Verification & Validation Plan

Deliverable 1.5

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Abstract	This verification and validation plan outlines the approach used to ensure that TraceBot meets its design requirements and functions as expected. Its goal is to ensure that all relevant parties are informed and involved in the validation process.

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Versioning and Contribution History

Version	Date	Modified by	Modification reason
v.01	03.06.2024	Coulon, INV	Document created with first batch of test cases
v.02	17.06.2024	Coulon, INV	Added test cases from AST
v.03	19.06.2024	Coulon, INV	Added test cases for clamp
v.04	20.06.2024	Coulon, INV	Updated the test case format to be more concise
v.05	20.06.2024	Coulon, INV	Added test cases for the tube insertion and kit unpacking based on partner feedback
v.06	21.06.2024	Coulon, INV	Added executive summary
v.07	24.06.2024	Coulon, INV	Added introduction
v.08	27.06.2024	Coulon, INV	Updated tests using feedback from AST
v.09	20.08.2024	Mania, TUB	Internal revision
V.10	22.08.2024	Raveendran, AST	Internal revision
V1.0	02.09.2024	Coulon, INV	Final Version

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1 Executive Summary

This verification and validation plan outlines the structured approach used to ensure that TraceBot meets its design requirements and functions as expected. The plan is intended for stakeholders at various levels within our partner organizations, third parties interested in adapting TraceBot technologies, and regulatory bodies. Its goal is to ensure that all relevant parties are informed and involved in the validation process. It forms the basis for a thorough and transparent acceptance of TraceBot within the pharmaceutical industry.

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2 Introduction

Verification and validation are essential processes to guarantee that a system fulfills its requirements. This comprehensive verification and validation plan outlines the procedures for ensuring the functionality and quality of the TraceBot demonstrator.

Two distinguishing features of TraceBot are its built-in verification and traceability capabilities. Built-in verification allows the system to automatically confirm the successful execution of a task (or detect a failure). Traceability enables the system to provide documented evidence of a successful (or unsuccessful) program execution via the generation of an audit trail. Given these capabilities, this verification and validation plan pays special attention to ensuring the system can robustly detect and document failures. Phrased differently, a key objective of this plan is to "verify TraceBot's built-in verification". Consequently, the tests outlined in this document often push the system beyond typical conditions. Forced failures, for example, are frequently used to challenge the system and demonstrate its robust verification and traceability capabilities.

The scope of this plan includes the definition of scenarios, programs, and test cases used to validate the system. Each scenario outlines the setup of the robot workspace for testing, while each program specifies the actions the robot should perform. A test case combines a scenario and program with a success criterion to validate specific aspects of the system's functionality. The system is considered to be validated if it passes all test cases.

Given the research-oriented nature of the TraceBot project, this document aims to validate the core technologies and novel capabilities developed for TraceBot. As such it does not consider standard failure modes like power outages and malfunctioning computer hardware that are normally considered as part of a Failure Modes and Effects Analysis (FMEA). A more comprehensive FMEA was developed by AST. Note, however, that even though the TraceBot FMEA considers a wider range of failure modes than this document, it too focuses on TraceBot's core contributions since a full FMEA would require a significant time investment for aspects that are not directly related to the core development of TraceBot (see D6.3 "Construction of mechanical framework" for details).

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3 Scenarios

This section defines four base scenarios that describe how the robot's environment should be set up before running one of the tests in Section 5. The first two scenarios describe setups that are used to test individual actions, operations, or other isolated aspects of the system. The third and fourth scenario correspond to steps in the sterility testing use case targeted by TraceBot[1]. They describe setups encountered during the system's normal operation. If a test requires deviations in order to force the system to fail or automatically detect a failure, the necessary scenario modifications are outlined as part of the corresponding tests in Section 5.

Name	**S1 Empty workspace**
Description	○ There are no objects in the robot workspace.

Name	**S2 Pump only**
Description	○ The sterility testing pump is set up in the robot workspace and can be seen by the camera. ○ Apart from the sterility testing pump, no other objects are present in the robot workspace.

Name	**S3 Kit mounting**
Description	○ The sterility testing pump is set up in the vicinity of the robot. ○ The sterility testing kit has been unpacked. The canisters, needle and tube are placed in the vicinity of the robot. ○ There are no other objects in the vicinity of the robot and all objects can be seen by the camera. ○ The canisters are standing upright. ○ The tube connects the two canisters with the needle. ○ The canisters, needle and tube have sufficient distance to other objects i.e. they can be picked up without causing a collision.

Name	**S4 Needle insertion**
Description	○ The sterility testing pump is set up in the vicinity of the robot. ○ The canisters have been inserted into the trays of the pump. ○ The tube connects the two canisters with the needle. ○ The tube has been inserted into the pump. ○ The needle (including the blue cap) is placed next to the pump. It has sufficient distance to other objects, i.e. it can be picked up without causing a collision. ○ The bottle is placed in the vicinity of the robot (upright orientation). ○ All of the above-mentioned objects can be seen by the camera. ○ Apart from the above-mentioned objects, no other objects are present in the robot workspace.

[1] https://tracebot.gitlab.io/tracebot_showcase/root_index/

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4 Programs

This section provides an overview of the programs used to validate the TraceBot system.

Name	**Locate canister**
Description	Uses the computer vision subsystem to locate all canisters in the scene. The robot does not move.

Name	**Grab canister**
Description	Uses the computer vision subsystem to locate all canisters in the scene. Afterwards, the robot grabs one of the canisters.

Name	**Insert canister**
Description	Uses the computer vision subsystem to locate all canisters in the scene. Afterwards, the robot grabs two canisters and inserts them into the trays of the sterility testing pump.

Name	**Needle insertion**
Description	Uses the computer vision subsystem to locate the needle and bottle. Afterwards the robot picks up the needle with one of its arms and removes the needle cap using the other arm. Then, the robot inserts the needle into the bottle.

Name	**Clamp localization**
Description	Uses the computer vision subsystem to locate all clamps, which are placed on the tube, in the scene. The robot does not move.

Name	**Clamp closure**
Description	The robot closes one of the clamps using the CEA gripper. The clamp is placed in a fixed position using a custom holder, i.e. it does not need to be located.

Name	**Tube insertion**
Description	The robot inserts the tube into the sterility testing pump using its two arms/grippers. The tube is manually inserted into the robot grippers such that the robot holds one end of the tube in each gripper.

Name	**Kit opening**
Description	The robot opens a sterility testing kit by removing the cover from the plastic packaging.

5 Test Cases

The system is successfully validated if it passes all of the tests in this section. Each test consists of its name, the list of subsystems targeted by the test, the scenario in which the test should be run, the

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external influences the system is exposed to, the program that should be run and a criterion that defines the requirements for successfully completing the test. The considered subsystems include the tactile verification, computer vision, digital twin and audit trail subsystems that make up TraceBot. The tests are grouped into four categories: canister handling, needle handling, clamp handling and miscellaneous, where the latter category consists of isolated tests for the tube insertion and kit opening steps.

5.1 Canister handling

Name	**A1 Canister in one of two predefined positions (1/2)**
Subsystems	Computer vision, digital twin, audit trail
Scenario	S2 Pump only but with the following changes: o There are two predefined locations with good visibility where a canister can be placed so that it can be picked up without causing a collision with other objects. o A canister is placed in the first of the two predefined positions.
External influences	None
Program	Locate canister
Success criterion	o The system successfully detects the canister. o A canister is spawned in the digital twin. The pose of the spawned canister matches the pose of the real-world canister. o The audit trail indicates a successful execution.

Name	**A2 Canister in one of two predefined positions (2/2)**
Subsystems	Computer vision, digital twin, audit trail
Scenario	S2 Pump only but with the following changes: o There are two predefined locations with good visibility where a canister can be placed so that it can be picked up without causing a collision with other objects. o A canister is placed in the second of the two predefined positions.
External influences	None
Program	Locate canister
Success criterion	o The system successfully detects the canister. o A canister is spawned in the digital twin. The pose of the spawned canister matches the pose of the real-world canister. o The audit trail indicates a successful execution.

Name	**A3 Canister near edge of table**
Subsystems	Computer vision, digital twin, audit trail
Scenario	S2 Pump only but with the following changes: o A canister is placed near the edge of the table (close to the robot base/bottom of the camera view but still fully visible).
External influences	None
Program	Locate canister
Success criterion	o The system successfully detects the canister. o A canister is spawned in the digital twin. The pose of the spawned canister matches the pose of the real-world canister. o The audit trail indicates a successful execution.

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Name	**A4 Two canisters in predefined positions**
Subsystems	Computer vision, digital twin, audit trail
Scenario	S2 Pump only but with the following changes: o There are two predefined locations with good visibility where a canister can be placed so that it can be picked up without causing a collision with other objects. o A canister is placed in each of the predefined positions.
External influences	None
Program	Locate canister
Success criterion	o The system successfully detects both canisters. o Two canisters are spawned in the digital twin. The poses of the spawned canisters match the poses of the real-world canisters. o The audit trail indicates a successful execution.

Name	**A5 Touching canisters**
Subsystems	Computer vision, digital twin, audit trail
Scenario	S2 Pump only but with the following changes: o Two canisters are placed in the robot workspace. o The sides of the two canisters touch each other. o The canisters do not obstruct each other from the camera view.
External influences	None
Program	Locate canister
Success criterion	o The system successfully detects both canisters. o Two canisters are spawned in the digital twin. The poses of the spawned canisters match the poses of the real-world canisters. o The audit trail indicates a successful execution.

Name	**A6 Closeby canisters**
Subsystems	Computer vision, digital twin, audit trail
Scenario	S2 Pump only but with the following changes: o Two canisters are placed in the robot workspace. o The canisters are placed next to each other with one canister slightly in front of the other. o The canisters do not obstruct each other from the camera view.
External influences	None
Program	Locate canister
Success criterion	o The system successfully detects both canisters but halts due to the canisters being too close to each other. o Two canisters are spawned in the digital twin. The poses of the spawned canisters match the poses of the real-world canisters. o The audit trail indicates a failed execution because the system is not able to grasp the canisters.

Name	**A7 Canister partially occluded by another canister**
Subsystems	Computer vision, digital twin, audit trail
Scenario	S2 Pump only but with the following changes: o Two canisters are placed in the robot workspace.

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	○ One of the canisters partially occludes the other.
External influences	None
Program	Locate canister

Success criterion	○ The system either successfully detects both canisters or halts due to not being able to detect the canisters.
	○ If the system is able to detect both canisters:
	    ○ The two canisters are spawned in the digital twin. The poses of the spawned canisters match the poses of the real-world canisters.
	    ○ The audit trail indicates a successful execution.
	○ Otherwise:
	    ○ The audit trail indicates a failed execution because the canisters cannot be detected.

Name	**A8 Canister partially occluded by fiducial marker**
Subsystems	Computer vision, audit trail
Scenario	S2 Pump only but with the following changes: ○ A single canister is placed in the robot workspace. ○ The canister is partially occluded by a fiducial marker.
External influences	None
Program	Locate canister
Success criterion	○ The system halts because the canister cannot be reliably detected. ○ The audit trail indicates a failed execution because the canister cannot be detected.

Name	**A9 Canister at edge of workspace**
Subsystems	Computer vision, digital twin, audit trail
Scenario	S2 Pump only but with the following changes: ○ A single canister is placed in the robot workspace. ○ The canister is placed at the right edge of the workspace. ○ The right half of the canister is not visible/outside the camera's field of view.
External influences	None
Program	Locate canister
Success criterion	○ The system successfully detects the canister. ○ A canister is spawned in the digital twin. The pose of the spawned canister matches the pose of the real-world canister. ○ The audit trail indicates a successful execution.

Name	**A10 Canister occluded by transparent box**
Subsystems	Computer vision, digital twin, audit trail
Scenario	S2 Pump only but with the following changes: ○ A single canister is placed in the robot workspace. ○ A transparent box is placed in front of the canister. The canister can be seen through the transparent box.
External influences	None
Program	Locate canister
Success criterion	○ The system successfully detects the canister. ○ A canister is spawned in the digital twin. The pose of the spawned canister matches the pose of the real-world canister.

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	○ The audit trail indicates a successful execution.

Name	**A11 No canister**
Subsystems	Computer vision, audit trail
Scenario	S2 Pump only (without changes)
External influences	None
Program	Locate canister
Success criterion	○ The system halts because the canister cannot be detected. ○ The audit trail indicates a failed execution due to the missing canister.

Name	**A12 Canister lying on its side (side view)**
Subsystems	Computer vision, digital twin, audit trail
Scenario	S2 Pump only but with the following changes: ○ A single canister is placed in the robot workspace. ○ The canister is lying on its side and facing the camera with its side.
External influences	None
Program	Locate canister
Success criterion	○ The system halts because one of the canisters is in an unexpected orientation. ○ A canister is spawned in the digital twin. The pose of the spawned canister matches the real-world pose (lying on its side). ○ The audit trail indicates a failed execution due to an unexpected canister orientation.

Name	**A13 Canister lying on its side (front view)**
Subsystems	Computer vision, digital twin, audit trail
Scenario	S2 Pump only but with the following changes: ○ A single canister is placed in the robot workspace. ○ The canister is lying on its side and facing the camera with its front.
External influences	None
Program	Locate canister
Success criterion	○ The system halts because one of the canisters is in an unexpected orientation. ○ A canister is spawned in the digital twin. The pose of the spawned canister matches the real-world pose (lying on its side). ○ The audit trail indicates a failed execution due to an unexpected canister orientation.

Name	**A14 Upside down canister**
Subsystems	Computer vision, digital twin, audit trail
Scenario	S2 Pump only but with the following changes: ○ A single canister is placed in the robot workspace. ○ The canister is leaning upside down against the sterility pump.
External influences	None
Program	Locate canister
Success criterion	○ The system halts because one of the canisters is in an unexpected orientation.

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	○ A canister is spawned in the digital twin. The pose of the spawned canister matches the real-world pose (leaning upside down against the pump). ○ The audit trail indicates a failed execution due to an unexpected canister orientation.

Name	**A15 Canister in center of right side of robot workspace**
Subsystems	Computer vision, digital twin, audit trail
Scenario	S2 Pump only but with the following changes: ○ A single canister is placed in the robot workspace. ○ The canister is placed in the center of the right side of the robot workspace.
External influences	None
Program	Grab canister
Success criterion	○ The system successfully detects the canister and picks it up. ○ A canister is spawned in the digital twin. The pose of the spawned canister matches the real-world pose. ○ The audit trail indicates a successful execution.

Name	**A16 Canister in center of robot workspace**
Subsystems	Computer vision, digital twin, audit trail
Scenario	S2 Pump only but with the following changes: ○ A single canister is placed in the robot workspace. ○ The canister is placed in the center of the robot workspace, between the left and right gripper.
External influences	None
Program	Grab canister
Success criterion	○ The system successfully detects the canister and picks it up. ○ A canister is spawned in the digital twin. The pose of the spawned canister matches the real-world pose at all times. ○ The audit trail indicates a successful execution.

Name	**A17 Disappearing canister**
Subsystems	Computer vision, digital twin, audit trail
Scenario	S2 Pump only but with the following changes: ○ A single canister is placed in the robot workspace.
External influences	The canister is manually removed from the robot workspace after it has been detected by the vision system.
Program	Grab canister
Success criterion	○ The system halts because the canister could not be picked up. ○ A canister is spawned in the digital twin. The pose of the spawned canister matches the real-world pose at the time of detection. ○ The audit trail indicates a failed execution due to a failed canister pick up.

Name	**A18 Moving pump**
Subsystems	Computer vision, digital twin, audit trail
Scenario	S2 Pump only but with the following changes: ○ A single canister is placed in the robot workspace.

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External influences	The sterility pump is manually moved after it has been detected by the vision system to force the canister insertion to fail.
Program	Canister insertion
Success criterion	○ The system should halt due to a failed canister insertion. ○ The digital twin indicates a successful canister insertion, as it is not aware that the real-world pump has been moved. ○ The real-world canister insertion fails and the canister is dropped. ○ The audit trail indicates a failed execution due to a pose mismatch between the canister in the digital twin and the real-world after the insertion attempt.

Name	**A19 Sliding canister**
Subsystems	Tactile verification, audit trail
Scenario	S3 Kit mounting (without changes)
External influences	The gripper is hardcoded to open slightly while moving one of the canisters (thereby loosening its grip on the canister and causing the canister to slip).
Program	Canister insertion
Success criterion	○ The system halts due to an error during the canister insertion. ○ The tactile verification subsystem detects that the canister is slipping. ○ The audit trail indicates that the canister was not grasped in a secure manner.

Name	**A20 Canister offset**
Subsystems	Computer vision, digital twin, audit trail
Scenario	S3 Kit mounting (without changes)
External influences	One of the canisters is manually removed from the tray of the pump and placed next to the pump after it has been inserted into the tray by the robot.
Program	Canister insertion

Success criterion	○ Start of program:
	    ○ The computer vision subsystem detects all objects in the scene.
	    ○ All objects in the scene are spawned in the digital twin.
	○ After inserting the canister and manually removing it from the tray:
	    ○ The system halts due to an unexpected real-world canister pose.
	    ○ The audit trail indicates a failed execution due to a pose mismatch.

Name	**A21 Tubes caught in an obstacle**
Subsystems	Tactile verification, audit trail
Scenario	S3 Kit mounting (without changes)
External influences	While manipulating one of the canisters, the tube connecting the canisters and needle is manually pulled to simulate the tubes being caught in an obstacle.
Program	Canister insertion
Success criterion	○ The system halts because the tactile verification subsystem detects that the canister is not grasped in a secure manner. ○ The audit trail indicates a failed execution.

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5.2 Needle handling

Name	**B1 Needle insertion with normal bottle**
Subsystems	Computer vision, tactile verification, digital twin, audit trail
Scenario	S4 Needle insertion (without changes)
External influences	None
Program	Needle insertion
Success criterion	○ The system successfully inserts the needle into the bottle. ○ The computer vision subsystem detects all objects in the scene. ○ The tactile verification subsystem detects the needle insertion. ○ All objects in the scene are spawned in the digital twin. The poses of the spawned objects match their real-world counterparts. ○ The audit trail indicates a successful execution.

Name	**B2 Needle insertion with manipulated bottle (1)**
Subsystems	Computer vision, tactile verification, digital twin, audit trail
Scenario	S4 Needle insertion but with the following changes: ○ The bottle cap/membrane is missing
External influences	None
Program	Needle insertion
Success criterion	○ The system halts after a failed attempt to insert the needle into the bottle. ○ The computer vision subsystem detects all objects in the scene. ○ The tactile verification subsystem detects that the needle insertion failed. ○ All objects in the scene are spawned in the digital twin. The poses of the spawned objects match their real-world counterparts. ○ The audit trail indicates a failed execution because the force required to insert the needle is outside of the expected bounds.

Name	**B3 Needle insertion with manipulated bottle (2)**
Subsystems	Computer vision, tactile verification, digital twin, audit trail
Scenario	S4 Needle insertion but with the following changes: ○ The bottle cap/membrane is replaced with aluminium foil
External influences	None
Program	Needle insertion
Success criterion	○ The system halts after a failed attempt to insert the needle into the bottle. ○ The computer vision subsystem detects all objects in the scene. ○ The tactile verification subsystem detects that the needle insertion failed. ○ All objects in the scene are spawned in the digital twin. The poses of the spawned objects match their real-world counterparts. ○ The audit trail indicates a failed execution because the force required to insert the needle is outside of the expected bounds.

Name	**B4 Needle insertion without bottle**
Subsystems	Computer vision, digital twin, audit trail
Scenario	S4 Needle insertion but with the following changes: ○ The bottle is missing
External influences	None
Program	Needle insertion

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Success criterion	○ The system halts because the bottle cannot be detected. ○ The computer vision subsystem detects all objects in the scene. ○ All objects in the scene are spawned in the digital twin. The poses of the spawned objects match their real-world counterparts. ○ The audit trail indicates a failed execution due to the missing bottle.

Name	**B5 Needle insertion without needle**
Subsystems	Computer vision, digital twin, audit trail
Scenario	S4 Needle insertion but with the following changes: ○ The needle is missing
External influences	None
Program	Needle insertion
Success criterion	○ The system halts because the needle cannot be detected. ○ The computer vision subsystem detects all objects in the scene. ○ All objects in the scene are spawned in the digital twin. The poses of the spawned objects match their real-world counterparts. ○ The audit trail indicates a failed execution due to the missing needle.

Name	**B6 Disappearing needle**
Subsystems	Computer vision, digital twin, audit trail
Scenario	S4 Needle insertion (without changes)
External influences	The needle is manually removed from the robot workspace after it has been detected by the vision system.
Program	Needle insertion
Success criterion	○ The system halts because the needle could not be picked up. ○ The needle is spawned in the digital twin. The pose of the spawned needle matches the real-world pose at the time of detection. ○ The audit trail indicates a failed execution due to a failed needle pick up.

Name	**B7 Missing needle cap**
Subsystems	Computer vision, digital twin, audit trail
Scenario	S4 Needle insertion but with the following changes: ○ The needle cap has already been removed
External influences	None
Program	Needle insertion
Success criterion	○ The system halts due to the missing needle cap. ○ The computer vision subsystem detects all objects in the scene. ○ All objects in the scene are spawned in the digital twin. The poses of the spawned objects match their real-world counterparts. ○ The audit trail indicates a failed execution due to the missing needle cap.

Name	**B8 Sliding needle**
Subsystems	Tactile verification, audit trail
Scenario	S4 Needle insertion (without changes)
External influences	The gripper is hardcoded to open slightly while moving the needle (thereby loosening its grip on the needle and causing the needle to slip).
Program	Needle insertion
Success criterion	○ The system halts due to an error during the needle insertion.

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	○ The tactile verification subsystem detects that the needle is slipping. ○ The audit trail indicates that the needle was not grasped in a secure manner.

5.3 Clamp handling

Name	**C1 Clamp localization (upright orientation)**
Subsystems	Computer vision, digital twin
Scenario	S1 Empty workspace but with the following changes: ○ The red and white clamp are detached from the tube and placed in the robot workspace. ○ The clamps are in an upright orientation and can be seen by the camera.
External influences	None
Program	Clamp localization
Success criterion	○ The system successfully detects both clamps. ○ Two clamps are spawned in the digital twin. The poses of the spawned clamps match the poses of their real-world counterparts.

Name	**C2 Clamp localization (lying on their side)**
Subsystems	Computer vision, digital twin
Scenario	S1 Empty workspace but with the following changes: ○ The red and white clamp are detached from the tube and placed in the robot workspace. ○ The clamps are lying on their side and can be seen by the camera.
External influences	None
Program	Clamp localization
Success criterion	○ The system successfully detects both clamps. ○ Two clamps are spawned in the digital twin. The poses of the spawned clamps match the poses of their real-world counterparts.

Name	**C3 Clamp closure**
Subsystems	Tactile verification
Scenario	S1 Empty workspace but with the following changes: ○ A single clamp with a small piece of the tube is placed in a holder. ○ The clamp and holder are placed in a predefined position close to the robot.
External influences	None
Program	Clamp closure
Success criterion	○ The system closes the clamp using the robot gripper. ○ The tactile verification system detects the clamp closure event.

5.4 Miscellaneous

Name	**D1 Tube insertion**
Subsystems	Constrained-based robot control framework
Scenario	S2 Pump only (without changes)
External influences	A sufficiently large piece of the tube (~40 cm) is manually inserted into the robot grippers such that the robot holds one end of the tube in each gripper.

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Program	Tube insertion
Success criterion	The system successfully inserts the tube into the sterility pump.

Name	**D2 Kit opening**
Subsystems	Computer vision, tactile manipulation
Scenario	S1 Empty workspace with the following changes: o A sealed sterility testing kit is placed in the robot workspace. o The kit is placed such that the removable cover is pointing up.
External influences	None
Program	Kit opening
Success criterion	The system successfully removes the cover of the sterility testing kit using its grippers. The contents of the kit remain in their packaging.

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6 Deviations from the workplan

None

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7 Conclusion

This document outlined the verification and validation plan for TraceBot. The plan ensures that TraceBot is thoroughly tested and is intended to provide stakeholders and other interested parties with confidence in the performance and reliability of the technologies developed within the TraceBot project. To this end, a number of different scenarios, programs, and test cases that focus on the core technologies and novel capabilities of the TraceBot system were defined. The test cases cover a variety of actions including the canister handling, needle insertion, clamp closure, tube insertion and kit unpacking steps of the sterility testing use case. Special attention was given to the built-in verification and traceability features that distinguish TraceBot from other solutions. In doing so, this plan established a basis for further acceptance, fostering trust in TraceBot's accuracy and dependability.

Horizon 2020

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8 References

Horizon 2020

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