# Use Case Specification

## Deliverable 1.6 v2

| Deliverable Title | D1.6 Use Case Specification |
|---|---|
| Deliverable Lead: | INVITE GmbH |
| Related Work Package: | WP1: Requirements management and verification preparation |
| Related Task(s): | T1.1: Use case specification |
| Author(s): | T. Cichon, C.-H. Coulon |
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| **Abstract** | In this deliverable the use case of sterility testing is described. This includes the generation of the use case description as well as the specification of the use case in terms of process steps that in the end should be executed by / executable for a robotic system. |

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# Versioning and Contribution History

| Version | Date | Modified by | Modification reason |
|---|---|---|---|
| v.01 | 12.01.2022 | T. Cichon (INV) | Initial start |
| v.02 | 24.01.2022 | T. Cichon (INV) | Update expected content after project meeting |
| v. 02 | 03.02.2022 | T. Cichon (INV) | update |
| v. 03 | 09.02.2022 | T. Cichon (INV) | update |
| v. 04 | 11.02.2022 | T. Cichon (INV) | Update for internal revision |
| v.1.0 | 11.02.2022 | T. Cichon (INV) | Ready for internal revision |
| v.1.1 | 21.02.2022 | T. Cichon (INV) | Update after internal revision |
| v.1.2 | 24.02.2022 | T. Cichon (INV) | Revised version ready for submission |
| v.2.0 | 21.11.2022 | T. Cichon (INV) | Created this v2 version of D1.6 |
| | 28.11.2022 | A. Remazeilles (TECN) | Added description on variability management. |
| | 28.11.2022 | T. Cichon (INV) | Update |
| | 01.12.2022 | T. Cichon (INV) | Update for internal revision |
| | 11.12.2022 | T. Cichon (INV) | Final touch and fonts, ready for internal revision |
| | 15.12.2022 | T. Cichon (INV) | Update after internal review |



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# 1 Updated Version of D1.6

Based on the Feedback of the Reviewers Deliverable D1.6 requires an updation.

Based on the feedback of our reviewers (excerpt of the project review report):
*"[…]*
*Following the review, on the review report received, the Commission recommended that:*
*To maximize the impact of the project, future work should consider in particular the detailed feedback on the deliverable 1.6 that has to be resubmitted.*
*Deliverable D1.6 will be resubmitted by the end of December 2022, as requested. Following the detailed feedback, we will extend the current version with targeted use-case implementations for each milestone.*
*[…]*
*[1.4] Here it is important to say what can and what cannot be automated (e.g., in the context of the removal of the foil of the sterilization kit) and what does not make sense to automate since in a robot system it can be realized easier (there no need to make a one-to-one copy of the human behavior).*
*Resubmission of D1.6 will provide indications in this direction. The task T1.3 ("Robot-friendly design rulebook", starting in M25) is devoted to proposing adjustments of the human process for being more suitable for robotic application.*
*[1.4] Also it should be clarified, how the adaptation process of the robot system in case a change of procedure occurs is supposed to be done: How is the system to be adapted? What kind of user interactions are expected to happen? How long should the adaptation process take? When and how this this supposed to be shown?*
*Deliverable 1.6 will provide indication about the expected adaptation options, and when such functionality will be demonstrated. We expect the design of the programming interface, and the learning functionality to permit to envision such adaptation.*
*[1.4] Traceability and task verification: the definition of clear and specific criteria for task verification is recommended, also compared to the procedures currently adopted in the field.*
*The distribution of the verification process according to the different modalities (vision, sensing, reasoning, digital twin) will be commented in the next report.*
*[…]"*

This update consists primarily of a **clarification of process variabilities and adaptations** and what will be covered by TraceBot and what not (see Chapter 4.3) and a **clear timeline and content of our isolated use case approach** (so which further Isolated Use Cases and why these) on demonstrating the capabilities of the TraceBot System (see Chapter 4.5).



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# 2 Executive Summary

Closely related to T1.1 this deliverable describes the use case specification.

**T1.1 Use case specification (M1-11 M25-45; INV, input from all)**
The sterility testing use case described above forms the basis for a comprehensive requirements document to include a description of the task workflow and its variants, the environment, tools, operator persona, traceability, for a set of prioritized capabilities. This will be structured around a lifecycle analysis (specify, acquire, install, qualification (IQ, OQ), maintain including set-up / changeover / clean, and upgrade, failure, and recovery). Data management will be included (e.g., ALCOAplus). This task will take as input the detailed knowledge with INV, input from subject matter experts, relevant training materials, standards, and regulations, as well as prior work carried out by INV and CEA. Emphasis will be placed on the technical gaps previously identified in state of the art and on overall robustness rather than throughput.
A final demonstrator will include consideration of an integrated sterile enclosure (isolator) and materials resistant to cleaning processes, but this will be held out of scope for the first proof of concept (M23).
By completion of the initial sterility testing use case the specification will be updated (M25-45) and a revised user requirement issued for a 2nd phase. This will consider learnings and elaborate a definition of an additional use case based on bioburden testing, an evolution of the initial use case to a second test set but still within the scope of pharmaceutical quantity control. The demonstrator scenario will be described with criteria for success defined by the verification plan, T1.4.

The use case we are looking at is the “sterility testing” which is executed in different companies (with slight variations). Based on input videos we derive a hierarchical workflow from main, high-level tasks down to atomic, robot-executable steps. This use case description is derived semi-automatically as we want to update, iteratively incorporate more information, and do data analytics on the generated use case description output. Thus, this deliverable is not only about the use case of sterility testing itself but also about a holistic approach on automatically generating use case descriptions based on video snippets. The result is a markdown documentation including description and videos which is always up-to-date and is used to identify differences in between the use case providers, identify terminology problems, the used objects etc. To sum it up, the use case specification is not only one description of a sterility testing use case but more a living (automatically generated) documentation of the sterility use case in its transition from manual to roboticized workflow execution.

This use case description can then most importantly be used to deduce important process information from it: the different process and handling steps, the objects and methods used, the variation observed in between the different application of the process, differences in between manual and roboticized process execution etc.



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# 3 Introduction

This document describes the sterility testing use-case that is guiding and directing the development within TraceBot.

The specification of the use case has been an iterative process. First, the sterility testing was already selected in the proposal as it is one process that is done in a feasible time frame by multiple companies in a currently manual way that has the potential of being automated with a robotic system.

Then, with the advisory board we initiated a set of actions that in the end lead to the prospect of having multiple industrial partners that are willing to share their knowledge with us in terms of video recording of the process executed by human operators. With this we got our hands on multiple video input sources.

Thirdly, we decided to focus on the video provided by the company RSSL (keeping the other video-sources and thus the other partners in scope), as the video quality, as well as the liberty of using and communicating about this material, suited our work best. Nevertheless, it is important for us to contrast this process analysis with the other videos received as well.

The video sequence could be cut in a set of main steps, later being detailed down to reach a state where the basic atomic operations could be related to operations that a robotic system could execute.

The use case documentation could be automated in a way that we now have a feasible and flexible way to generate a set of documents to detail the process, interact on it from different perspectives.

All in all, the Use Case Specification is always derived from a video input source and afterwards split up into process steps to get from a video to high-level/generic process steps down to atomic, robot-readable actions.



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# 4 Description of work & main achievements

As the use case is very complex and one basis for all the other Work packages, we use the content management tool GitLab (see https://tracebot.gitlab.io/tracebot_showcase/ ) to provide it to the project in a well-structured, manage- and maintainable, multi-level and easy to verify data structure which is human and machine readable at the same time.

While section 4.1 describes the structures and the mechanisms used to document the use-case, section 4.2 describes the use-case it-self as documented in GitLab.

## 4.1 From Manually to Automated workflows description

Although workflows in the chemical/pharmaceutical industry are generally described in a standard operation procedure (SOP) and transferred into a test specification, these are normally not used for deriving an automation concept. The description is highly based on the human (and his intelligence and education in this field) in-the-loop and thus process understanding is a prerequisite for reading and understanding these. As a result, for automating processes it makes the most sense to use a video of the conduction of the process by an experienced operator.

To achieve a comprehensive, single source of truth, always up-to-date documentation of the process including (a) a hierarchical structure (of task, sub-tasks, etc.) (b) text and tables for description and (c) also embedded video snippets we chose markdown (*.md) as the documentation data standard. As markdown is already natively directly accessible and rendered in the GitLab wiki this leads to the (aforementioned) required features. In the end, this markdown documentation should be the comprehensive plan where “everything” can be derived from.

### 4.1.1 Human-readable documentation

The human-readable documentation in the GitLab wiki is done with markdown files. These are structured hierarchically and linked against each other, with the hierarchy levels of tasks, subtasks, and steps (cf. Fig. 1). Tasks/subtasks are more about understanding the process for a human and steps (as the „leaves of the tree”) go down to atomic process steps and specific robotic actions.

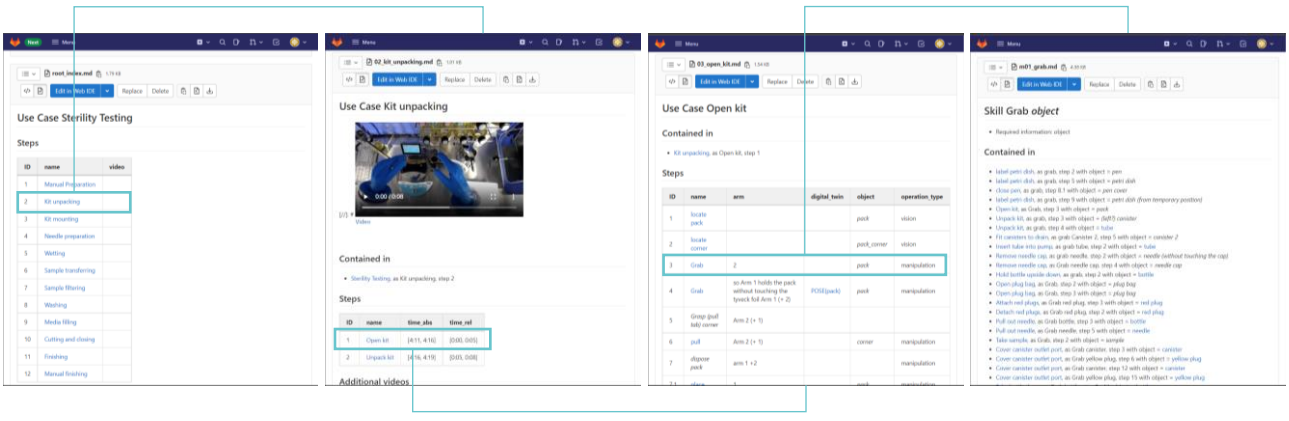


Fig. 1: Overview of hierarchical process description



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Exemplarily, one example of this hierarchical process description is shown in Fig. 1 resp. Fig. 2, Fig. 3, Fig. 4, Fig. 5.

The first use case segmentation, as presented in Fig. 2 highlights the 12 main steps of the process. They are easily understandable by humans and should be kept referring for instance any advancement in the automation process. Nevertheless, the description is not sufficient to understand the robotic actions required to implement it with a robotic system.

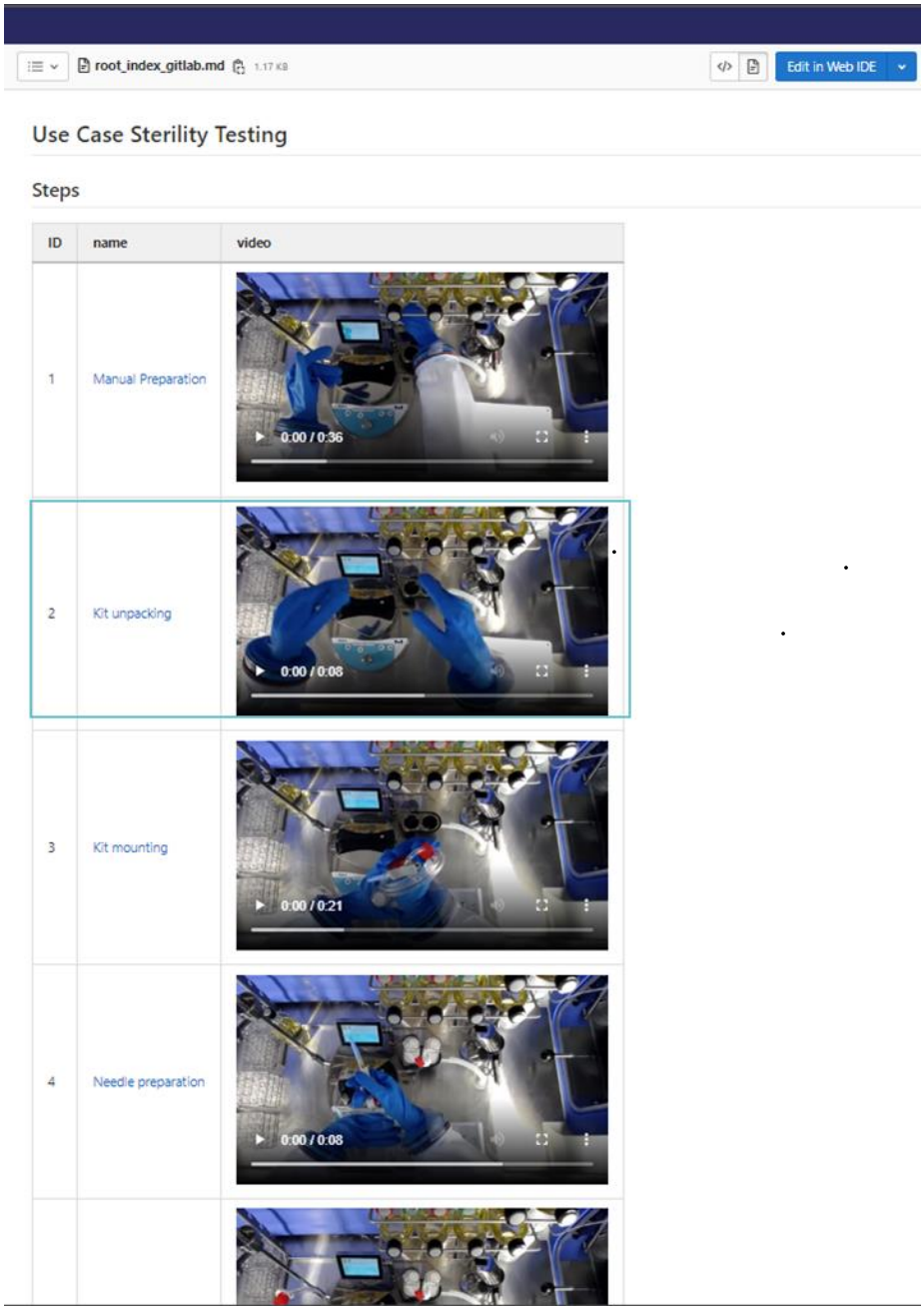


Fig. 2: Human-readable Use Case Description, Abstraction Level 1



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Each main step highlighted in Fig. 2 is then detailed in sub steps in Fig. 3, together with timing indication within the video.

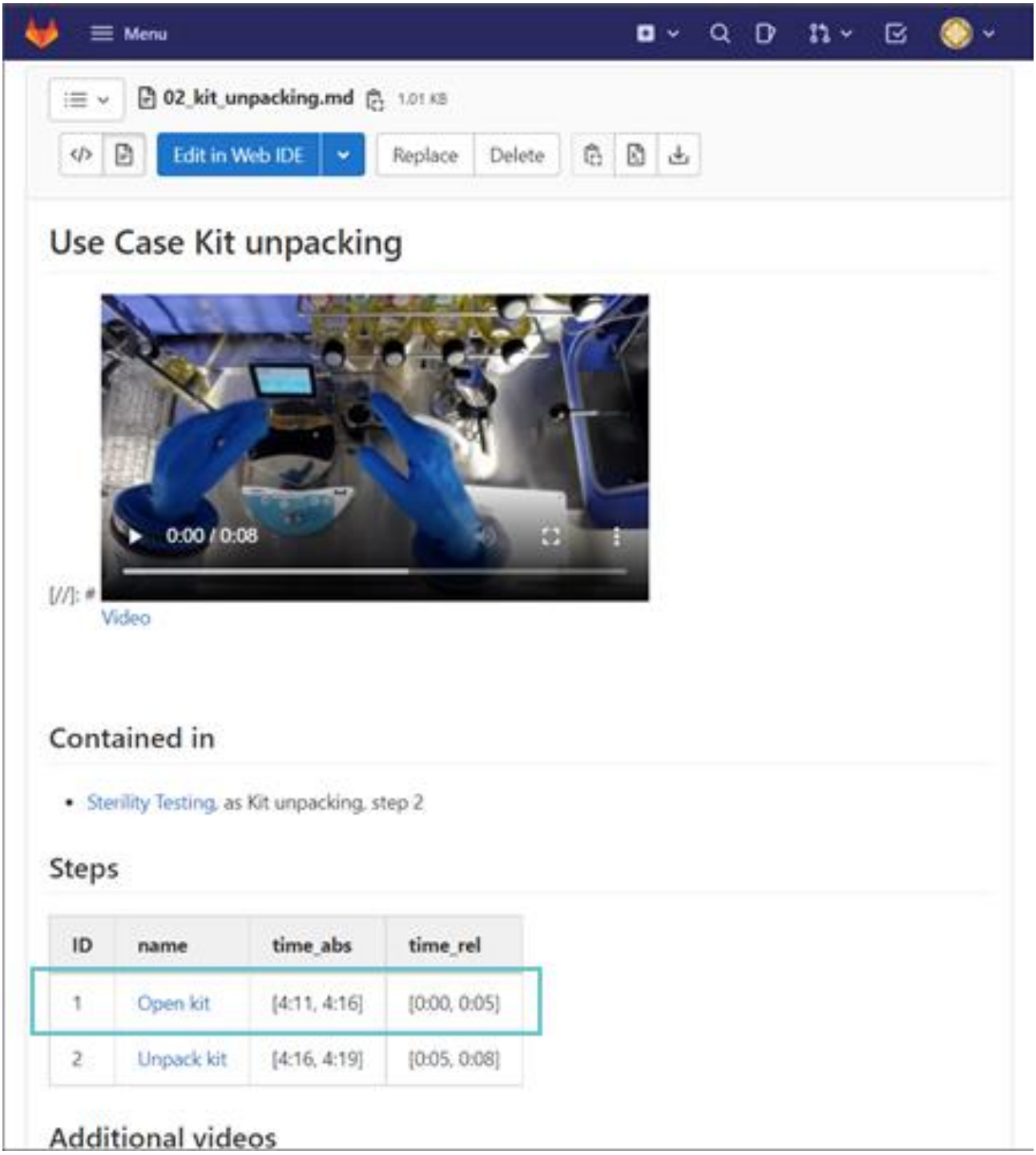


Fig. 3: Human-readable Use Case Description, Abstraction Level 2 w.r.t Fig. 2



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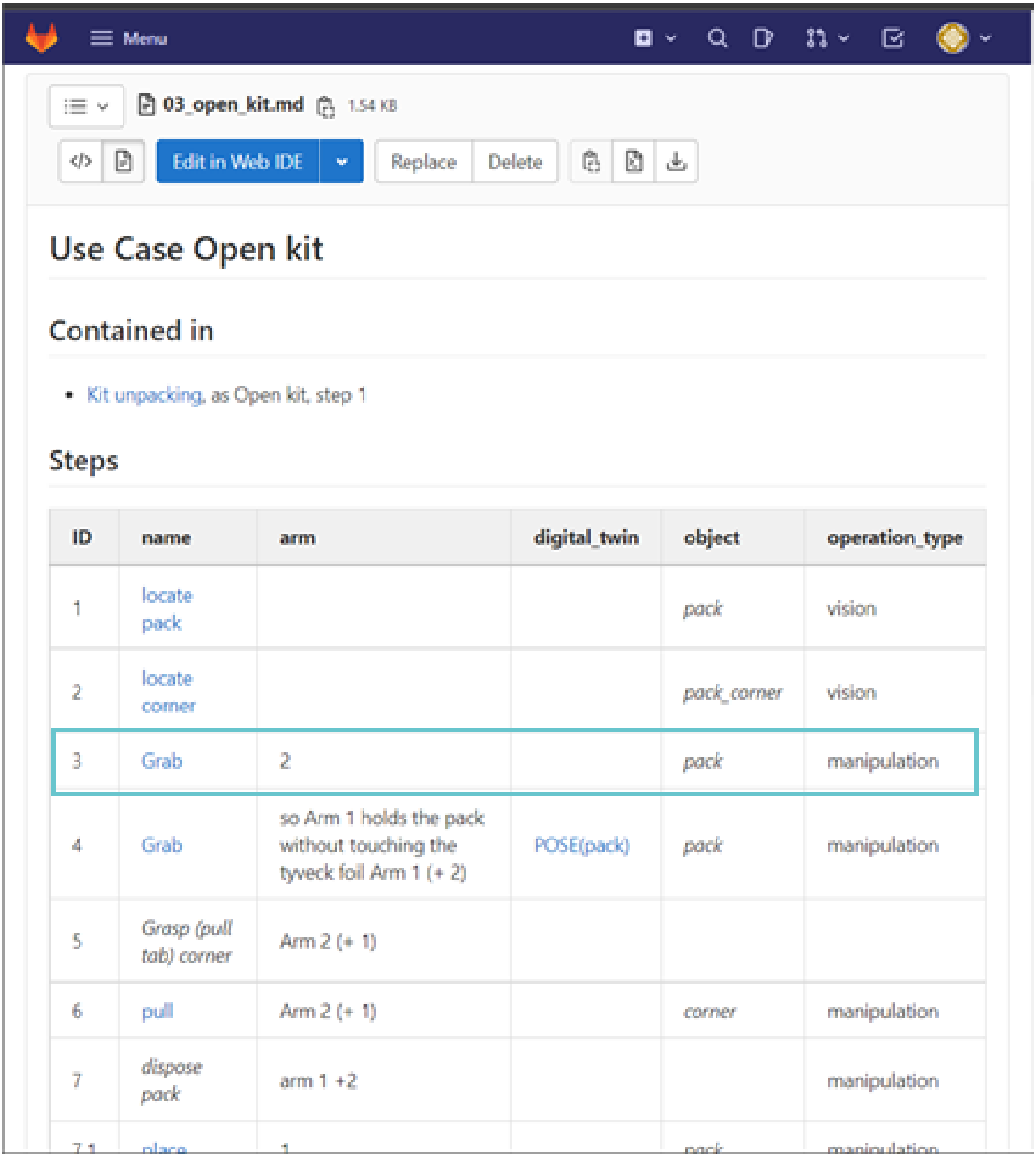
Fig. 4 illustrates the description of the open kit step. We can identify operations here that are meaningful on a robotic perspective, such as vision operation (object detection), manipulation (grasp, pull, ...).



Menu

03_open_kit.md 1.54 KB

Edit in Web IDE | Replace | Delete

# Use Case Open kit

## Contained in

- Kit unpacking, as Open kit, step 1

## Steps

| ID | name | arm | digital_twin | object | operation_type |
|---|---|---|---|---|---|
| 1 | locate pack | | | *pack* | vision |
| 2 | locate corner | | | *pack_corner* | vision |
| 3 | Grab | 2 | | *pack* | manipulation |
| 4 | Grab | so Arm 1 holds the pack without touching the tyveck foil Arm 1 (+ 2) | POSE(pack) | *pack* | manipulation |
| 5 | *Grasp (pull tab) corner* | Arm 2 (+ 1) | | | |
| 6 | pull | Arm 2 (+ 1) | | *corner* | manipulation |
| 7 | *dispose pack* | arm 1 +2 | | | manipulation |
| 7.1 | place | 1 | | pack | manipulation |

Fig. 4: Human-readable Use Case Description, Abstraction Level 3 w.r.t. Fig. 3



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Fig. 5 presents a "leaf" operation in the process description, which is the grab operation. From the complete description, we can automatically identify where this functionality is required, and which is the object that must be manipulated.

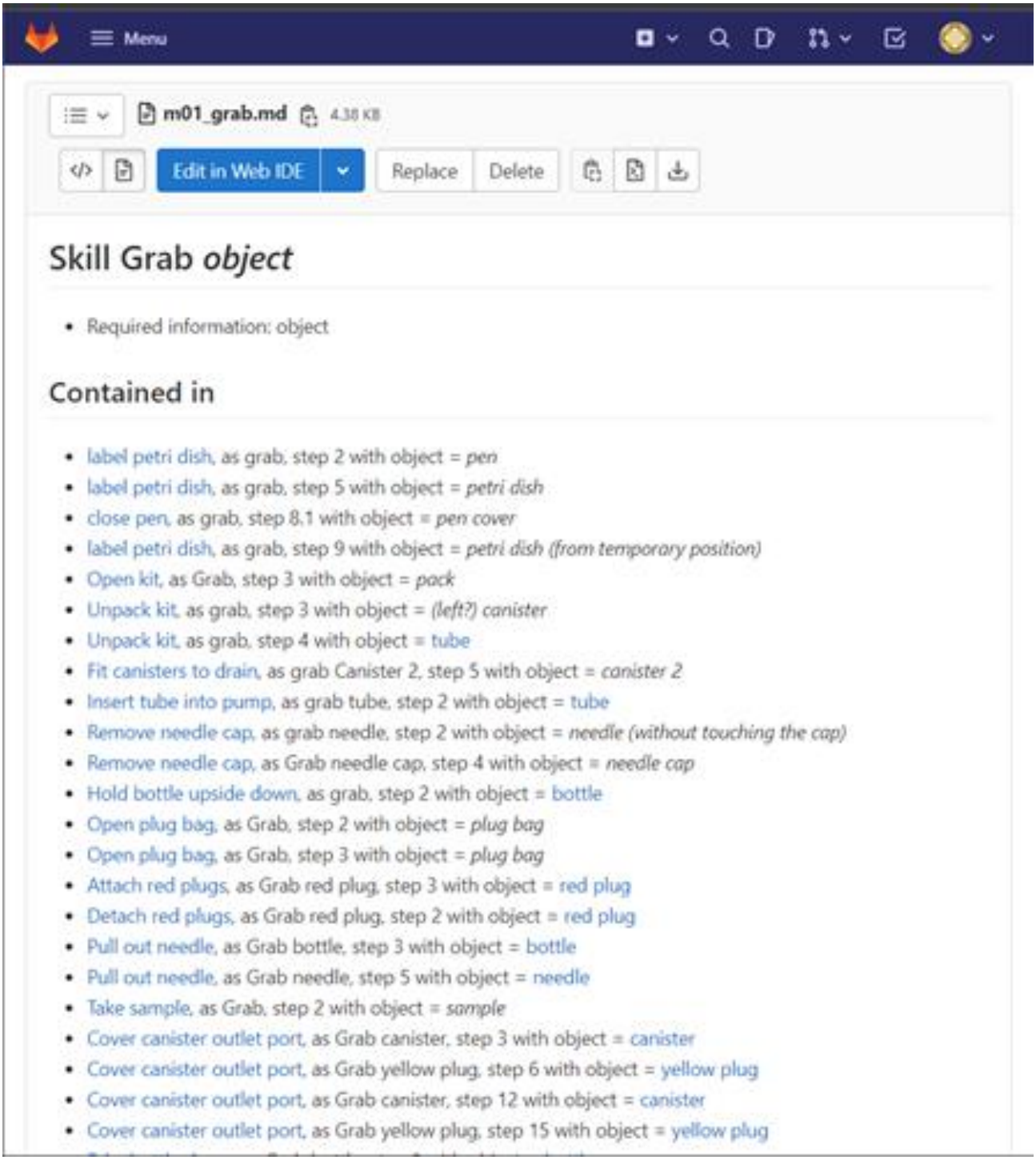


Fig. 5: Human-readable Use Case Description, Abstraction Level4 w.r.t. Fig. 4



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### 4.1.2 “Machine-readable” atomic operations

As initially stated, we aim at an always up-to-date automatically generated, single source of truth, documentation and thus automated the generation of a documentation, where we chose markdown for visual rendering.

So, previous description is rendered from a computer data information format. We chose the YAML format, as it is compact, and easy to understand by humans. The advantage of using a computer format for the data is that it permits to handle the rendering automatically. It also permits handling the cross-references automatically and detects potential inconsistencies in the descriptions. A YAML file is written for each step, connecting to the sub steps it contains. Items of the environment like objects, can also be described and incorporated this way. Thus, the definition of the use case tasks/subtasks/steps is done through YAML files, exemplarily shown in Fig. 6, analogously as they are later rendered in the markdown-GitLab-wiki. Thus, everything that is needed to describe each process steps is pinned down in these YAML files – as detailed and as precise as needed especially for the “robot-readable”, atomic task steps.

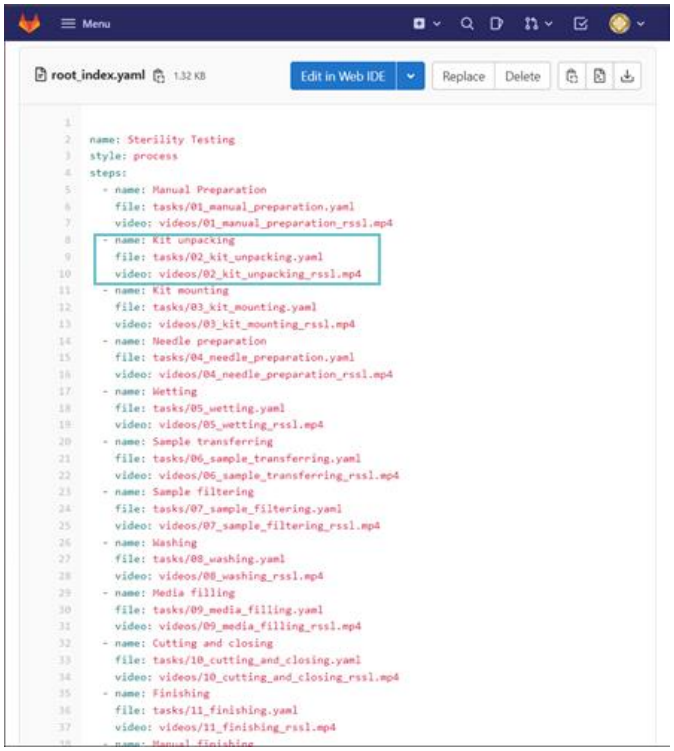


Fig. 6 : Machine-readable use case description, representing the backend of Fig. 2



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## 4.2 Use Case “Sterility Testing”

The use case of “Sterility Testing” is primarily described in the Gitlab-wiki in the aforementioned markdown files (including video and text documentation).

This section starts with a general simple description of the use case at hand, before going into more details. These comprise a deep dive into the tasks and process steps and afterwards an analysis of the use case. The analysis led to a clustering of operations into categories, main items handled and the given process variability.

### 4.2.1 Sterility Testing – straightforward description

For reasons of simplicity this first description should align everyone with (what are) the central steps and what is the central goal of sterility testing.

Fig. 7: General overview of the sterility testing

The sterility testing procedure (cf. Fig. 7) starts by **setting up** of materials, the central pump, and the sterility kit (as well as the transfer kit) in an isolator. Afterwards the sample is **pumped from the sample containment** (either the sample directly, e.g., in a vial, or the sample is **transferred** to another bottle first using the transfer kit before the filtration begins) **through a membrane** (where the filtering takes place) **into the canister**. For the complete test first a washing medium and afterwards the samples to be tested are pumped through the membranes on the bottom of two canisters and each canister is then closed and filled by one of two grow media. Afterwards, the canisters can **visually be inspected,** and a cloudy appearance indicates contaminant growth (whereas the main goal is to not detect contamination). This finishes the process within the isolator and the canisters are transferred into incubators outside the isolator.



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### 4.2.2 Tasks/Process Steps

Starting from the straightforward description we looked at each manual handling step and came up with a full process description consisting of the following **12 tasks** (cf. Fig. 8), described shortly and illustrated with characteristic images taken from one of the videos afterwards.

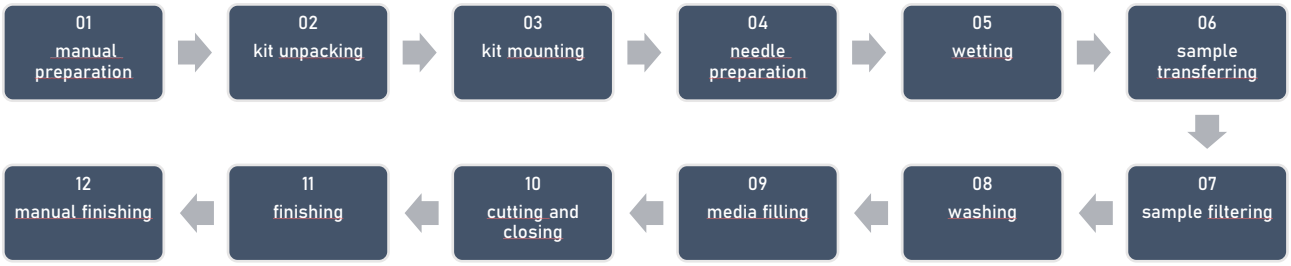
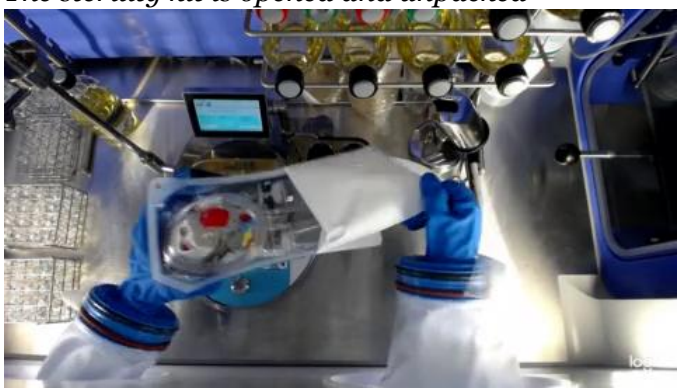



Fig. 8: Flowchart of the 12 tasks

In the following each of the mentioned tasks is introduced with a description in italic and an iconic screenshot of one video that should explain the current process step.

01. Manual Preparation
*The control petri dish is labeled and placed in the workbench*

02. Kit unpacking
*The sterility kit is opened and unpacked*





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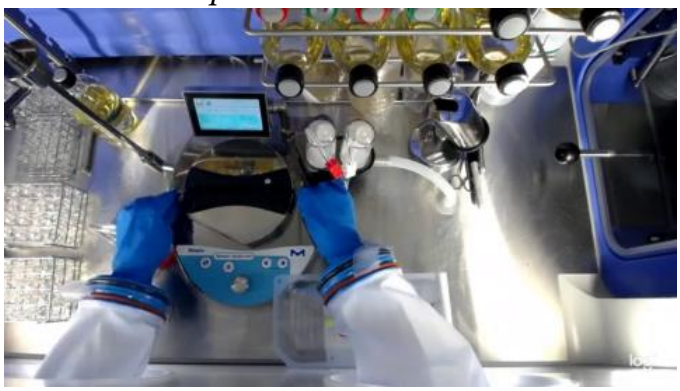
03. Kit mounting

*The canisters are placed into the canister tray, the tube is inserted into the pump, which is closed and set up.*

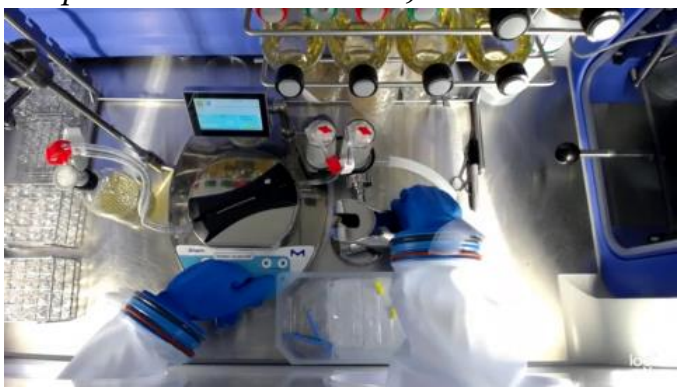


04. Needle preparation

*The needle cap is removed and inserted into the bottle through the membrane*

05. Wetting

*The filter gets prepared for the sample filtering by running the pump with the needle attached to a new upside-down washing bottle, filling the canisters with washing medium. The bottle gets turned back down and the red plugs get attached. The pump runs (creating overpressure in the canisters) until there is no washing medium left in the canisters.*





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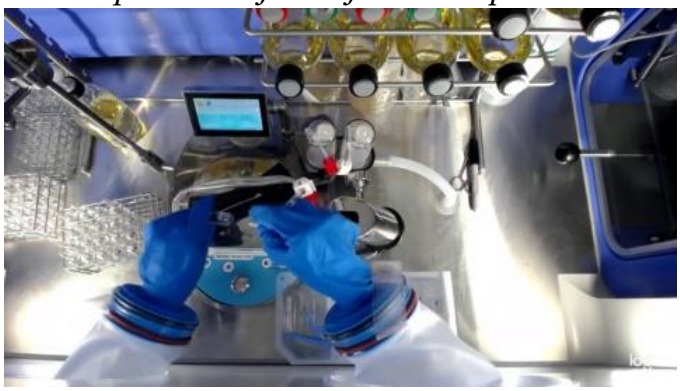
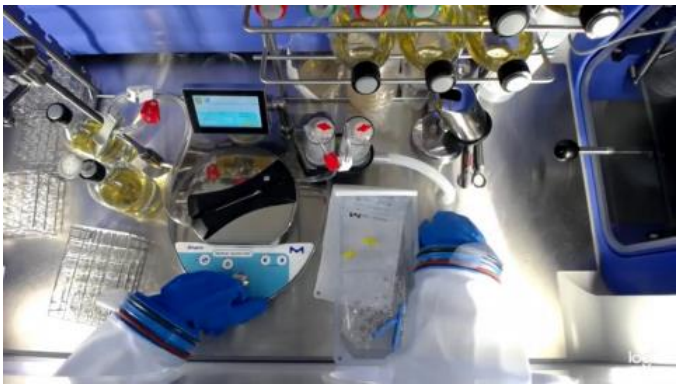
06. Sample transferring

*The sample is transferred from multiple vials into both canisters, one after the other*



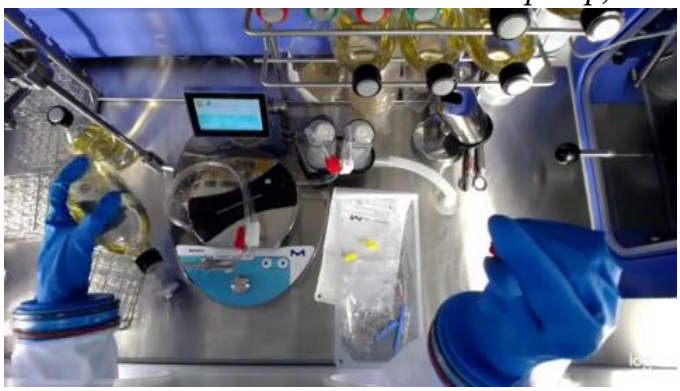
07. Sample filtering

*Samples are filtered (which means that overpressure in the canisters pushed the sample through the membrane to the outlet port of the canisters and thus into the drain) and the canisters are labeled*



08. Washing

*Put wash solution into holder and start pump, leaving the drain of the canisters open*





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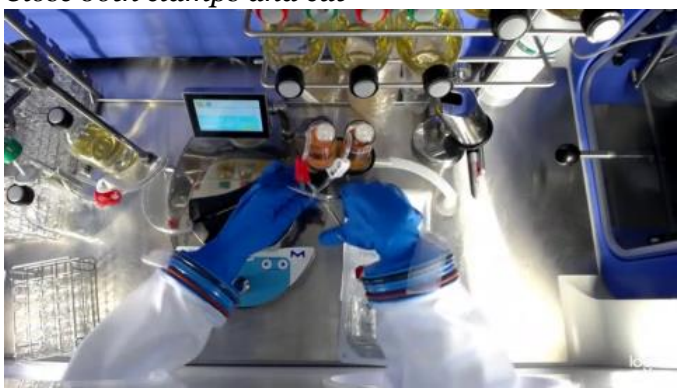
09. Media filling
*The media (small red and green bottles) is pumped and fills the two canisters, each canister with only one media.*

10. Cutting and closing
*Close both clamps and cut*



11. Finishing
*Unmount everything and tidy up the workbench, moving apart consumables.*



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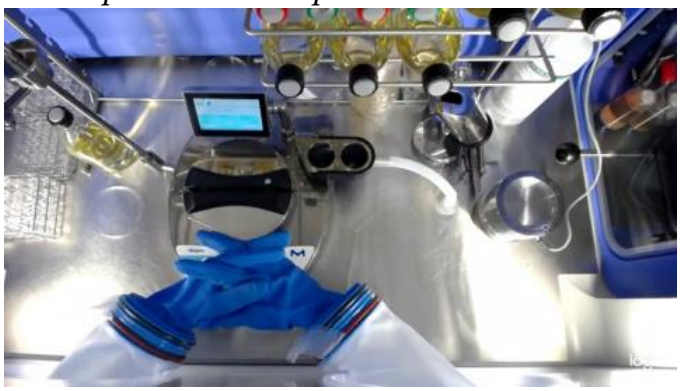
12. Manual finishing
    *Clean up and move out petri dish*



Based on these 12 main tasks, we hierarchically go deeper and deeper into single handling operations to get a holistic understanding of each atomic process step. Additionally, this will enable us understanding each manual process step and describing it afterwards even better.

Indeed, all these steps are related to high-level manipulations, which could be used by a human operator to describe the successive operations of the process. The underlying perception operations, or object affordances are not present. Therefore, we introduced finer description to the process, to get a description listing exhaustively the operations the robot should perform (the atomic process steps).

These 12 steps are the main successive operations, a first quantification of the process. All these 12 steps are being decomposed in 36 sub-steps, connected for now to 28 atomic operations[1]. Right now a 2 level depth was enough to reach atomic operations which can be related to concrete robotic operation (involving manipulation, vision, or the Digital Twin).

### 4.2.3 Categories

If we look closer at the sub-steps, we encountered that these (or at least some of these) may be reused in other steps. So far, we identified ***8 categories*** of operations that can be found in more than one sub-step.

#### 4.2.3.1 Labelling

The labeling is an operation consisting in writing with a pen an identifier onto the object.

Some examples are:

- label petri dish (in step 01- manual preparation)
- label canister (step 07- sample filtering)

[1] The complete process has been detailed, but some sub-steps and atomic actions are still subject to adjustment, so that these numbers are provided as an indication.



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#### 4.2.3.2 Pick and Place

Several objects must be moved from one place to another in the environment. The initial picking requires locating initial the object (visually), and the placing is either connected to a specific site onto the pump, or basically aiming at putting aside the object. The location for picking may be simplified according to the knowledge of the previous actions, which may indicate where the object should be in the environment.

Some examples are:

- Place petri dish (01- manual preparation)
- take sample (06- sample transferring)
- put down sample (06- sample transferring)
- clean up (11-finishing)
- move out petri dish (12-manual finishing)

#### 4.2.3.3 Insert/ Attach

The insert / attach category gathers operations consisting in inserting an object into another or placing an object onto another.

Some examples are

- Fit canisters to drain (03-kit mounting)
- Insert needle (04-needle preparation, 06-sample transferring, 09-media filling)
- Attach red plugs (05-wetting, 07-sample filtering, 08-washing)
- Cover canister outlet port (09-media filling)

#### 4.2.3.4 Tube Manipulation

The management of the tube is critical in the process, and several steps require handling them precisely. Most of these operations require bimanual system to be conducted.

Some examples are:

- Insert tube into pump (03-kit mounting,
- Close Clamp valve (09-media filling, 10-cutting, and filling)
- Open clamp valve (09-media filling)
- Cut tubes (10-cutting and filling)
- Attach cut tube to canister air vent (10-cutting and filling)
- Remove tube from pump (11-finishing)

#### 4.2.3.5 Assemble/disassemble (Pull Out / Detach)

These operations consist in disassembling connected elements, and require applying controller pulling force on the objects

- Remove needle cap (04-needle preparation)
- Detach red plugs (05-wetting, 07-sample filtering, 08-washing)
- Pull out needle (06-sample filtering, 09-media filling)
- Store canisters (11-finishing)



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#### 4.2.3.6 Containments Moving

Several bottles and containers are used to in the process of sterility testing. As this manipulation is not only a simple pick and place but moreover also a force-based insertion (including an inclination and/or a turn of the containment) it requires to coordinate well the grasping and release strategies.

Some examples are

- Hold bottle upside down (05-wetting, 08-washing, 09-media filling)
- Move bottle into holder (08-washing, 09-media filling)
- Take bottle down (09-media filling, 11-finishing)

#### 4.2.3.7 Complex manipulation

These operations are labeled as complex mainly as they require a coordinated bi-manual manipulation, and do not fall in the previous categories.

Some examples are:

- open kit (02-kit unpacking)
- unpack kit (02-kit unpacking)
- open plug bag (05-wetting)
- break vials (06-sample transferring)

These tasks involve multiple, often complicated steps and thus are categorized in here. In detail this means:

- The kit opening involves the two arms, one to hold the kit package, and the other one must grab the cover part and pull it.
- The unpack kit requires taking out from the package all the different element, while taking care of the cables connected to the canister.
- The open plug bag requires opening the small plastic bag in which they are placed.
- The vial break requires two hands to hold the vial and generate the required force on its head to break it.

#### 4.2.3.8 button management

These different operations are performed interacting with the physical interface of the pump, through the buttons present on the pump.

Some examples are:

- Close pump (03-kit mounting)
- Setup pump (03-kit mounting)
- Start pump (05-wetting, 07-sample filtering, 09-media filling)
- Stop pump (05-wetting, 08-washing, 09-media filling)
- Pump sample (06-sample filtering)
- Open pump (11-finishing)

This categorization is mainly a classification of the manual operations, as they are observed within the process. It does not necessarily reflect the complexity of the underlying operations, or the robotic challenge associated to it. In a close future we would like to complete that description with the



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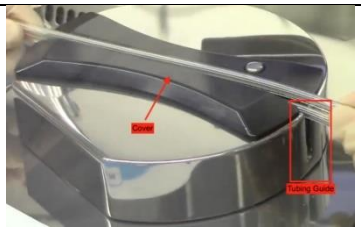
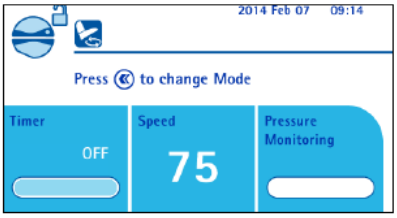
classification of the different operations as scientific challenges brought by this concrete use case, which we would like to share with the robotic community.

### 4.2.4 Main items/objects

Based on the video description we identified 16 main items that are used / handled in this process which we already clustered/ categorized into the following.

Table 1: Pump related items

| | | |
|---|---|---|
|  |  |  |
| drain tray (Merck Millipore Sigma, 2021) | pump head | bottle holder (Merck Millipore Sigma, 2021) |
|  |  |  |
| pump screen (Merck Millipore Sigma, 2021) | pump (Merck Millipore Sigma, 2021) | pump buttons (Merck Millipore Sigma, 2021) |

The Pumping system (cf. Table 1) is the central element of the environment around which all operations are taking place. The pump system is equipped with a *drain tray* where the *canisters* must be placed for enabling the liquid transfer in and out. The head of the machine (*pump head*) is the mechanism enabling the liquid transfer in between the different containers. This linear hole is designed to host the tube connected to the liquid container, and by pressure mechanism, provokes a sucking mechanism which creates the liquid transfer from one container to the other. On the left side of the pump is the *bottle holder* located where bottles (containing liquids which are to be transferred to the canister) are placed once the transfer tube is placed in it. The pump is also equipped with a screen where several information is provided to the human operator (especially the green, yellow, or red pump pressure monitoring). It also provides a set of buttons that are used to activate / deactivate the pumping mechanism and change pump parameters (timer, speed, pressure).



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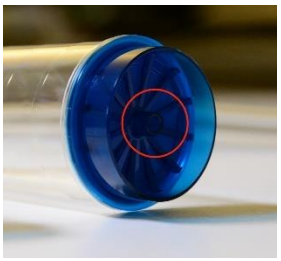
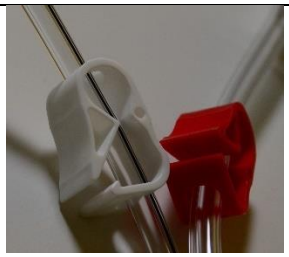
Table 2: Sterility test kit items

| | | |
|---|---|---|
|  |  |  |
| Sterility kit | Sterility kit package | Tube |
|  |  |  |
| Canister | Canister air vent | Canister outlet port |
|  |  |  |
| Needle | Clamps (red and white) | Plug (red and yellow) |

The steri test kit (cf. Table 2) is another key component of the process. It is provided in a sterilized package, the steri package, which is covered with a foil. It contains all the non-liquid consumables that are used in the process. All are connected to the two canisters. The two canisters are connected to a tube from their upper part. On the tube are placed four set of clamps, two per tube (red and white). One extremity of the tube is thus connected to the canister. The other extremity leads to the needle, covered by a blue stopper, which will be introduced to the different media containers. The clamps are open or closed depending on if we want to transfer the liquid in it, towards each of the canister independently. Two set of plugs are also present in the sterility test kit, the red and yellow plugs used to close the canister containers.



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Table 3: Additional items

| | | | | |
|---|---|---|---|---|
|  |  |  |  |  |
| (Big black) Bottle | (Small green/red) bottle | Septum | Petri dish | Vials (Adobe Stock image) |

For execution of the process additional items (cf. Table 3) are required. First, the bottle (with a Volume of 300ml and a mass of 561g) that is afterwards placed in the pump's bottle holder. This bottle is then equipped with a septum which must be penetrated by the needle.

As an additional verification measure a petri dish is placed in the isolator, when starting the process and analyzed after completion of the process to see if any contamination spread inside the chamber.

Then there are variations in the initial sample containments. For now, we either take the bottle directly, or use vials that are then transferred into a bottle prior to their use in the pump system.

### 4.2.5 Process Variability

Based on the video input sources we already deduced that there are differences in between different companies' execution of the (same) task.

In this Gantt chart in Fig. 9 one can also see that (i) not all companies cover all the relevant process steps. Whereas some include manual preparation and finishing steps in their process description, others start describing the process starting from "02 kit unpacking" and end at "11 finishing". Whereas this be a neglectable difference as it is a difference in how to define start and stop of the workflow description, there are other differences as well.

Secondly, we derived that there are (ii) different containments used for the sample input either vials or bottles directly. And after re-consultation with the use case providers, we found out that even more initial containments may be possible, like capsules or syringes which could even vary in one batch / experiment. One example of such a "variant" can be seen in the step 06 "sample transferring" where most of the companies use (a) vials for transferring, whereas (b) uses a bottle for transferring. This must be considered in the use case description as this also results in a variance in the overall time needed for completing this task.

Another aspect we saw is the (iii) timing. Not only that some take longer or shorter for some tasks also the order of some steps varies. Where one first connects the bottle to the pump others first opened the whole sterility kit. These deviations even arise within one company, where different human operators operate differently in these terms.



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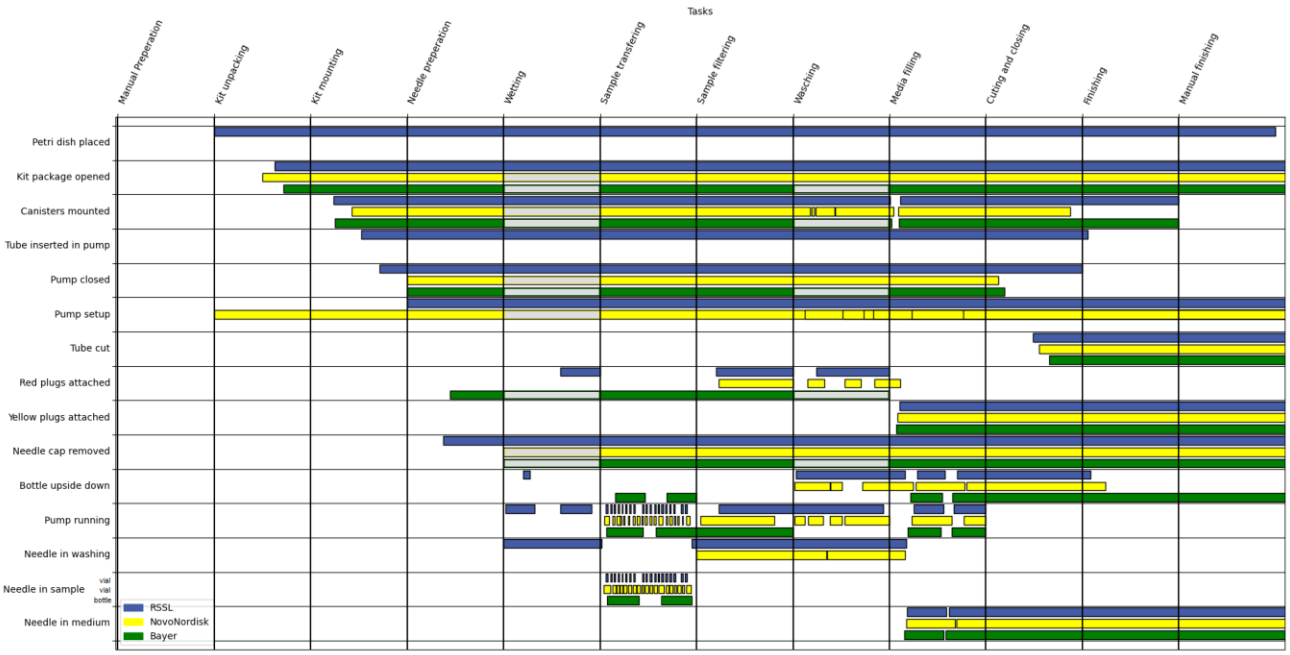


Fig. 9 Gantt chart of process variations

There are some (iv) use case parameters that are defined for each sterility testing and need to be considered when conducting the workflow with a robot. These are the pump pressure and pump speed that must be set on the pump and also the overall processing time that could be limited w.r.t. the sample that is tested.

Additionally, if we look closer at the process and the manual steps that are executed, there is also a set of (v) steps that are feasible for the human but their execution by a robotic system as done by the human is of a questionable interest and will be studied and contrasted with the advisory board and then described through the work of task T1.3 (robot-friendly design rulebook) in order to come up with other technical solutions to meet the requirements.

One example: initial mark of the petri dish by the human in step 01
This comprises the steps of “taking a pen”, “opening a pen”, “writing on a petri dish”, “closing a pen”, “putting a pen away”. Not only taking, opening, and handling a pen is a not so easy task for a robot but with the intention of labeling a petri dish there exist better automated solutions already, than letting a robot write a letter, that he should afterwards identify again. So, in this example a labeling device with a unique ID for each petri dish / each batch should be used which could either be a normal 1D barcode or even a state-of-the-art 2D marker that could additionally be used for pose estimation.

All in all, we are not only looking at a direct 1:1 mapping of the human arm trajectory to the robot arm trajectory and a perfect replication of the human actions but moreover we are focusing on a feasible execution of the tasks with the goal of a traceable successful execution of the required process.



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## 4.3 Process steps and Process Variability

As stated in the project plan, T1.1 Use Case Specification is defined firstly in M1-11 and additionally from M25-45. This, in addition with T1.3 Robot-friendly design guidebook (M25-45), will tackle specifically the process steps which should be done in a different way by a robot in contrast to a human in the upcoming reporting periods.

As mentioned in the chapter before we already encountered different **steps that are prone to be not executed by a robot as they were executed by the human**. These will be detailed out in T1.3 "Robot-friendly design rulebook" but for now these are:

- Labeling with a pen vs. using a labeling machine
- Cutting with a knife vs. a cutting machine or sharp robot finger attachments

These and others will be evaluated further but still the main goal of TraceBot is also to use the robot for the majority of tasks and thus our goal is to be as close as possible to the human execution.

Considering the **variability** observed, we consider that the development of the programming cognitive interface (see task 3.6) will permit to handle the majority of it. The cognitive interface will provide access to the high-level behaviors the robot is able to perform. This will permit the operator to schedule the operations in his/her preferred orders, as long as the overall process sequencing remains coherent. Also, the cognitive interface will enable to let the operator configure some of the generic operations, to set the precise sterility set used, and the different containers available (e.g., containing the sample, the wetting liquid, etc.).

Thus, the operator is able to cover **small adaptations** to the process by the cognitive interface by himself. As the sterility testing use cases (and also the majority of pharmaceutical use cases in sterile environment) are regulated and follow a standardized operation procedure one can expect no bigger adaptations to the defined process workflow.

Note that this would presuppose that the desired item is already known by the system. If this is not the case, the learning methodology may be employed to deduce from the human demonstration (to be developed in task 3.5) how to grasp and manipulate the new object. Nevertheless, the complete insertion of such new object in the full modeling scheme would require updating the perception model and the Digital Twin scene.



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## 4.4 Isolated Use Case(s)

The progressive development of the physical prototype and of its software capabilities requires selecting in the complete sterility process a subset of operations which can be reasonably implemented. This is the purpose of the isolated use cases.

An isolated use case is a **subset** of the real full process. The first isolated use case considered can be seen in Fig. 10, which is the third sub-task of the full sterility testing use case described in section 4.2.2.

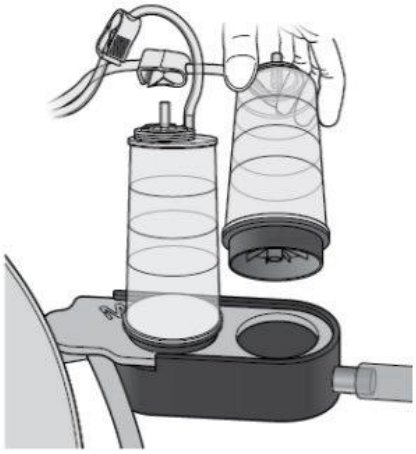

Fig. 10 Fit canister to drip tray

As one can see, this sub-task involves the mounting of the sterility kit or the “fit canisters to drain” task which consists of the sub-tasks of “detect canister”, “grab canister”, “move towards tray” and “insert canister” and thus it includes vision as well as manipulation steps. Regarding the robotic execution it not only requires pick and place capabilities but also insertion of one object into another. If possible, we also want to already include some Digital Twin functionalities in this early state of the process.

This complexity of such a simple task can also be seen in Fig. 11 where the sub-tasks are further subdivided into atomic process steps and are even associated with the responsible work package lead, as it was distributed to reach the first (software) integration milestone.

This example is also interesting to highlight the gap that may exist in between a human process description as we did for the sterility testing process, and its implementation for automation, since the latter needs to consider all specificities and requirements of the implementation, which are not necessarily directly related to elements of a regular human process analysis. Nevertheless, the encapsulation of the operations (with step and sub step in this document) should drive us to an appropriate level of mapping in between the human and the robot process (as presented with the four main blocks of the process in the following figure).



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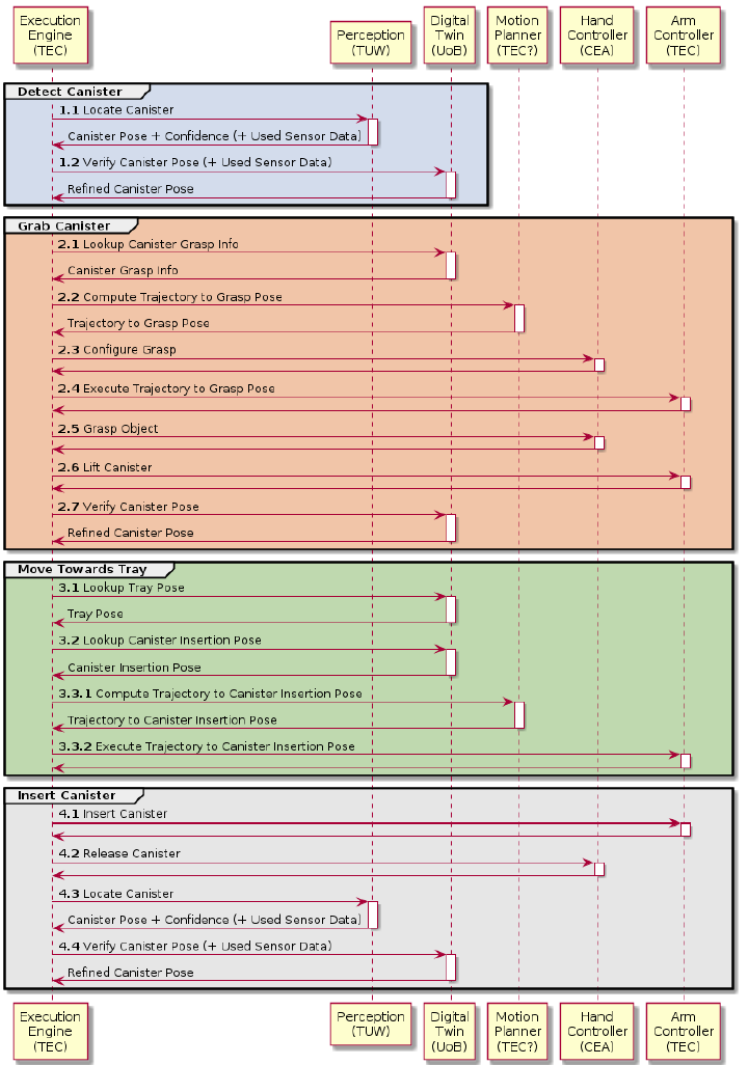


Fig. 11 SysML visualization of isolated use case steps

More isolated use cases like this one will be defined, where we go more into detail regarding the robotic process implementation, assuming with this approach we will progressively put together the building blocks required to complete most of the operations for the final (full) use case.



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## 4.5 Timeline and Content of Isolated Use Cases

Based on the overall use of TraceBot the chosen use case of sterility testing is subdivided into a set of isolated use cases. This is done because as a research and innovation action we are not targeting a full coverage of the sterility testing use case, but we are focusing on relevant steps and robotic actions that are necessary for robots operating in sterile environments. Thus, we chose the following milestones covering all challenging and/or critical points that can also be found in the sterility testing use case. But, once more, we are not targeting the full execution of all steps.

| **Milestone** | **Demo** | **From step** |
|---|---|---|
| **MS2** | Canister insertion | 3.1 |
| | Needle cap removal | 4.1 (6 as well |
| | Needle insertion | 4.2 (6 as well) |
| *Additional demos* | | |
| | Single Finger Demo | All manipulation steps |
| | PoC of Audit Trail pipeline | All steps |
| **MS3** | Red plug insertion – detach | 5.7 (wetting) |
| | Bottle (with tube) in holder | 5.2 (wetting) |
| | Close the clamp, with dexterous gripper | 9.5, 9.12 |
| | Liquid transfer | All steps with liquid transfer |
| *Additional demos* | | |
| | Multi-finger hand demo | All manipulation steps |
| | MVP of Audit Trail pipeline | All steps |
| **MS4** | Insert tube into pump | 3.2 |
| | Open pack | 2.1 |
| | Take canister out of the pack | 2.2 |
| | Bi-manual yellow plug insertion | 9.1 – 9.2 |
| *Additional demos* | | |
| | Combined demo | 2->3->4->5 |
| | Liquid transfer monitoring (DT-wise) | All steps with liquid transfer |
| | Final Audit trail | All steps |

With these isolated use cases associated with the four milestones we approach the full process, and the aforementioned points include:

- All relevant categories:
    - Pick and place, insert/attach, pull out/detach, complex (e.g., squeeze)



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- All relevant verification methodologies:
  - visual, tactile, functional
- All relevant technical challenges:
  - entangling of tubes, small tolerance fits (peg-in-hole insertion), transparent objects, deformable objects, perforating, small objects, force control, dexterous manipulations, robust location, and many more…
- All relevant objects:
  - bottles, canisters, plugs, cables, needle, pump, etc.

And with that one can say that all major technical challenges of the sterility testing use case will be covered by the isolated use cases. On top of that one can say that also other tasks/steps (of the sterility testing use case and also in general use cases in sterile environments) can be seen as achieved as they are very similar to the presented ones. All tasks/steps that are not explicitly investigated "just" require more resources (and are not additional technical challenges) to be fulfilled and are thus not in scope of a research and innovation action but would be the next steps towards a final implemented system.

## 4.6 Challenging the system

In the end, we would like to challenge the system. From the use case specification and the main goal of verification (w.r.t D1.3 (Cichon & Coulon, 2022)) the challenge is always to detect and document any deviations. To which extend deviations are tolerable needs to be defined and/or learned throughout the process. For example, for the human when piercing the septum with the needle, the required force is not always the exact same as it depends on the inclination angle, the septum quality, the needle diameter etc. but for a robotic system one would design it in a way that it is always the same and thus for now the challenge would lie in the detection of any deviation and the seamless audit trail.

Challenges regarding technical realization like "the system cannot handle that because its fingers are too bulky" are not being investigated/challenged from the use case/verification perspective. From our perspective it could be of interest if our system can cope with different input containments (like vials with screw head closure, break up vials, syringes, bottles – which are also used in reality) or with different samples (samples vary especially in flowability etc. and sometimes other steps are involved) instead of challenging technical limitations that are due to our technical concept and implementation.

How to exactly formulate challenges for the final system still needs to be defined and will also be part of the next deliverables. WP1 main target is to define the use case, and how we will, within the integration stage, verify that from the use case perspective the system performance is on a feasible level.

# 5 Deviations from the workplan

none.



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# 6 Conclusion

The description of the use case of sterility testing is based on a set of videos provided by companies involved in the Advisory Board, and effectively applying this process in their laboratories. The analysis mainly consisted so far to divide the use case hierarchically down to atomic (robot-execution-ready) steps, whereas all tasks and subtasks are documented including video-snippets, descriptions, and links. Especially the automation of this documentation generator leads not only to a very good and feasible workflow to always update and keeping the use case specification up to date, but it also enables us to derive problems and bottlenecks in the process. Iterative, upcoming updates include special focus on the differences/variances observed across the different videos we could process.

## 6.1 What we already achieved

☐ With the **automated workflow generator,** we achieved a single source of truth that is always up to date giving the most comprehensive use case description that can also be used to identify bottlenecks in implementing the process with robots.

☐ Based on the use case description we could already identify most of the used/handled **objects** and are iteratively updating the workflow to have a full picture of all **objects** currently used, **variants** – in terms of process steps, objects used, or handling operations – in between different companies (or even within one). One aspect of interest is that it may not make sense to reproduce with the robot some of the human operations as they are done, and discussion with the relevant stakeholders is needed to consider different robotic approaches to get to the same result (e.g., writing with a pen vs. labeling device, or having a direct data connection with standardized interfaces like SILA)

☐ The iterative and progressive development of the TraceBot process required us to define **isolated use cases**, which are getting implemented. The first one developed, the canister insertion, has been detailed in the document. We will in the next iteration of this document collect the other use case description.

## 6.2 What is next

☐ We will now continue **utilizing and completing** the use case description. We will identify and describe the main robotic challenges, in term of perception, manipulation, reasoning, to provide a common ground to the interested community, and possibly foster comparison, collaboration in the lab automation community.

☐ In the spirit of the first **isolated use case**, we will continue selecting elements of the complete process for the integration purposes, and study in more detail the operations required. This will take the overall project advancement and progress into account. All these additional use cases will be detailed in the second iteration of this deliverable.

☐ We would like to make this material **accessible to the community**. A direct and simple approach is making the use case description as hosted in the GitLab repository accessible, and we are



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looking at other ways to disseminate this material, which could be used to position related work and possibly compare advancement.

# 7 References

Cichon, T., & Coulon, C.-H. (2022). *TraceBot deliverable D1.3 - Verification Plan*.

Merck Millipore Sigma. (2021, 04). *Steritest(R) Symbio Pumps*. Retrieved from Merck: https://www.merckmillipore.com/



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# 8 Appendix

The following table is a working document which is the basis for Section 4.5 “Timeline and Content of Isolated Use Cases”.

Table 4 Isolated Use Cases: working document

| Milestone | Num | Name | Objects manipulated | Technical challenge | Verification | Category | Rationale | Who & What |
|---|---|---|---|---|---|---|---|---|
| MS2 | 3.1 | Canister Insertion | canister | Entangle tubing, small tolerance to fit canister (peg in hole insertion), transparent object | Visual, DT, tactile, AV: canister in tray | Pick and place, insert | 1st envisioned real implementation. | UOB: Knowledge Representation of the sterility testing use case; Basic robot simulation and canister manipulation capabilities based on simulator. |
| | 4.2 | Needle Insertion | Needle, bottle | Perforating, forces | Check force profile (tactile verification) Needle vs. septum location (visual verification) | Insert / attach | transparent object, Specific manipulation law, small error tolerance small object, force to manipulate | UOB: Basic robot simulation of real-world robot and object interaction; Ontology extension towards Action representation and link into the Skill Engine of TECN. |
| | 4.1 | Remove Needle Cap | needle | Small object, force | can see needle tip (visual verification) | Pull out detach | | UOB: Representation and reasoning about the physics of nested and force-constrained objects. |
| | --- | Tactile Demo on Finger | None | Finger capabilities | None | Manipulation | Iteratively evaluate the finger capabilities | CEA: First demo on one exemplary finger |
| MS3 | 5.7 | Bottle with tube in holder | Bottle plugs | Connected, multiple objects | Visual, DT | Insert/attach | Insert connected parts | Integration effort especially w.r.t. manipulation |
| | 5.2 | Insert plugs (Wetting) | plugs | Small object, force | Location of plug on canister (VV) Force for placing the plug (TV) | insert | small object, force to manipulate deformable object (learning demo) | UOB: Action representation of plug and cap attachment operations in the hybrid knowledge base. |
| | 9.5, 9.12 | Closing clamps | Clamp | Small object, dexterous grippers | Functional / “click” | Manipulation | Dexterous manipulation required, functional verification | Integration effort especially w.r.t. verification |
| | --- | Liquid Transfer | All steps with liquid transfer | Data connection | Data connection | Device handling | Operation of devices (bi-directional data transfer) | Integration effort especially w.r.t. data connection |
| | --- | Tactile Demo on multi-fingered Hand | None | Finger capabilities | none | Manipulation | Iteratively evaluate the finger capabilities | CEA: Second demo, now on multi finger hand |

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| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| MS4 | 3.2 | Insert Tube into Pump | tube | Flexible objects, force to insert | Pull at both ends of tube (tactile verification) | insert | bimanual operation, force to insert, transparent object<br><br>small object, force to manipulate, connected parts | UOB: Modelling of the tube, robot, and pump interaction. |
| | 2.1 | Open Pack | Pack, Tyvek foil | Flexible material, small pull-tab<br>Robust locate of pack and contents | Foil removed | Pick & place, pull out / detach | Complex handling of foil | UOB: Modelling of pre- and post-conditions of the pack in the hybrid knowledge base. |
| | 2.2 | Take canister out of the pack | Pack, Tyvek foil | | Get sth. Out of sth. | Pick & place, pull out / detach | Take out of housing | CEA: complex manipulation with hand |
| | 9.1 | Media filling open clamp | Clamp | Force | Detect click (Tactile Verification) | Complex (squeeze) | Complex finger manipulation task | Integration effort manipulation and verification |
| | 9.2 | Media filling – close clamp | clamp | Force | Shape of open clamp (Visual Verification) | Complex | Complex finger manipulation task | CEA: finger manipulation<br>UOB: Interaction-based modelling of the different clamp states and derived functional conditions and action effects. |
| | --- | DT liquid transfer monitoring | Pump | Pump interfacing with DT | DT, functional verification | Device handling | Operation of devices (bi-directional data transfer) combined with DT | UOB: DT |
| | --- | Combined Demo (2>3>4>5) | All of the above | All of the above | All of the above | All of the above | Complete system | Integration effort |
| | --- | Final Audit Trail Demonstration | All of the above | Audit trail | all of the above | Audit trail | Final audit trail | UOB: Production and Exploration of timestamped action trees, robot motions and object states from NEEM-based Audit Trails of a Traceable Process execution. |

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