in the Automated Dispensing Machine.
 - Nurses remove treatments from the cabinet under patient name.
 - The cabinet notifies Hexagon Elite of the *Removal from Storage* so that the medication can be billed to the ward. When the lower thresholds are reached, the cabinet sends a refill request to Hexagon Elite. This refill request contains the regular supply based on a set consummation frequency plus the individual doses as needed.
- 1160
 - Orders are prepared at the pharmacy by pharmacy technicians.

- The refill list is returned by Hexagon Elite to Automated Dispensing Machine to operate storage of the command.

1165 • Treatments administrations are traced manually through a paper process.

Care Unit C:

- Hexagone administration

- Elite

1170 ○ Orbis Medication

- Patient identities and movements are tracked in Hexagone Administration.
- Prescription order is placed in Orbis.
- Pharmaceutical validation is accomplished in Orbis Medication.
- The standard ward stock is set in Orbis.

1175 • Nurses remove physically medications from the ADM.

- The administration is traced in Orbis. The Inventory standard stock decreases according to these administrations.

- When the lower thresholds are reached, Orbis sends Hexagon Elite a refill request based on a preset consummation frequency plus the individual doses as needed.

1180 • The pharmacy technicians prepare the order at the pharmacy and bill medications using Hexagon Elite.

- Hexagone Elite sends to the Orbis Medication the information concerning the quantities added to the standard stock refill.

1185 **Care Unit D: 1st variant: Standard Stock is managed by the Cabinet**

- Hexagone Administration

- Elite

- Orbis Medication

- Automated Dispensing Machine

- 1190
 - Patient identities and movements of are tracked in Hexagone Administration.
 - Prescription orders are placed in Orbis.
 - Pharmaceutical validation is accomplished through Orbis Medication.
 - Nurses have a standard stock of medications stored in Automated Dispensing Machine.
- 1195
 - Nurses remove stock needed for patient treatments from Automated Dispensing Machine by selecting a line of prescription for a given patient.
 - The cabinet notifies Hexagon Elite of the *Removal from Storage* so that the medication can be billed to the ward.
- 1200
 - When the lower thresholds are reached, the cabinet sends a refill request to Hexagon Elite based on a preset consummation frequency plus the individual doses.
 - Orders are prepared at the pharmacy by pharmacy technicians.
 - The refill list is sent back by Hexagon Elite to Automated Dispensing Machine in so that the order can be processed accordingly.
 - The drug administration is documented in Orbis Medication.

1205
Care Unit D: 2nd variant: standard stock managed by Orbis

- Hexagone Administration
- Elite
- Orbis Medication
- 1210
 - Automated Dispensing Machine
- Patient identities and movements are tracked in Hexagone Administration.
- Prescription orders are placed in Orbis.
- Pharmaceutical validation is accomplished in Orbis Medication.
- Nurses have a standard stock of medications stored in Automated Dispensing Machine.
- 1215

- Nurses remove stock needed for patient treatments from Automated Dispensing Machine by selecting a line of prescription for a given patient.
- The standard stock of the ward is entered in Orbis.
- The administration is documented in Orbis. This in turn decreases the Inventory standard stock according to the administrations.
- Orbis Medication informs Hexagone Elite of all drug administration so that the medications can be billed to the ward. When the lower thresholds are reached, Orbis sends Hexagon Elite a refill request based on the regular frequency of consummation and the individual doses.
- Orders are prepared at the pharmacy by pharmacy technicians.
- The refill list is returned by Hexagon Elite to Automated Dispensing Machine so that the order can be processed accordingly.
- The Automated Dispensing Machine sends the Orbis Medication information concerning the quantities added to the standard stock during this refill.

1220

1225

1230

2 Computerized DJIN⁶ with Bar-Code Management, and Both Centralized and Decentralized Automated Dispensing

2.1 Context

- 1235 • **Equipment:** Care Unit equipped with an Automated Dispensing Machine Pyxis, Pillpick unit dose robot at the pharmacy.
- **Software:** Cerner Millennium EMR, WMS Copilote, GAM Mc Kesson (ADT) and proprietary software of automated systems (Pyxislink, Pillpick manager)
- **Organization:** Daily Nominative Automated Dispensing
- 1240 • **Medication Status:** Amoxicillin in formulary, with standard stock in the ward as present in the Automated Dispensing Machine.

2.2 Prescription

1245 Mr. X is admitted to the Hospital Good Fortune. Doctor Goodcare, hospital physician in ward A, after assessing the current treatment and examined the patient, prescribed using the prescription module Millennium on 14 October, 20:00 Amoxicillin IV 1g TID for a 3 days period, the first dose to be administered STAT. The prescription also contains specific instructions concerning medication administration and/or special monitoring for this patient.

The information is in the formulary.

2.3 Supplying/Dispensing Using Ward ADM

1250 The ward nurse receives the information concerning Mr. X's prescription either through the Millennium station or directly from the cabinet software (depending on how the physician logged in the information). Since the treatment is to be started immediately, she takes out the necessary amount for injection of Amoxicillin for the next twenty-four hours (3×1 g of
1255 amoxicillin) from the Automated Dispensing Machine. She logs into the cabinet software, selects Mr. X from the patient list, and the prescription is displayed. She selects the

⁶ NT: *Dispensation journalière individuelle nominative* - Individual Daily Nominative Dispensing.

medication needed from the prescription, Amoxicillin 1 g, and takes 3 vials (the antibiotic can be all removed at once, or on a daily basis).

The removal of the three vials is sent by Pyxislink to Copilote.

1260

2.4 Administration

The Electronic Medical Record (EMR) has received the information that the prescribed product had been dispensed by Pyxis. The product the status *supplied* but it is not yet administered. The nurse returns to the patient's room, scans a vial with a scanner connected to the EMR, administers the product, and then confirms the administration in the EMR.

1265

2.5 Pharmaceutical Advice

In the morning the pharmacist sees the prescription, provides advice for therapeutic follow-up, and validates the prescription. The pharmacist also informs the physician via a form that the route of administration could be changed to oral. Since the patient is able to swallow, this recommendation is useful.

1270

2.6 Supplying/Dispensing by Pharmacy

In the early afternoon, the pharmacy prepares the 24-hrs treatment for Mr. X (from October 15 18:00 to October 16, 18:00) using a unit dose automated system. The night dose administered by the nurse is taken into account. The medication is sent to the ward at 16:30.

1275

Copilote sends to Millennium a dispense report for the unit doses prepared especially for this patient

1280

2.7 Changing Prescription

In the late afternoon, the condition of Mr. X has improved. Dr. Goodcare decides to change the route of administration from IV to oral. He stops amoxicillin 1g IV TID, and prescribes Amoxicillin 1g capsule TID for 6 days.

2.8 Continuing Administration

- 1285 In the evening the nurse commences to administer the treatment as it was delivered by the pharmacy at 16:30. She scan a vial of Amoxicillin 1g inj, but the EMR sends back a message indicating that this medication is not to administered. The nurse checks the care plan and notices that the prescription order has changed to Amoxicillin 1g capsule, and that this medication was not dispensed by the pharmacy.
- 1290 She takes Amoxicillin 1 g capsule from the Automated Dispensing Machine and returns the IV Amoxicillin not used either directly to the pharmacy or to the cabinet.

The ADM is required to be consistent in this scenario.

2.9 Prerequisites

- 1295 Formulary; Staff Directory; User Rights

3 Nominative Dispensing Robot (Re/Over-wrap) Packager, and Unit Doses Storer + Re-globalized Dispensing by Carousel (Blister and Boxes Storer)

3.1 Prerequisites

The following medications are defined in the hospital formulary:

- Medication TBT_NOMI_1 in the form of bi-dose divisible tablets grouped in blisters available in boxes. In the hospital this medication is distributed through nominative dispensing and dispensed in unit doses (tablets) by an automated system (re/over-wrap) packager ROBOT_UD_1. The half-tablets are not managed in this facility.
- Medication TBT_NOMI_2 in the form of bi-dose divisible tablets grouped in blisters available in boxes. In the hospital this medication is distributed through nominative dispensing and dispensed in unit doses (tablets) by an automated system (re /over-wrap) packager ROBOT_UD_1.
- Medication AMP_NOMI_1 in the form of ampoules delivered in boxes. In the hospital this medication is distributed through nominative dispensing and dispensed in unit doses (ampoules) by an automated Storer ROBOT_UD_2.
- Medication TBT_GLOB_1 in the form of tablets grouped in blisters available in boxes. In the hospital this medication is distributed through globalized dispensing and is dispensed in blisters through an automated Storer ROBOT_BLIST_1.
- Medication AMP_GLOB_1 in the form of ampoules delivered in boxes. In the hospital, this medication is distributed through globalized dispensing and is dispensed by box by an automated Storer ROBOT_BOX_1.

3.2 Summary

Name of medication	Form	Dispensing mode	Location	Quantity Dispensed by Automated System
TBT_NOMI_1	Bi-dose divisible tablet	Nominative Dispensing	ROBOT_UD_1	Tablet
TBT_NOMI_2	Bi-dose divisible tablet	Nominative Dispensing	ROBOT_UD_1	Whole tablet Half-tablet
AMP_NOMI_1	Ampoule	Nominative Dispensing	ROBOT_UD_2	Ampoule
TBT_GLOB_1	Tablet	Globalized Dispensing by Blister	ROBOT_BLIST_1	Blister
AMP_GLOB_1	Ampoule	Globalized Dispensing by Box	ROBOT_BOX_1	Box

Table 8 – Summary of the Medication Handled by the Nominative Dispensing Robot

Software and automated systems share a common local drug registry specific to the site hence the following are possible:

- 1330 • ROBOT_UD_1 automated system is able to deliver (re/over-wrap) packaged tablets according to the required safety conditions. Since it knows at least the national and local brand medication references (TBT_NOMI_1 and TBT_NOMI_2) it can distribute an entire tablet (or half-tablet for TBT_NOMI_2). The automated system also knows how to identify these brands as ordered by the management software in charge of nominative picking. The management software, in its turn, knows what brands the automated system can distribute and whether or not it is able to dispense fractions.
- 1335 • ROBOT_UD_2 automated system is able to store ampoules and other liquids (either heavy or fragile forms), and can make them available upon orders placed by a nominative picking management software. It knows at least national and local brand medication references (AMP_NOMI_1), and it can identify them in an order placed by the nominative picking management software. The nominative picking management software knows in its turn what brands this automated system is able to process.
- 1340 • ROBOT_UD_2 automated system is able to store ampoules and other liquids (either heavy or fragile forms), and can make them available upon orders placed by a nominative picking management software. It knows at least national and local brand medication references (AMP_NOMI_1), and it can identify them in an order placed by the nominative picking management software. The nominative picking management software knows in its turn what brands this automated system is able to process.
- 1345 • ROBOT_BLIST_1 automated system is able to deliver blisters and it knows at least the national and local brand medication parameters (TBT_GLOB_1) and how to

identify them in an order placed by the globalized picking management software. The globalized picking management software knows in its turn what brands this automated system is able to process.

- 1350
- ROBOT_BOX_1 automated system is able to store ampoules and other liquid (either heavy or fragile forms), and can make them available upon orders placed by an operator of a control center specific to the automated system. It knows at least the national and local brand medication references (AMP_GLOB_1). The globalized picking management software knows in its turn what brands automated system is able to process.
- 1355
- ROBOT_UD_1 automated system associates an identifier to each unit dose supplied. This identifier is affixed to the packaging of the dose (for example using a barcode). The automated system is able to transmit this identifier to the nominative picking management software.

1360

3.3 Use Case 1: Prescription, Nominative Dispensing/Globalized, Administration

1365 **A –NOTE:** the medication prescribed meets the following criteria: present in the formulary, not suspended, present in sufficient quantities in the stock, and that can be prescribed at specific times without any conditions of administration (the contrary would be: medication not present in the formulary, suspended, low in stock quantities, conditional prescribing, that can be prescribed at any time or prescribed as per nurse demand).

The prescriber enters the prescription into the CPOE:

- 1370
- Medication TBT_NOMI_1 in nominative dispensing (entire tablet supplied by unit by an automated (re/over-wrap) packager ROBOT_UD_1).
 - Medication AMP_NOMI_1 in nominative dispensing (ampoule supplied by an automated Storer ROBOT_UD_2).
 - Medication TBT_GLOB_1 in globalized dispensing (tablets supplied in a blister by an automated Storer ROBOT_BLIST_1).
- 1375
- Medication AMP_GLOB_1 in globalized dispensing (ampoules supplied in a box by an automated Storer ROBOT_BOX_1).

B1 – This order is automatically transmitted by the CPOE to the pharmaceutical validation management software.

- 1380 The pharmacist may provide pharmaceutical advice such as proposing a brand change for a medication not present in the formulary, that is out of stock or otherwise not present due to market changes, or he or she can indicate that the medication is not appropriate for this patient. When no pharmaceutical advice is given, the prescription is simply validated. The pharmaceutical validation management software automatically transmits the information to
- 1385 the relevant actors (CPOE, EMR and the Supply Management Software).

In this use case no additional action is required from the other software actors because none of the prescribed medications require pharmaceutical validation before being administered or dispensed.

- 1390 **B2** – The order is expressed as nominative and globalized picking which are automatically transmitted to the supply management software(s) of the pharmacy. The methods of calculating the quantities are different depending on the type of cabinet. In nominative or globalized dispensing all picking lists are compiled and made available to the pharmacy staff (pharmacists and pharmacy technicians).
- 1395 The pharmacist checks the content of nominative and globalized picking lists and starts the process of picking. These operations are performed by dedicated software.

- The nominative picking management software orders the medication TBT_NOMI_1 from the automated re-packer ROBOT_UD_1 and medication AMP_NOMI_1 from the automated Storer ROBOT_UD_2. The medications are available at the automated systems and are
- 1400 dispensed by them (cases where the medication is not known by the automated system or not present in stock in sufficient quantities are not considered). The automated systems report the dispensing to the nominative picking management software. The latter informs the pharmacy technician about the medications dispensed.

- 1405 Medications are placed in nominative pillboxes. The different medications dispensed by the automated systems are reviewed by the pharmacy technician / pharmacist to see that the dispensing matches what was expected (the exceptions are not considered here). The pharmacist logs this information in the in the nominative picking management software. The pillboxes are sent to wards and information is sent by nominative picking management

1410 software to all relevant actors (EMR, pharmacy and/or ward stock management system and finance software).

1415 Globalized picking management software orders the medication TBT_GLOB_1 from the automated Storer ROBOT_BLIST_1 and indicates to the pharmacy technician that the medication AMP_GLOB_1 could be retrieved from the automated Storer ROBOT_BOX_1. The medications are available at the automated systems and are dispensed by them (cases where medications not available, not known by the automated system or not present in sufficient quantities are not considered here). The automated systems report the dispensing in the globalized picking management software. The latter informs the pharmacy technician about the medications dispensed.

1420 Medications are placed in boxes. The different medications dispensed by the automated systems are reviewed by the pharmacy technician / pharmacist to see that the dispensing matches what was expected (exceptions are not considered here). The pharmacist validates the globalized pickings in the globalized picking management software. Boxes are sent to wards. The information is sent by globalized picking management software to all relevant actors (pharmacy and/or ward stock management system and finance software).

1425 All medications dispensed by the pharmacy are delivered to wards by personnel.

B3 – The prescription is translated into an administration order which is automatically transmitted to all workstations so that all caregivers are informed.

1430 When caregivers need to administer medication it is assumed that all needed supplies have been received by the ward (globalized or nominative dispensing). Exceptions are not considered in this use case. If needed, the nominative pillboxes are supplemented with medications available in ward cabinet by nurses.

1435 The nurse administers successfully the medication and documents it in the MAR in the EMR. The information is sent to all relevant actors (ward stock management system and billing software).

3.4 Use Case 2: Management of Fractions of Tablets

1440 **A** - The prescriber enters the prescription in the CPOE. This order relates to medications documented in the formulary, not suspended, present in stock in a sufficient quantity, prescribed at fixed times without condition of administration:

- Medication TBT_NOMI_1 in nominative dispensing (entire tablet supplied by unit by an automated (re/over-wrap) packager ROBOT_UD_1)
- Medication TBT_NOMI_2 in nominative dispensing (entire tablet and half-tablet supplied by unit by an automated (re/over-wrap) packager ROBOT_UD_1)

1445 For both medications the prescribed amount is 1.5 tablets.

B1 – This order is automatically transmitted by the CPOE to the pharmaceutical validation management software.

1450 The pharmacist may provide pharmaceutical advice such as proposing a brand change for a medication not present in the formulary, that is out of stock or otherwise not present due to market changes, or he or she can indicate that the medication is not appropriate for this patient. When no pharmaceutical advice is given, the prescription is simply validated. The pharmaceutical validation management software automatically transmits the information to the relevant actors (CPOE, EMR and the Supply Management Software).

1455 In this use case no additional action is required from the other software actors because none of the prescribed medications require pharmaceutical validation before being administered or dispensed.

1460 **B2** – The order is expressed as nominative picking which is then automatically transmitted to supply management software(s) in the pharmacy. The latter makes all picking lists available to the pharmacy staff (pharmacists and pharmacy technicians).

The pharmacist checks the content of the nominative picking list and starts the process of picking. These operations are performed in dedicated software.

1465 The nominative picking management software orders from the automated re-packer ROBOT_UD_1:

- 2 tablets of medication TBT_NOMI_1
- 1 tablet of medication TBT_NOMI_2 and 1 half-tablet of same medication.

1470 Medications are available at the automated re-packer which also dispenses them. The automated systems report the dispensing to the nominative picking management software. The latter informs the pharmacy technician about the medications dispensed.

1475 Medications are placed in nominative pillboxes. The different medications dispensed by the automated systems are reviewed by the pharmacy technician / pharmacist to see that it corresponds to what was expected. The pharmacist validates the nominative picking in the nominative picking management software. The pillboxes are sent to wards. The information is sent by nominative picking management software to all relevant actors (EMR, pharmacy and/or ward stock management system and finance software).

1480 **B3** – The prescription is translated into an administration order which is automatically transmitted to all workstations so that all caregivers are informed.

When caregivers need to administer medication it is assumed that all needed supplies have been received by the ward (nominative dispensing). Exceptions are not considered in this use case.

1485 If needed, nominative pillboxes supplemented with medications available in ward cabinet by nurses.

1490 At the time of administration, the nurse halves one TBT_NOMI_1 tablet to match the prescription. The remaining half-tablet will be handled according to the hospital policy. The nurse performs successfully administrations and documents it in the MAR module in the EMR. The information is sent to all relevant actors (ward stock management system, billing software).

3.5 Use Case 3: Barcode Reading of the Unit Dose Administration

1495 **A** - The prescriber enters the prescription in the CPOE. This order relates to medications documented in the formulary, not suspended, present in stock in a sufficient quantity, prescribed at fixed times without condition of administration:

- Medication TBT_NOMI_1 in nominative dispensing (entire tablet supplied by unit by an automated (re/over-wrap) packager ROBOT_UD_1).

B1 – This order is automatically transmitted by the CPOE to the pharmaceutical validation management software.

1500 The pharmacist may provide pharmaceutical advice such as proposing a brand change for a medication not present in the formulary, that is out of stock or otherwise not present due to market changes, or he or she can indicate that the medication is not appropriate for this patient. When no pharmaceutical advice is given, the prescription is simply validated. The pharmaceutical validation management software automatically transmits the information to
1505 the relevant actors (CPOE, EMR and the Supply Management Software).

In this use case no additional action is required from the other software actors because none of the prescribed medications require pharmaceutical validation before being administered or dispensed.

1510 **B2** – The order is expressed by nominative picking which is then automatically transmitted to the supply management software(s) of the pharmacy. The latter makes all picking lists available to the pharmacy staff (pharmacists and pharmacy technicians).

The pharmacist checks the content of nominative picking lists and starts the process of picking. These operations are performed in dedicated software.

1515 The nominative picking management software orders the medication TBT_NOMI_1 from the automated re-packer ROBOT_UD_1.

1520 Medications are available at the automated re-packer which also dispenses them. The automated systems report the dispensing to the nominative picking management software and indicate the identifiers of supplied doses for each patient/brand /administration. The software stores the information returned by the automated re-packer and makes it available to the EMR. It then informs the pharmacy technician about the medications dispensed.

1525 Medications are placed in nominative pillboxes. The different medications dispensed by the automated systems are reviewed by the pharmacy technician / pharmacist to see that they correspond to what was expected. The pharmacist validates the nominative picking in the nominative picking management software. The pillboxes are sent to wards. The information is sent by the nominative picking management software to all relevant actors (EMR, pharmacy and/or ward stock management system and finance software).

B3 – The prescription is translated into an administration order which is automatically transmitted to all workstations so that all caregivers are informed.

1530 When caregivers need to administer medication it is assumed that all needed supplies have been received by the ward (nominative dispensing). Exceptions are not considered in this use case.

If needed, nominative pillboxes can be supplemented with medications available in ward cabinet by nurses.

1535 At the time of administration, the nurse enters in the EMR the identifier of the dose (scans the barcode on the dose). The software automatically displays the patient and the administration information linked to that particular dose.

1540 The nurse administers successfully the medication and documents it in the MAR module of the EMR. The latter transmits information to all relevant actors (ward stock management system and billing software).

4 Nominative Dispensing Robot + Weekly Supply + Ward Cupboard

4.1 Context

1545 The Hospital Douarnenez has partly automated dispensing functionalities as of January 2011
which is used in nursing homes, long term care and rehabilitation. The Management Services
Organisation (MSO) plans to automate the “cold services” in the future. The medications
involved are mostly in dry form and not disease-specific, such as those used in hypertension,
analgesics, and hypnotics. Narcotics, antibiotics and anticancer medications are not handled
1550 by the automated process due to concerns about possible contamination with other medication
and excessive variations in the prescription.

The Information Systems in place at Douarnenez are:

- ADT system (Pastel)
- Finance management system (Magh2)
- 1555 • EMR (Sillage)
- Dispensing system (Génois).
- Automated system Euraf.

The day of automated production and supply to the wards is Monday. The wards use their
own ward cabinets supplied with minimal stock when this is needed (in-between production
1560 days).

4.2 Pharmacy: Reception of Stock

The pharmacy technician controls the reception of medications. They are recorded in the
finance management system Magh2 (quantity received, price).

1565 The medications are then stored on shelves in the pharmacy. A secondary stock with
medications used by the automated system is kept near it. The pharmacy technician unpacks
the medications from the blister packs to supply the automated system. The refill is performed
"on request" (the automated system Euraf does have the possibility of indicating the status of
a medication in the automated process but it is not used).

1570 4.3 Ward: Prescription in the Care Unit

On the arrival of the patient (Mr. Verysick) in the Aftercare and Rehabilitation Unit on Saturday afternoon, Dr. Goodcare prescribes in EMR Sillage:

- 1 tablet of *Dafalgan* 1g, TID, PRN, during 7 days.
- 1 tablet of *Clamoxyl*, 1g, TID, during 7 days (with food).
- ½ tablet of *Lévothyrox* (20 mg), evening.

1575 4.4 Ward: Administration in the Care Unit on the Weekend

The list of prescriptions is then sent automatically to the EMR. The application is configured in such a way that the administration does not need to wait for pharmaceutical validation.

1580 The nurse is informed by her EMR station of the prescription. Since the automated system is producing doses required by the wards only on Mondays, she uses the ward medication cupboard (or if the medication is not available, those from other nearby wards) to prepare the pillbox until Monday.

1585 The instructions and advices (during meals) associated with the prescription are available in the EMR Sillage. The validation of the successful administration and any other comments associated with it is done in Sillage (for example the patient finds that the tablet of Paracetamol is too big and hard to swallow, but nevertheless takes it).

1590 4.5 Pharmacy: Monday Morning Dispensing

1590 Monday morning the pharmacist processes the weekend prescription orders in the dispensing software. He validates them, possibly providing pharmaceutical advice, and then he launches the supply production. Using the Aftercare and Rehabilitation Unit information the pharmacist:

- Prints (via pharmacy software Génois) a picking list, including *Clamoxyl* which is a medication outside the automated circuit. He prepares *Clamoxyl* boxes, and validates their dispensing in Génois. This last action decreases automatically the pharmacy stocks in the financial system Magh2 (and is subsequently billed to the ward).

- Electronically transmits the information concerning the *Dafalgan (Paracetamol)* to the automated system. This results in decreasing the pharmacy stocks in Magh2 (and is subsequently billed o the ward).

The automated system:

- Produces, by patient, a packet strip, containing one medication per packet. The pharmacist or the pharmacy technicians verify the production. All *Dafalgan* is prepared until the following Saturday (end date of the prescription). Each packet has the following configurable information: medication name, dosage (time of administration planned), patient name, and the ward.
- Prints a production plan, by patient, for divisible medications, in this case, *Levothyrox*. This paper plan helps the pharmacy technician prepare the medication for the dedicated feeding tray feeding of the automated system so that it can get packaged.

The boxed medications (*Clamoxyl*) as well as the packet strips are sent by courier to the Aftercare and Rehabilitation Unit which is a few miles away from the main hospital where the Pharmacy is located.

4.6 Ward : Medication Reception and Administration, Treatments change

The nurse takes the supply delivery from the hospital Pharmacy and divides the packet strips and *Clamoxyl* boxes according to the medication carts.

The nurse then consults the care plan in the EMR which might include a possible message from the pharmacist and begins the medication administration. The strip is unrolled progressively during the week.

On Thursday morning, the tablet of *Paracetamol* is regurgitated by Mr. Verysick. This event is recorded in the EMR and is available for Dr. Goodcare to see.

On Thursday evening visit Dr. Goodcare changes *Dafalgan* to effervescent *Paracetamol* (*Efferalgan* brand).

The nurse is informed in her EMR module of the treatment change. She crosses out the *Dafalgan* to avoid errors. A “service request” for *Efferalgan* is placed in the EMR Sillage to

the pharmacy. While waiting for the Pharmacy to deliver the medication, the nurse uses the ward cabinet.

5 Nominative Dispensing of Oral Liquid Forms + Ward Cupboard

5.1 Background

Hospital A has been using for a while patient drug management processes software. The pharmacy works in DJIN⁷ for drinkable forms for the entire hospital using the automated system (APG2). As the pharmacy is closed from Saturday afternoon to Monday morning and on bank holidays, the wards have a cupboard containing the brands they commonly use.

Automated systems APG2: the doses produced by the robot correspond as closely as possible to the prescription as the automated system works exclusively in micro-liters. Below a certain volume, the robot completes the production with water to a volume of 5 ml (to be confirmed).

This example is applicable to the handling of "dry forms" by an automated system.

5.2 Patient arrival

Mr. Y is admitted to Day Care West ward, Saturday, October 22 afternoon at 16:30 and examined by the physician on duty at 16:45, who orders:

- LOXAPAC 25 MG/ML drinkable solution: 50 mg morning, 50 mg noon, 50 mg evening and 40 mg night (PRN) + 30 mg STAT.

5.3 Saturday 22nd October

Nurse 1 knows that no drinkable preparations are available for Mr. Y for his STAT dose of 30mg of *Loxapac* since the doses are manufactured only on Monday morning by the Pharmacy automaton. She uses the local supply of LOXAPAC 25 mg /ml 60 ml, 30 drops (1 drop = 1mg). She plans to use the local supplies in the ward cabinet for the evening supply if needed by the patient. However, at bedtime Mr. Y's condition does not require the PRN drug administration.

⁷ NT: *Dispensation journalière individuelle nominative* - Individual Daily Nominative Dispensing.

5.4 Sunday, October 23

1655 Nurse 2 who starts her shift continues the administration of medication according to hospital procedures. She prepares the doses from the vial of LOXAPAC 25 mg /ml 60 ml L present in the ward.

The medication administration is shown below and each time is validated in the EMR:

- 50 mg (drops) morning
- 50 mg (drops) noon
- 1660 • 50 mg (drops) evening
- At bedtime, 40 mg (drops) were administered due to the patient's condition.

5.5 Monday, October 24

1665 The morning dose is prepared with the vial of LOXAPAC 25 mg /ml 60 ml present in the cabinet ward.

1670 In the pharmacy, at 09:00, the pharmacist validates Mr. Y's prescription. At 09:30 the pharmacy technician starts to prepare the drinkable forms needed by the Day Care West ward. In her patient drug management process software she queries all the drug brands that need to be processed by the automated system APG2. The software will determine the necessary unit conversions so that the automated system can interpret correctly the orders in its working list. The software sends a request by patient and administration time.

The pharmacy management software is configured so that it can support past administration and current orders.

1675 The query returns the following results for the period Monday, October 24 at 14:30 through Tuesday, October 25 at 14:30 pm:

- 2011-10-24 at (12:00) noon UCD: 9287285 LOXAPAPINE SUCCINATE for M. Y 50 mg or 2000 UL
- 2011-10-24 at (18:00) evening UCD: 9287285 LOXAPAPINE SUCCINATE for M. Y 50 mg or 2000 UL

- 1680
- 2011-10-24 at (22:00) bedtime (PRN) UCD: 9287285 LOXAPAPINE SUCCINATE for M. Y 40 mg or 1600 UL
 - 2011-10-25 at (08:00) morning UCD: 9287285 LOXAPAPINE SUCCINATE for M. Y 50 mg or 2000 UL
- 1685
- 2011-10-25 at (12:00) noon UCD: 9287285 LOXAPAPINE SUCCINATE for M. Y 50 MG or 2000 UL

6 Dynamic Storage in Pharmacy Logistic Area

6.1 Background

Hospital W uses a pharmacy information system interfacing with dynamic storage devices drivers so that it can manage its stock. The dynamic storage device consists of a pallet rack with six vertical rotary carousels.

All the dynamic Storers are controlled by the manufacturer's application software. The inventory of the pallet racks and the storage area are controlled by the pallet rack software. The pallet rack stores the products in their tertiary packaging and sometimes in their secondary packaging. The products used for Storers are stored in their primary packaging.

The grouping of the pallet rack and storage area is defined as the main store. The exit area of the unloading is considered as the secondary store. A product can have multiple locations per store.

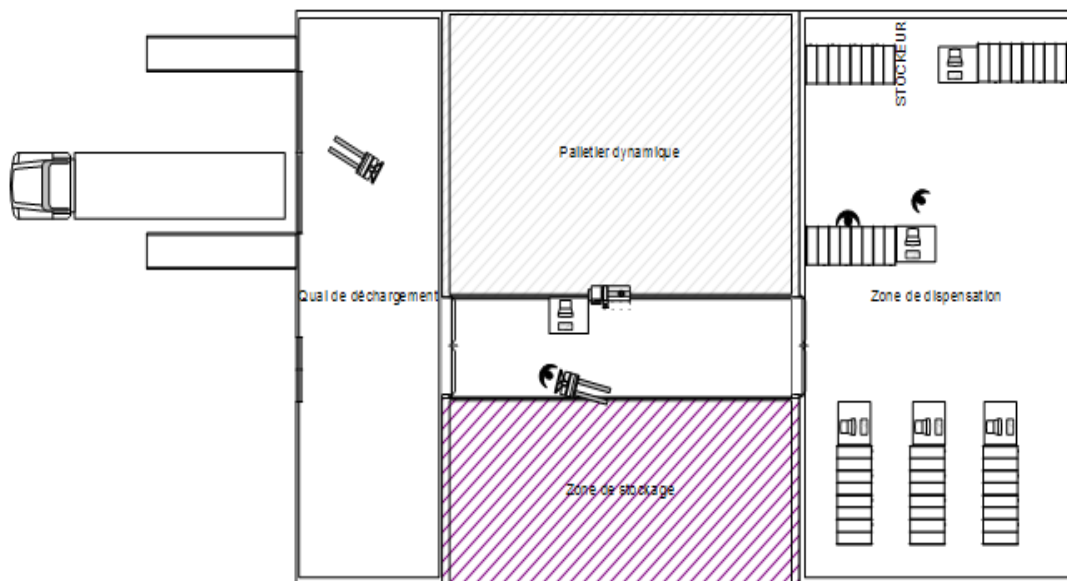


Figure 20 – Dynamic Storage in Pharmacy Logistic Area

6.2 Use Cases

6.2.1 Step 1: Order to the Supplier

1710 A stored product in the pallet racks and in Storers 1 and 3 is below its minimal stock threshold. The pharmacist validates an order for the supplier in the Pharmacy Information System (PIS). This information is transmitted to the rack pallet driver.

6.2.2 Step 2: Receipt of Products

1715 The product is delivered by the supplier in its tertiary packaging. The received stock is entered in the pallet rack management software and the stock is updated with the type of product and lot number by the stock controller. This information is transmitted to the PIS where the pharmacy technician validates it. All pharmacy applications are then updated with this information.

6.2.3 Step 3: Secondary Store Supply Request

1720 The pharmacy technician approves the secondary store supply request as the product present in the stock is below the minimal threshold. The request is transmitted to the pallet rack and the Storer driver software.

6.2.4 Step 4: Stock Removal from Main Store

1725 The request is processed by the software driving the pallet rack. As the stock in the storage area is not sufficient, the software driving the pallet racks suggests using the stock in the pallet rack. The difference between the tertiary packaging and the request is handled in the storage area.

1730 The transfer is then sent to the PIS.

6.2.5 Step 5: Secondary Store Supplying

1735 The pharmacy technician validates the stock entry into the PIS based on the stock items and lot number sent by the pallet racks. This information is then transmitted to the Storers management software in order to update the stock by product name and by lot number. The Storers software tells the pharmacy technician the available Locations for this product.

6.2.6 Glossary

1740 **Pallet rack:** storage device with a system (arms, conveyor belt) that transports between the product *Location*, entry points and exits. It is controlled by software managing *Locations* and allowing management of secondary and tertiary packaging.

Storer: vertical or horizontal dynamic storage device (carousels) controlled by a software that is managing *Locations*. It allows management of Primary and Secondary Packaging.

Primary Packaging: packaging intended for the user

1745 **Secondary Packaging:** packaging intended to group, protect or ease handling and storage without changing the characteristics of conservation.

Tertiary Packaging: packaging intended for transporting a pallet.

Appendix II – Sequence Diagrams of Typical Use Cases

- 1750
1. Automated Dispensing Machine
 2. Computerized Daily Nominative Individual Dispensing (*dispensation journalière individuelle nominative – DJIN*) with Barcode Management, and Both Centralized and Decentralized Automated Dispensing
- 1755
3. Nominative Dispensing Robot (re /over-wrap) Packager, and Unit Doses Storer + Re-Globalized Dispensing by Carousel (Blisters and Boxes Storer)
 4. Nominative Dispensing Robot + Weekly Supply + Ward Cupboard
 5. Nominative Dispensing of Oral Liquid Forms + Ward Cupboard
 6. Dynamic Storage in Pharmacy Logistic Area

1760 **1 Automated Dispensing Machine**

1.1 Version B

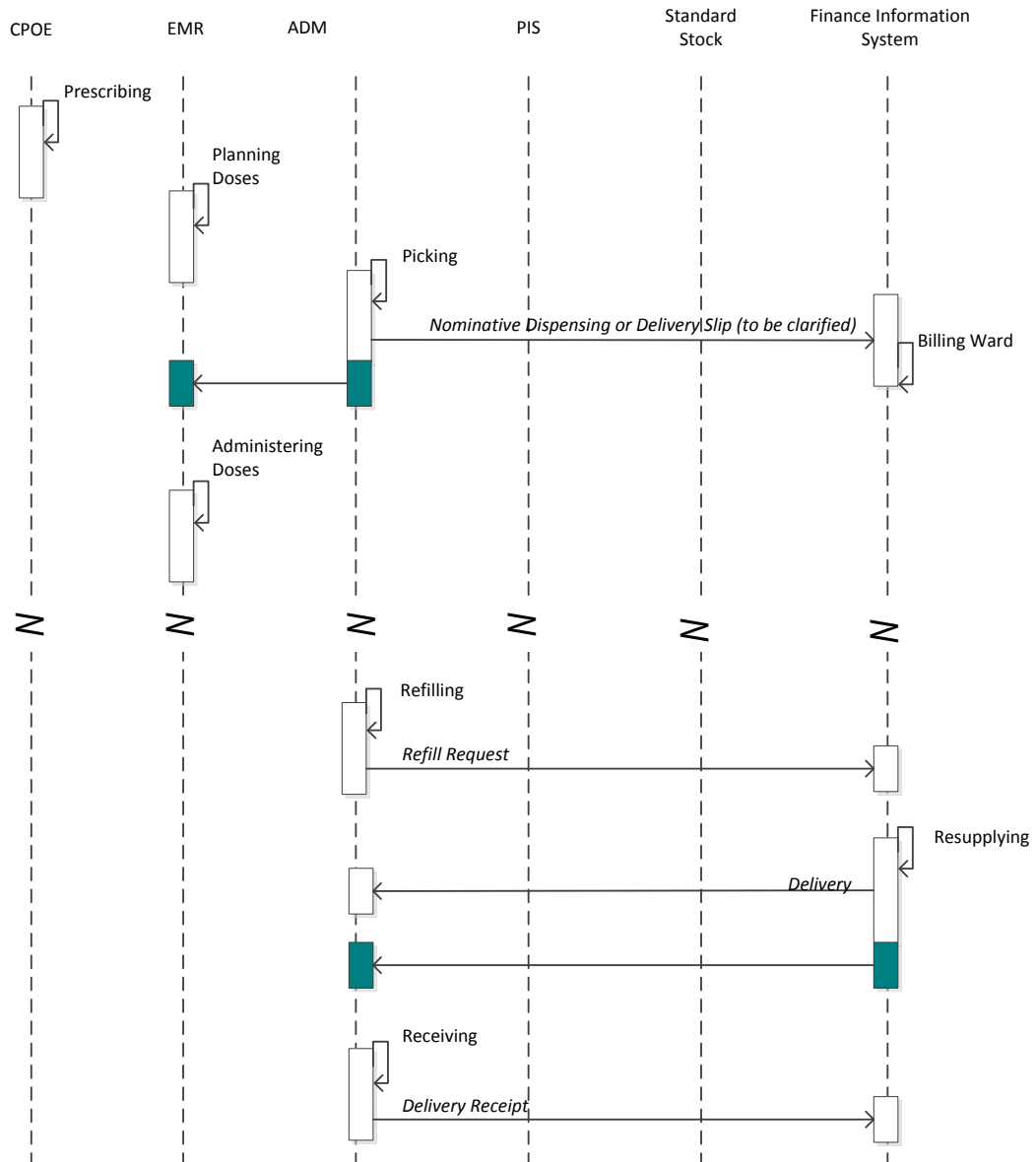


Figure 21

1765 1.2 Version C

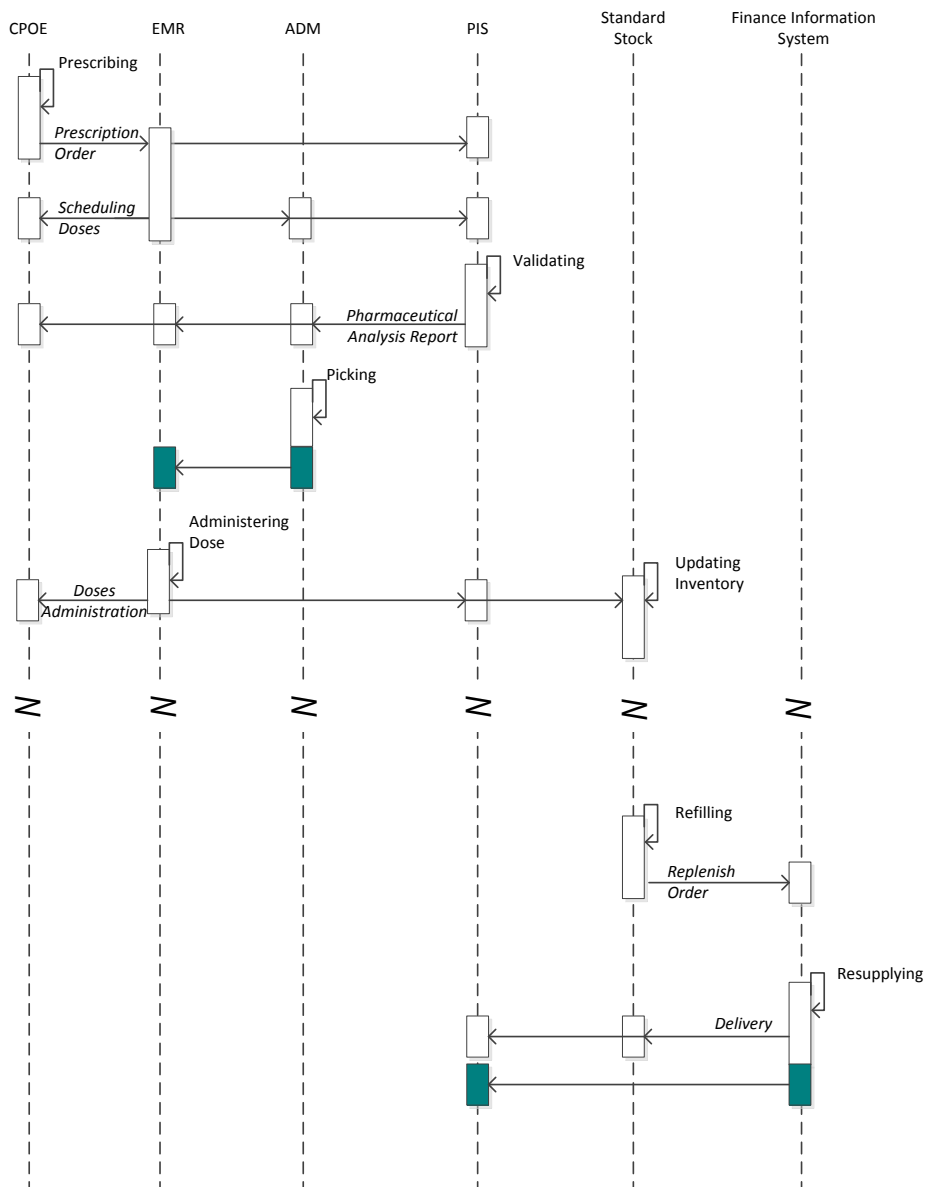
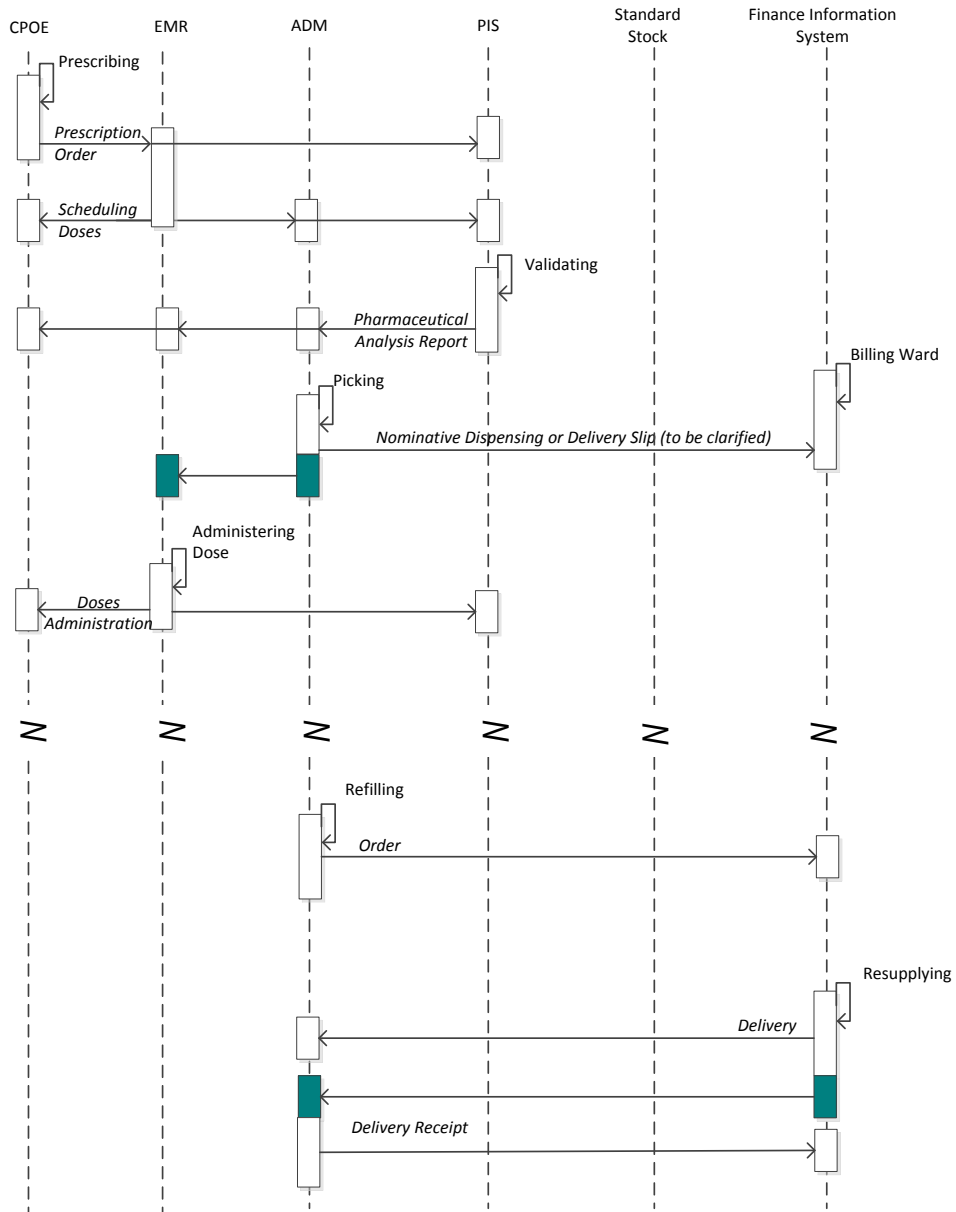


Figure 22

1.3 Version D



1770

Figure 23

1.4 Version E

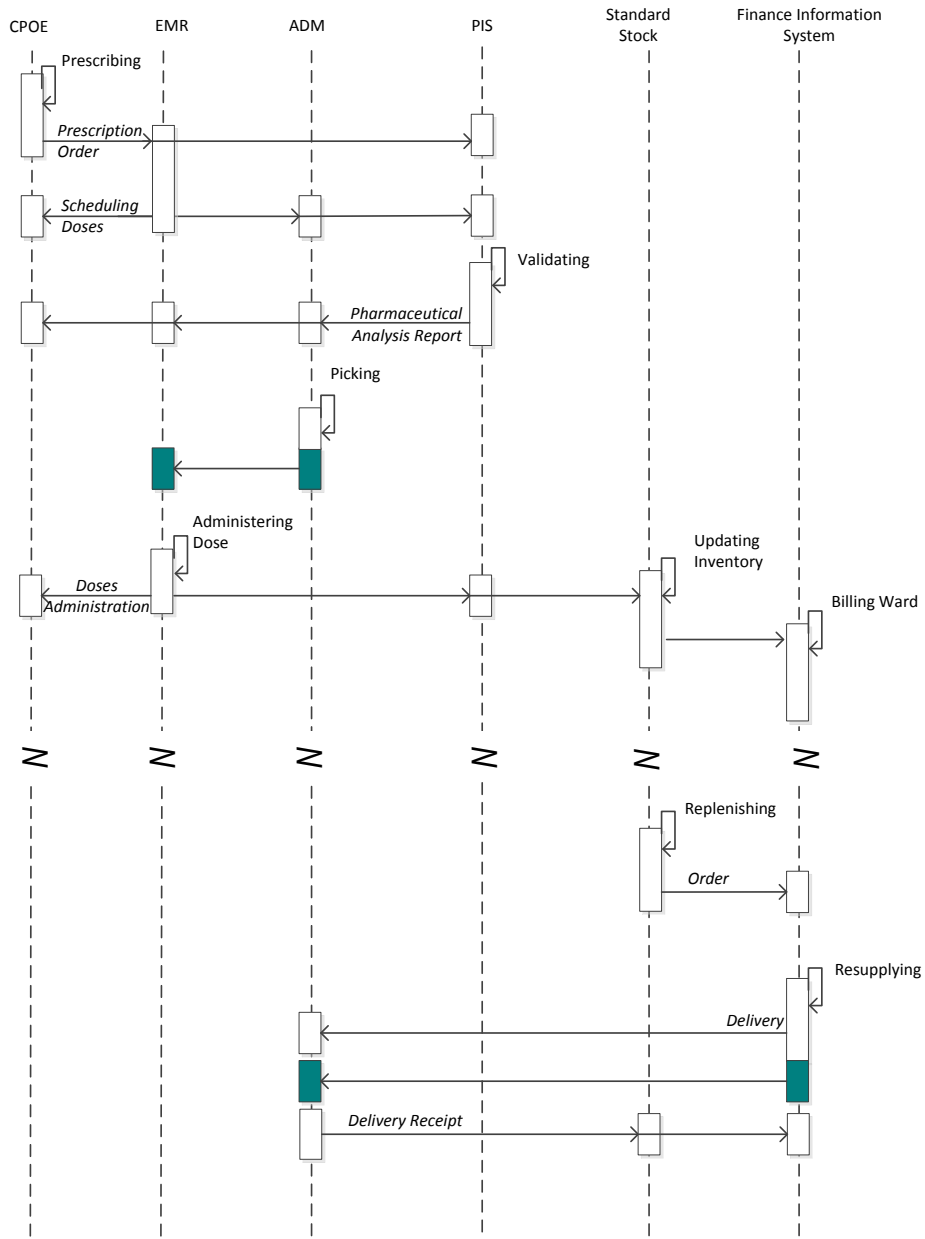


Figure 24

1775

2 Computerized DJIN with Barcode Management and Both Centralized and Decentralized Automated Dispensing

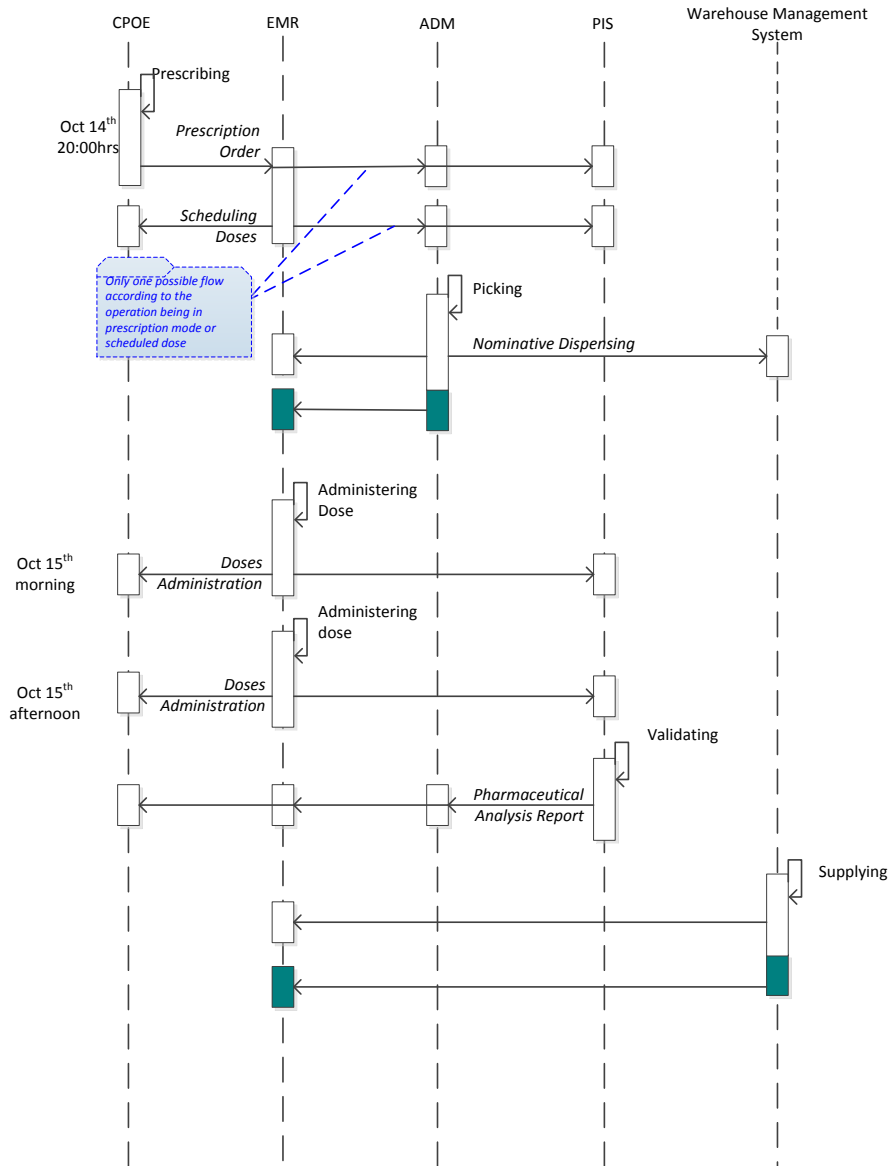


Figure 25

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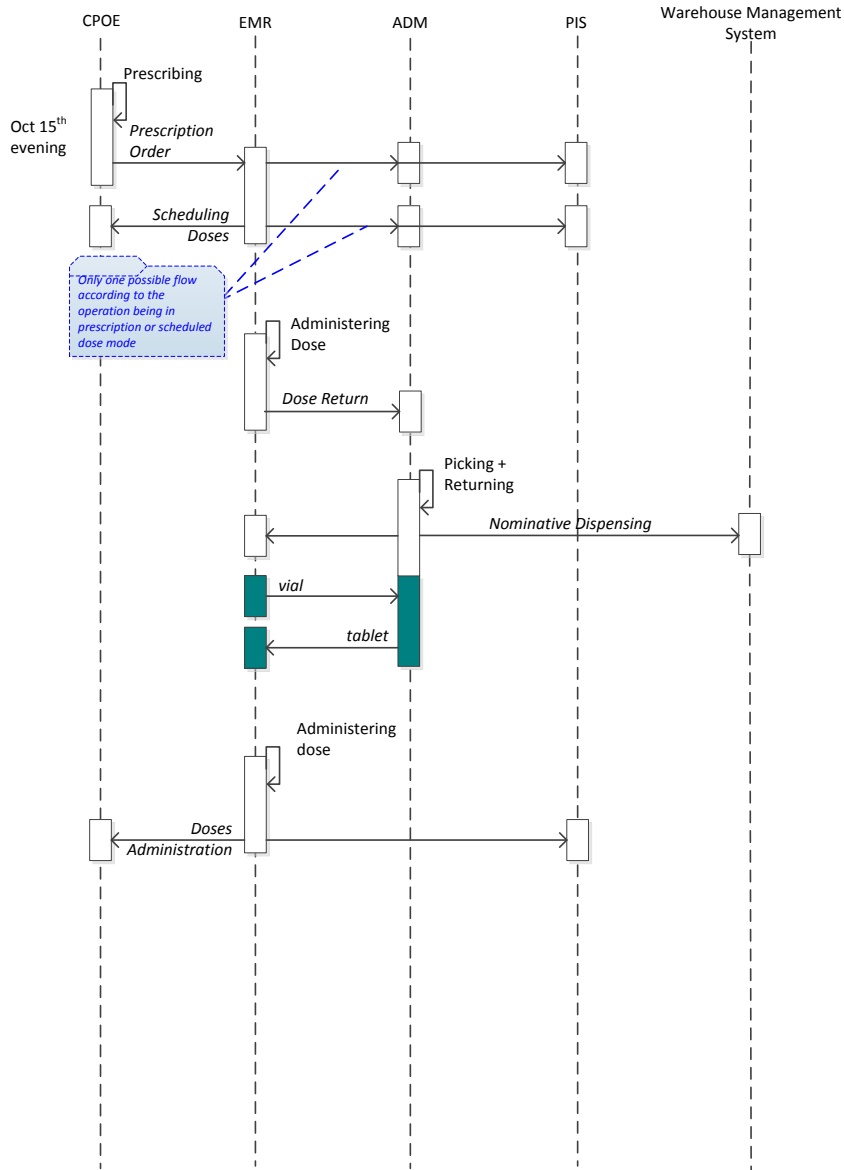


Figure 26

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3 Nominative Dispensing Robot (re /over-wrap) Packager, and Unit Doses Storer + Re-globalized Dispensing by Carousel (Blister and Boxes Storer)

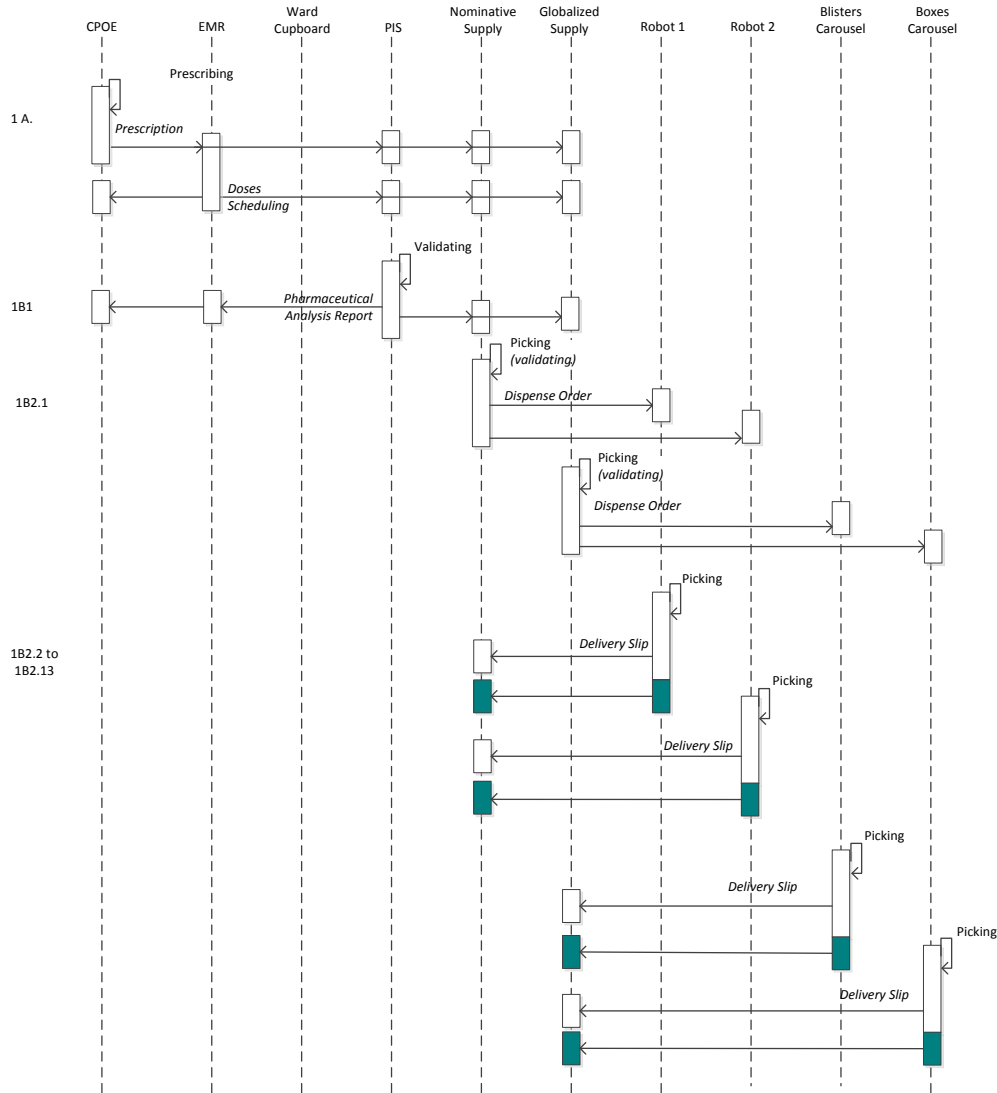
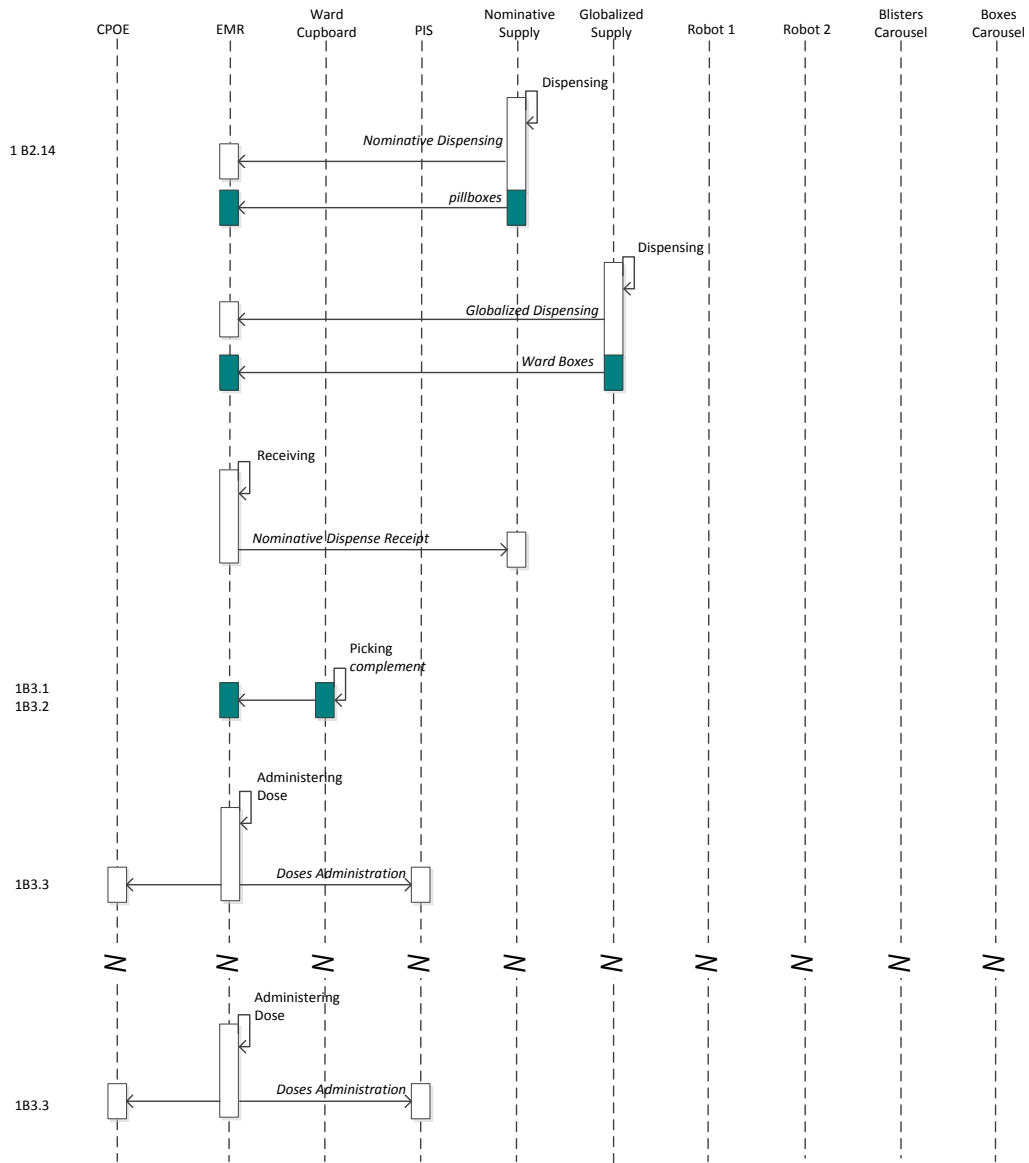


Figure 27

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1795

Figure 28

3.1 Case 2

The relevant automated systems manage fractions of tablets. The complexity is driven by automated systems that are managing tablets.

3.2 Case 3:

Same as case 2, with Bar Code control of the administration of doses. The complexity of bar-codes is carried by the Medication Administration Records feature and logistical features of identification of the products delivered.

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1805

4 Nominative Dispensing Robot + Weekly Supply + Ward Cupboard

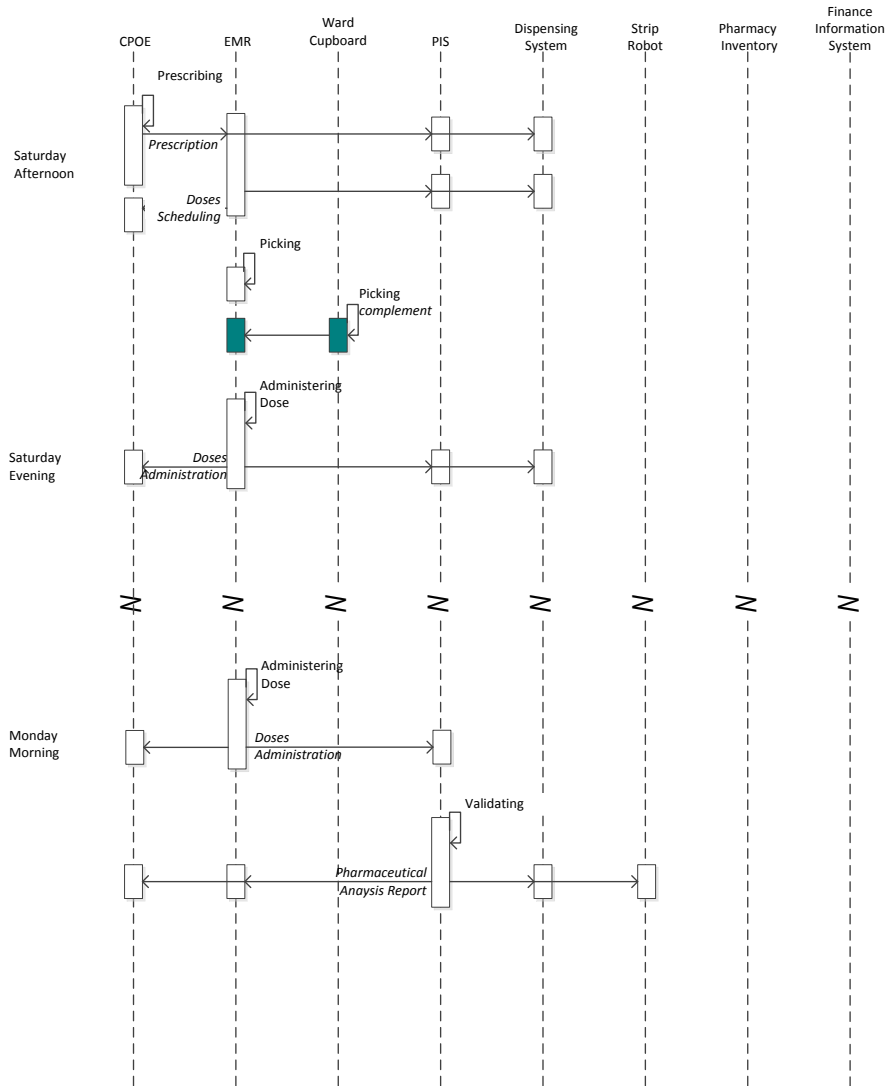


Figure 29

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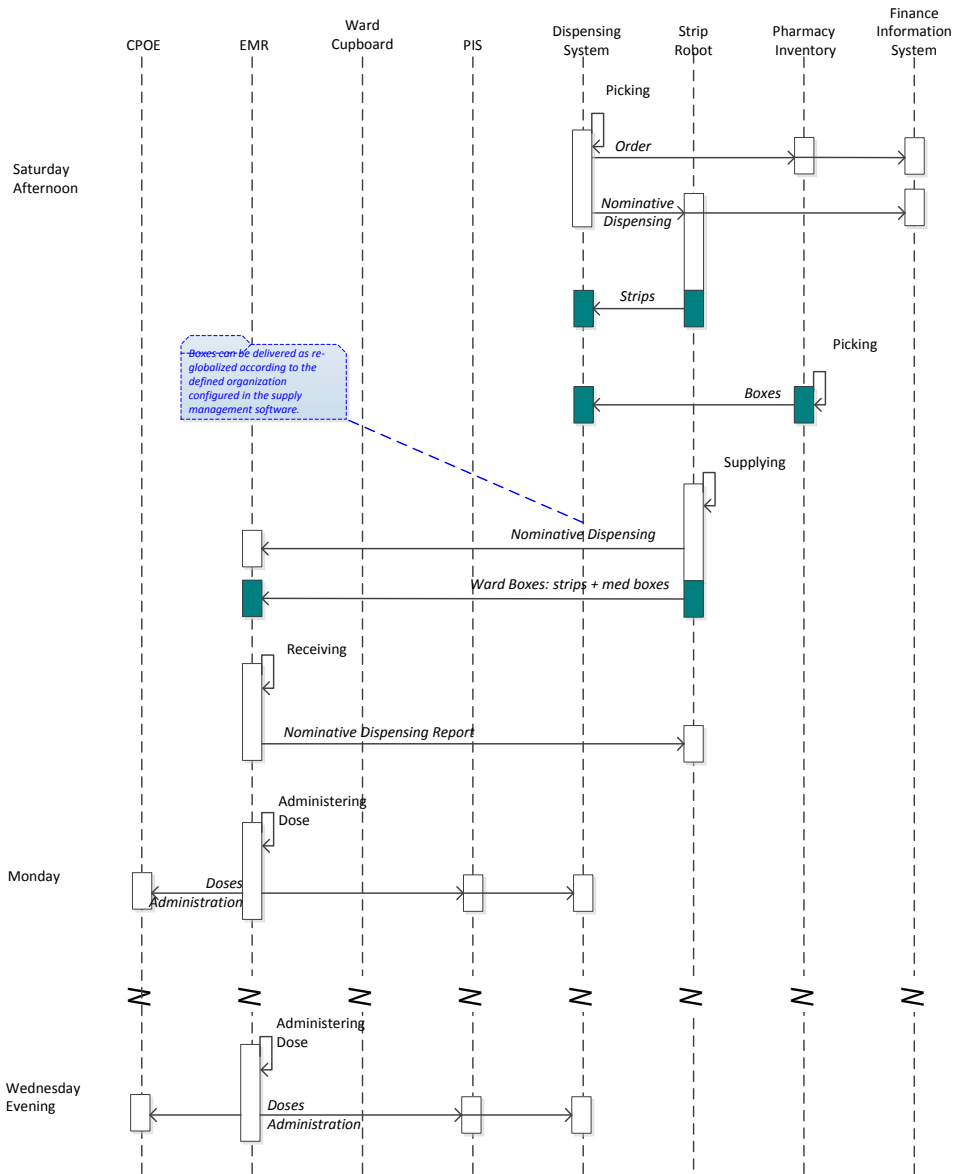


Figure 30

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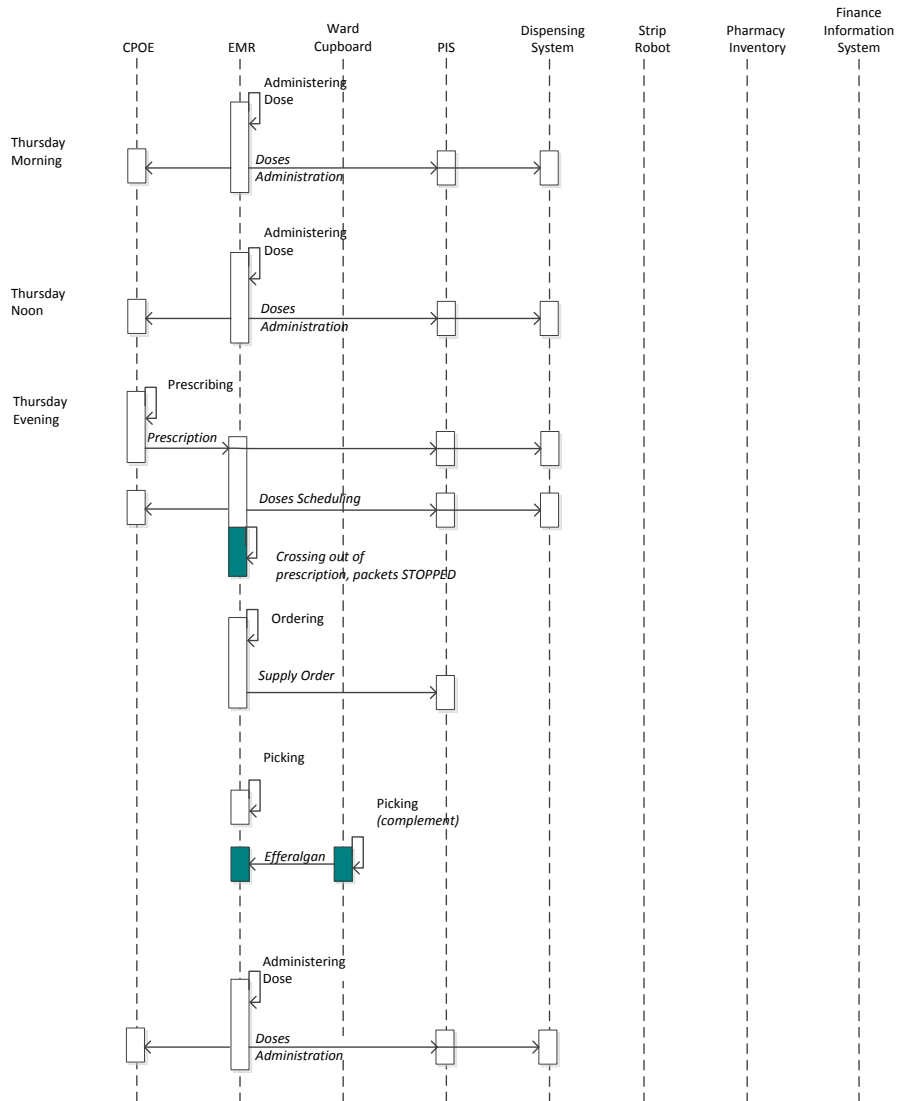


Figure 31

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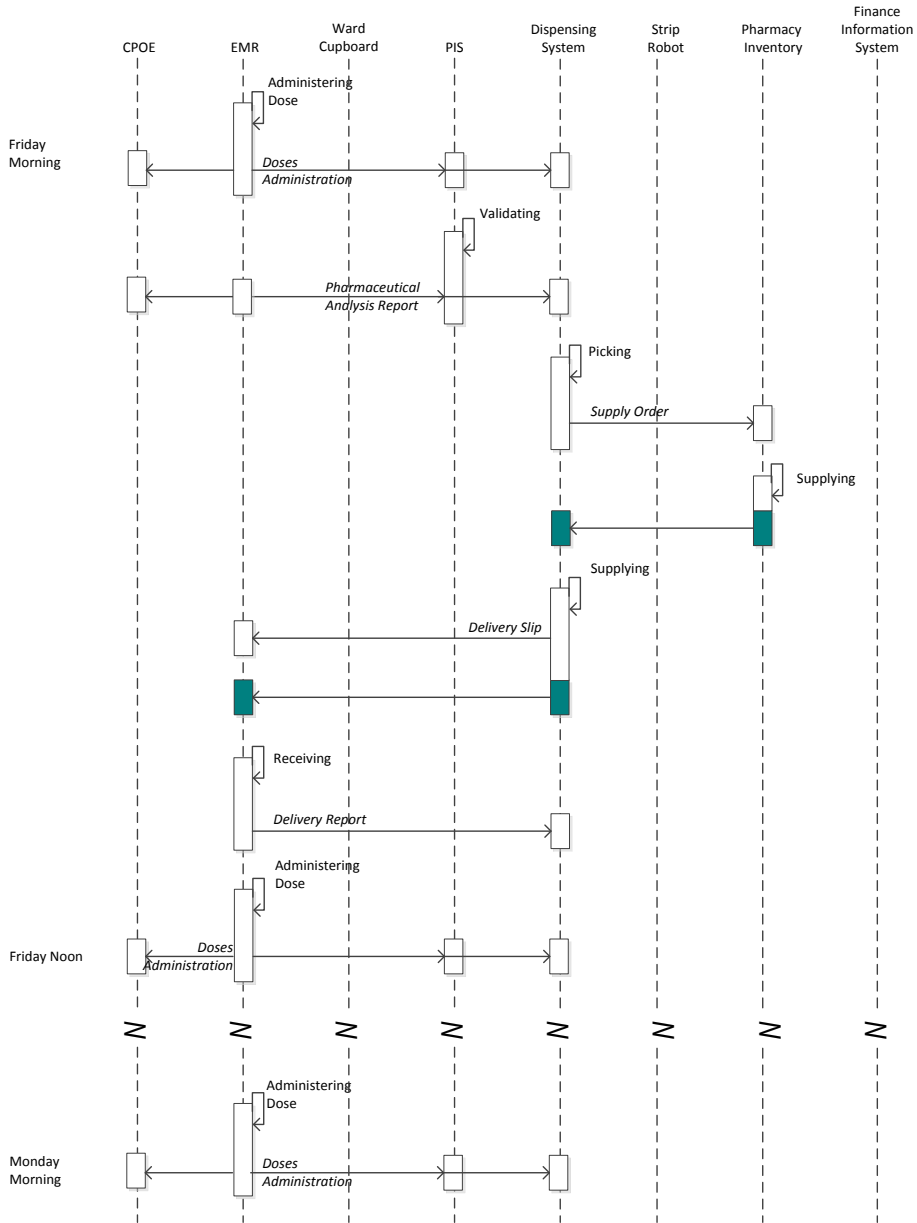


Figure 32

5 Nominative Dispensing of Oral Liquid Forms + Ward Cupboard

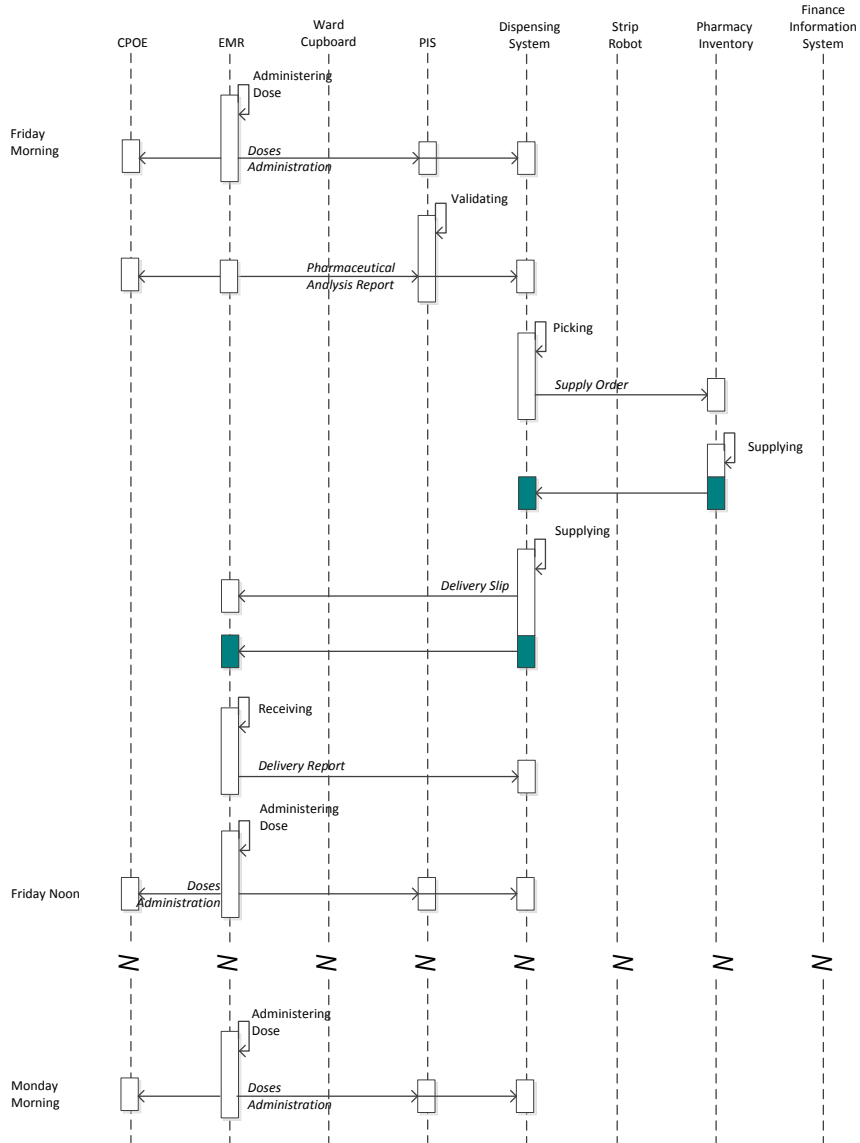


Figure 33

1825

6 Dynamic Storage in Pharmacy Logistic Area

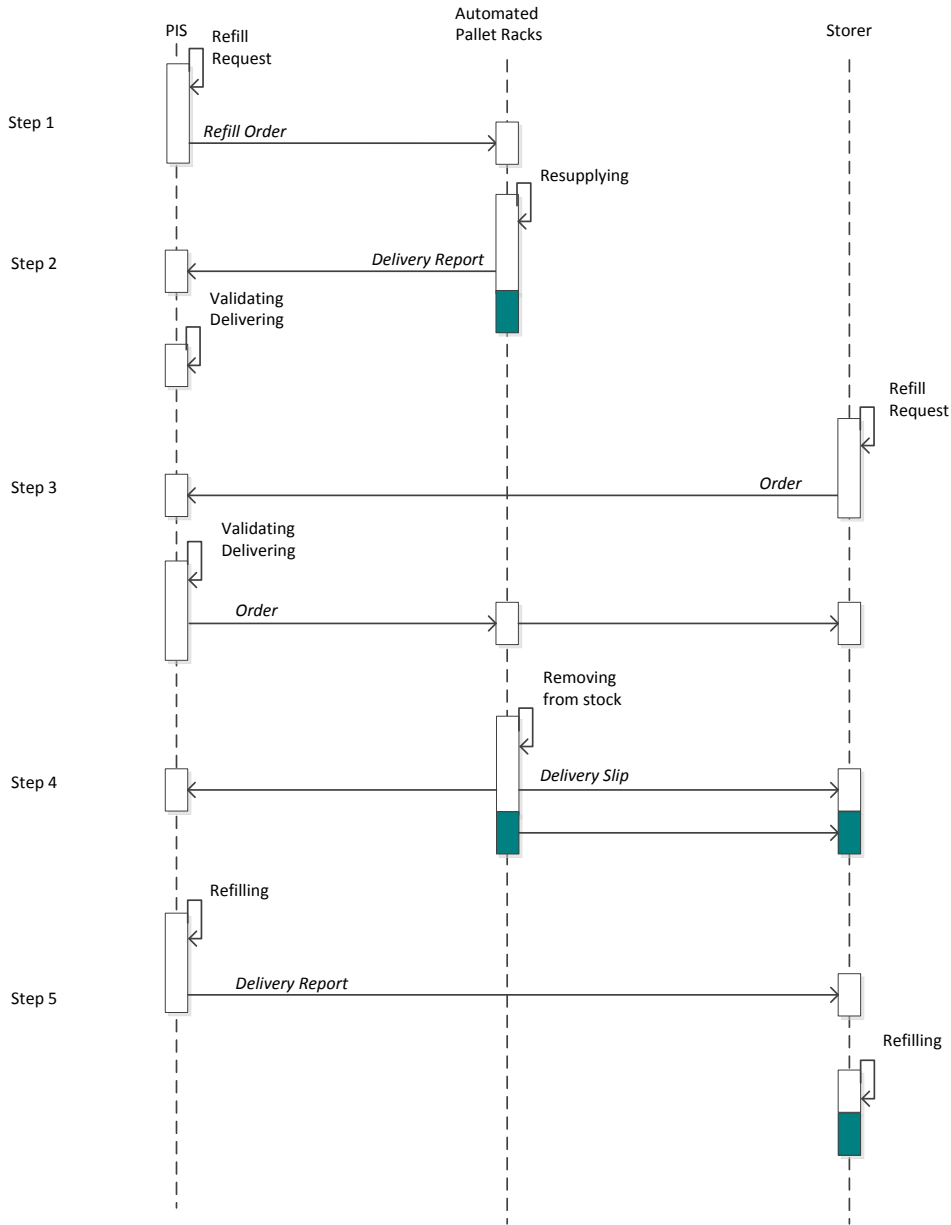


Figure 34

7 Appendix III – Production of this framework

7.1 Working Group

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Final Revision: Olivier BOUX

For their contribution in the submission of type use cases, we thank especially:

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- Audrey VAIRAC
- Étienne COUSEIN

- Thierry GERAUD
- Jérôme JEUNOT
- Ronan LARGEAU
- Vincent MARY
- Éric RUBIER

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7.3 Meetings

Date	Type of Meeting	Objective
30/06/2011	Mid-Year Meeting SIPh	Registration of the project « automated systems » (P1.1.2) to the annual program
25/08/2011	Conference call	Initialization of the working group
03/10/2011	Web-conference	Connection with international work (IHE and HL7 Pharmacy)
19/10/2011	Face to face meeting	Scoping, description and classification of automated systems, inventory of usages
18/11/2011	Face to face meeting	Analysis of use cases provided, operating methodology of these cases.
15/12/2011	Face to face meeting	Draft of sequence diagrams
19/01/2012	Web-conference	Model Validation
27/01/2012	Web-conference	Sequence diagrams Validation
30/01/2012	Face to face meeting	Finalization of the document
09/02/2012	Web-conference	Model Development
16/02/2012	Web-conference	Model Development, sequence diagrams
02/03/2012	Web-conference	Finalization of the Model
26/03/2012	Web-conference	Final Questions

1850