Test protocol for Receiving a

HomeCareObservation

07-03-24

The test protocol relates to the following standard:

|  |  |  |  |
| --- | --- | --- | --- |
| Standard’s name ENG | Standard’s name DK | **Version** | **Type** |
| Standard: HomeCareObservation | Kommunale Prøvesvar | 1.0.0 | HL7 FHIR  |

|  |
| --- |
| **Versioning** |
| **Version** | **Initials** | **Date** | **Description** |
| 1.0.0 | KRC/TMS | 07-03-24 | First release  |
|  |  |  |  |

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# Introduction

This is the test protocol for receiving a HomeCareObservation (DK: Kommunale prøvesvar).

It is important to note that **HomeCareObservation** in the first place is part of the project [‘Kommunale prøvesvar på ny infrastruktur’](https://medcom.dk/projekter/kommunale-proevesvar-paa-ny-infrastruktur/) with the purpose of carrying out a **production trial**. Therefore, this test protocol will reflect the scope agreed upon with the Sender, and Receiver, of HomeCareObsertion in the trial period. **This means that not all requirements in the standard may be part of this test protocol, e.g. the requirements for receiving cancellations and corrections.**

Documentation concerning HomeCareObservation and Governance (see [Background material](#_Background_material)) will be the subject of testing, and the test protocol will be continuously updated to reflect the requirements in the best way possible.

Versioning of the test protocol will follow the major- and minor-version of the standard but may have a patch version that is different from the standard’s patch-version.

**Regarding Sending** **an Acknowledgement:** Approval requires, that the system under test (SUT) is approved for sending FHIR Acknowledgements (DK: Kvittering). This test is managed in a separate test protocol for [Acknowledgement](https://medcomdk.github.io/dk-medcom-acknowledgement/).

## Purpose

The test protocol forms the basis for the tests, which must ensure that SUT complies with the established rules and requirements for the standard. The test protocol also forms the basis for the self-test that vendor carries out prior to a live test.

## Prerequisites for live test

The following prerequisites must be met prior to the live test:

1. The vendor has read the following standard documentation:
	* [Clinical guidelines for application](#_Baggrundsmaterialer_2)
	* [Use cases](#_Baggrundsmaterialer_2)
	* [Implementation Guide](#_Baggrundsmaterialer_2)
	* [Governance](#_Baggrundsmaterialer_2)
	* And other relevant materials, cf. the [background material](#_Baggrundsmaterialer_2).
2. The vendor has performed [self-test](#_Documentation_of_self-test), approved by MedCom.
3. The vendor has created the [relevant test persons](#_Test_examples_and) in system under test (SUT). Please note that one of these test persons must be a citizen with an E-cpr (a replacement personal identification number) in SUT.
4. The vendor uses the same version of SUT during self-test and live test.
5. Approval requires that SUT is approved for sending FHIR-Acknowledgement (DK: Kvittering).

## Documentation of self-test

**Self-test**

**Prior to the test, the vendor must have performed self-test, including successfully completed TouchStone self-tests, which are approved by MedCom.**

The self-test is documented by the vendor completing this test protocol.

For self-tests, only the following two columns must be completed by the vendor:

* [Test data]: is filled in with the file name(s), which are uploaded and downloaded.
* [Actual result]: is filled in with the results of the self-test and relevant descriptions.

The other columns are reserved for MedCom.

**During the self-test the vendor must document the test results by saving relevant files and screen dumps, and subsequently send these in a combined ZIP file (together with the completed test protocol) to** **fhir@medcom.dk****.**

All files and screen dumps must be named with:

* Standard name
* The number of the relevant test step
* Consecutive letter
* File type

Example: HomeCareObservation\_3.4\_A.xml

Alle filer og skærmdumps skal navngives med:

* Standard name
* The number of the relevant test step
* Consecutive letter
* File type

Eksempel: HomeCareObservation Message \_3.4\_A.xml or HomeCareObservation Message\_2.2\_B.png

## Background material

| **Name** | **Version** | **Link/reference** | **Description** |
| --- | --- | --- | --- |
| HomeCareObservation Dokumentations site |  | <https://medcomdk.github.io/dk_HomeCareObservations/>  | Documentation site with references to all relevant documentation, including:* Clinical guidelines and documentation (DK: Sundhedsfaglig dokumentation)
* Use cases

Technical specifications |
| HomeCareObservation Implementation Guide |  | <https://medcomfhir.dk/ig/homecareobservation/index.html>  | The FHIR technical guidelines for the standard. |
| Governance for MedCom FHIR  |  | <https://medcomdk.github.io/MedCom-FHIR-Communication/>  | Governance for MedCom’s FHIR standards, which describes general rules for all MedCom standards and if relevant specific rules for the standards.  |
| Acknowledgement documentation site |  | <https://medcomdk.github.io/dk-medcom-acknowledgement/>  | Documentation site with references to all relevant documentation, including:* Use cases (and matching test scripts) to be used in TouchStone
* Technical specifications

Test protocols and test scripts |
| SOP for MedCom’s test and certification |  | <http://svn.medcom.dk/svn/qms/Offentlig/SOPer/SOP-7.2-MedComs%20test%20og%20certificering_godkendelse.docx> | Description of test and certification of MedCom standards and other tests courses. |

## Test examples and test persons

|  |  |  |
| --- | --- | --- |
| **Name** | **Link/reference** | **Description** |
| Test examples | *In preparation*  | Test examples used during the test and approval for the trial. |
| Overview of the test persons to be used | <https://www.medcom.dk/opslag/koder-tabeller-ydere/tabeller/nationale-test-cpr-numre> | Overview of national test personal identification number (DK:CPR-nummer), that can be used during test. **Please notice:** During the test, the vendor must be able to use any of the test persons on the list. |

## Test tool

|  |  |  |
| --- | --- | --- |
| **Navne** | **Link/reference** | **Description** |
| FHIR-server with MedCom profiles | <https://fhir.medcom.dk/>  | FHIR-server that validates against MedCom's FHIR profiles. It is permitted to use the server for testing the upload/download of FHIR resources. To get access to the server contact MedCom at fhir@medcom.dk |
| TouchStone | <https://touchstone.aegis.net/touchstone/>  | Test tool for testing the FHIR standard. The vendor can get access to TouchStone as an organisation - either through a license that MedCom supplies (inquiry at fhir@medcom.dk), or a license that the vendor has acquired itself.Find [instructions for TouchStone](https://medcomdk.github.io/MedComLandingPage/assets/documents/TouchStoneGettingStarted.html) here |
| TouchStone test scripts | *In preparation*  | Test scripts relevant for the standard. Find [instructions for TouchStone](https://medcomdk.github.io/MedComLandingPage/assets/documents/TouchStoneGettingStarted.html) here |

## Test Result

The result for each test step is categorised based on the table below:

| **Marking** | **F1** | **F2** | **F3** | **F4** | **Ok** | **Not relevant** |
| --- | --- | --- | --- | --- | --- | --- |
| **Evaluation** | **Critical** | **Serious** | **Significant**  | **Less significant** | **Approved**  | **Not an error** |

To get the test and certification approved, the test protocol must consist exclusively of [F4] as well as [OK] results. All [F1], [F2] and [F3] must, therefore, be fixed prior to final approval.

When a test step isn’t relevant for the test course, it is noted with ‘Not relevant’.

Approval requires that SUT is approved for sending FHIR Acknowledgement (DK: Kvittering)

For further information, please read [MedCom’s test og certification](#_Baggrundsmaterialer_2).

# Information about vendor, system under test (SUT) and test result information

## Information about the vendor

This table must be completed by **the vendor** prior to the test.

|  |  |
| --- | --- |
| Company | Completed by vendor |
| Address | Completed by vendor |
| Contact person  | Completed by vendor |
| Telephone | Completed by vendor |
| E-mail | Completed by vendor |

## Information about system under test (SUT)

This table must be completed by **the vendor** prior to the test.

|  |  |
| --- | --- |
| System | Completed by vendor |
| Version | Completed by vendor |
| Description | Completed by vendor |
| Test type | [ ]  Self-test[ ]  Final test/certification |

## Information about the test result

Note: This table must be completed by MedCom when the test has been completed.

|  |  |
| --- | --- |
| Test date | 2023-01-01 |
| Test location | Completed by MedCom |
| Approved  | [ ]  Yes[ ]  No |
| Remarks | Completed by MedCom |
| Carried out by | Completed by MedCom. The name of the MedCom responsible (initials) for this test is inserted. |

# The test

This section describes the requirements which SUT must meet before final approval.

The test is divided into three sections:

1. [Test of TouchStone testscripts](#_Test_of_TouchStone)
2. [Test of requirements for content and flow/workflows](#_Test_of_requirements)
3. [Test of technical requirements](#_Test_of_general)

Test participants will be asked to complete tests as described in the tables.

## Documentation of the test

**Documentation of the test**

As valid documentation, the test participant or test manager must document completion by continuous screen dumps (.png/.jpeg) and/or files/log files (.xml/.json). **Before the test, it is agreed who is responsible for this.**

The following applies:

* The files must be viewable in a standard tool and must not require further processing by MedCom
* All files and screen dumps must be named with:
	+ Standard name
	+ The number of the relevant test step
	+ Consecutive letter
	+ File type

Example: HomeCareObservation\_3.4\_A.xml

If the vendor has documented the test themselves, the files must be sent in a ZIP file to fhir@medcom.dk.

## Test of TouchStone test scripts

The purpose of these tests is to ensure that, SUT generates HomeCareObservartion technically correct and complies with the rules in the [Implementation Guiden](#_Baggrundsmaterialer_2).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Test step #** | **Action** | **Test data** | **Expected result** | **Actual result** | **MedCom assessment** |
|  | **Optional test step:** Run all test scripts for use cases and user flows in TouchStone. |  | All test scripts completed without errors. |  | Choose |

## Test of requirements for content and flow/workflows

The purpose of these tests is to ensure that the standard is implemented with a satisfactory quality, i.e. that implementation meets the business requirements for flow and content as described in the [clinical guidelines for application](#_Baggrundsmaterialer_2)  and [use case-material](#_Baggrundsmaterialer_2). These test steps are mainly for testing of the user interface.

As previously described, **HomeCareObservation is part of a production trial** and consequently this test protocol will reflect the scope agreed upon with the Sender, and Receiver, of HomeCareObservation in the trial period. **This means that not all requirements in the standard may be part of this test protocol, e.g. the requirements for receiving cancellations and corrections.**

The table below lists the cases which are relevant in relation to content and flow/workflows. The cases marked with “N/R” will not be tested in this protocol, as they are not to be part of the production trial. However the case relating to receiving attached files as part of R1, can be tested if requested by the receiver, therefor test steps for this case are included in this test protocol.

The table contains references to the use cases and the test steps within this test protocol. Furthermore, the table indicates if the cases are mandatory or optional in the standard documentation and shows if they will be part of the production trail to be realized.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| [**Use case**](#_Baggrundsmaterialer_2) | **Description** | **Section** | **Mandatory (M) / Optional (O)** | **Not relevant (N/R) in production trial** |
| R1 | Receive HomeCareObservation  | 3.3.1 | M |  |
| Part of R1 | Receive HomeCareObservation with attached files | 3.3.2 | M | N/R |
| R1.A1 | Receive HomeCareObservatin with refused consent to share observation results | 3.3.3 | M |  |
| R.CANC | Receive a cancellation to a HomeCareObservation | NOT PART OF TEST PROTOCOL | M | N/R |
| R.CORR | Receive a correction to a HomeCareObservation | NOT PART OF TEST PROTOCOL | M | N/R |

*Table: Listing of the use cases for the standard*

### R1: Receive a HomeCareObservation

| **Test step #** | **Action** | **Test data** | **Expected result** | **Actual result** | **MedCom assessment** |
| --- | --- | --- | --- | --- | --- |
|  | Load a HomeCareObservation test example.  | *In preparation* | The HomeCareObservation test example is loaded. |  | Choose |
|  | Describe and demonstrate how SUT supports distribution of a received HomeCareObservation based on enclosed initials of the general practitioner or the status code indicating that the initials are unknown. *It is recommended that SUT, when the initials of the general practitioner have been received in the HomeCareObservation, supports the possibility of automatic distribution according to the received initials with the purpose of presenting the general practitioner for only the HomeCareObservation(s) that he preliminary has requested. If the initials of the general practitioner are not enclosed in the HomeCareObservation, SUT is recommended to use the status indicating that the initials are “unknown“ to filter out HomeCareObservation(s) without initials to for example a shared inbox.*  |  | If SUT supports distribution of a received HomeCareObservation:* SUT distributes the HomeCareObservation according to the enclosed initials
* SUT distributes the HomeCareObservation according to the status indicating that the initials are "unknown”
 |  | Choose |
|  | Describe and demonstrate how SUT notifies the user that a HomeCareObservation has been received.  |  | The user is notified in the user interface that a HomeCareObservation has been received. |  | Choose |
|  | Demonstrate that the user opens the received HomeCareObservation.  |  | The user has opened the received HomeCareObservation. |  | Choose |
|  | Demonstrate that SUT in the user interface shows the relevant and received information from the HomeCareObservation for the user.*It is a requirement that SUT clearly displays producer and signature (author) information in the user interface.* *It is a requirement that SUT clearly displays the status of the observation results and the status of the DiagnosticReport in the user interface.* *It is a requirement that SUT clearly displays information about that the observation results have not been interpreted in the user interface.* . |  | SUT presents the following information from the HomeCareObservation for the user:* Patients personal identification number (CPR)
* Patient name
* Receiver name
* Observation results
* Information that the observation results have not been interpreted (DK: ikke reference vurderet)
* Observation(s) samling date and time
* Status of the observation(s) and DiagnosticReport
* Producer information
* Signature (author) information from the sender

If included:* Clinical comment
* Analysis comment

Optional to display in the user interface:* Initials of the general practitioner (if inserted) OR status indicating that the initials are „unknown“
* DiagnosticReport generation date and time
 |  | Choose |
|  | Demonstrate that SUT displays observation results correctly in the HomeCareobservation with regard to using the comparator sign < and/or > when relevant and necessary.Demonstrate that SUT also displays unit to observation results, if relevant and enclosed in the HomeCareObservation.  |  | SUT presents observation results in the HomeCareObservation with the following information, when relevant and needed:* < and/or >
* Unit, if relevant and enclosed in HomeCareObservation
 |  | Choose |
|  | Describe and demonstrate how SUT will add the analysis short name to the received observation(s) in the HomeCareObservation.*It is recommended that the presentation of the observation results happens along with the analysis short name.**The short names can be obtained via MedComs terminology server.*  |  | If SUT supports presentation of the observation results along with the analysis short name:* SUT adds the short name to the received observation results in the HomeCareObservation.
 |  | Choose |
|  | Demonstrate that SUT also makes it possible for the user to access and see the analysis long name in the HomeCareObservation.  |  | The user can via the received HomeCareObservation access and see the analysis long name.  |  | Choose |
|  | Demonstrate that the user saves the results from the HomeCareObservation in the laboratory chart (DK: Laboratoriekort) in SUT. |  | The user saves the results from the HomeCareObservation in the laboratory chart in SUT.  |  | Choose |
|  | Demonstrate that the user also afterwards can access the received results from the HomeCareObservation in the laboratory chart in SUT.  |  | The user accesses the received results from the HomeCareObservation in the laboratory chart. |  | Choose |
|  | Desribe and demonstrate how the user in the laboratory chart can see the received results from the HomeCareObservation.*It is a requirement to clearly display in the user interface that the results have not been interpreted. Demonstrate that SUT clearly displays this in the user interface.**It is recommended that all results, that has the same sampling date and time, is placed in the same column in the presentation in the laboratory chart. It is also recommended that the presentation of results happens according to the national observation result groups. The national result groups can be obtained via the terminology server. Furthermore, it is also recommended that SUT supports grouping of the received results in the user interface.*  |  | The user can see all the received observation results in the laboratory chart in SUT and it is displayed that the results have not been interpreted. If SUT supports the recommendations:* SUT places results in the same column if they have the same sampling and date time.
* SUT presents the results according to the national observation result groups.
* SUT support grouping of the results.
 |  | Choose |
|  | Demonstrate that SUT displays observation results correctly in the laboratory chart with regard to using the comparator signs < and/or > when relevant and necessary. Demonstrate that SUT also displays unit to observation results in the laboratory chart, if relevant and enclosed in the HomeCareObservation.  |  | SUT presents observation results from the HomeCareObservation in the laboratory chart with the following information, when relevant and needed:* < and >
* Unit, if relevant and enclosed in HomeCareObservation
 |  | Choose |
|  | Demonstrate that the user in the laboratory chart can see the analysis short names according to the received observation results in the HomeCareObservation. *It is recommended that the presentation of the observation results happens along with the analysis short name.**The short names can be obtained via MedComs terminology server.*  |  | If SUT supports presentation of the observation results along with the analysis short name in the laboratory chart:* The user can see the analysis short name to the received observation results in the laboratory chart.
 |  | Choose |
|  | Demonstrate that SUT also makes it possible for the user to access and see the analysis long name for the received observation results in the laboratory chart.  |  | The user can in the laboratory chart access and see the analysis long name to the received observation results.  |  | Choose |
|  | Desribe and demonstrate how the user in the laboratory chart can see that the a clinical comment has been received as part of the HomeCareObservation and how it is visible that the clinical comment applies to all the received observation results. *It is a requirement that it is clearly displayed for the user that a clinical comment has been received and that the clinical comment applies to all the received observation results in the HomeCareObservation.*  |  | The user can see if a clinical comment has been received as part of a HomeCareObservation and can access, and see, the clinical comment. It is clear for the user that the clinical comment applies to all the received observation results.  |  | Choose |
|  | Describe and demonstrate how SUT supports the display of the clinical comments in a united view/display. *It is recommended that received clinical comments is united in a shared view/display, other than the laboratory chart, with the purpose of ensuring overview for the general practitioner.*  |  | If SUT supports a united view/display of received clinical comments:SUT has united the received clinical comments in a shared view/display.  |  | Choose |
|  | Desribe and demonstrate how the user in the laboratory chart can see that an analysis comment has been received as part of the HomeCareObservation.*It is a requirement that it is clearly displayed for the user that an analysis comment has been received and that the analysis comment only applies to a specific received observation result in the HomeCareObservation. It must be clear which observation result the analysis comment refers to.*  |  | The user can see if an analysis comment has been received as part of a HomeCareObservation and can access, and see, the analysis comment. It is clear for the user that the analysis comment only applies to a specific observation result and that it is clear which one. |  | Choose |
|  | Demonstrate that SUT stores the relevant technical information and data received in the HomeCareObservation. |  | SUT stores the relevant technical information and data from the HomeCareObservation, including but not limited to, observation(s) codes and sending date and time.  |  | Choose |

### Part of R1: Receive a HomeCareObservation with attached files

| **Test step #** | **Action** | **Test data** | **Expected result** | **Actual result** | **MedCom assessment** |
| --- | --- | --- | --- | --- | --- |
|  | Load a HomeCareObservation test example which contains attached files, clinical comment and analysis comment.  | *In preparation* | The HomeCareObservation test example is loaded. |  | Choose |
|  | Complete the test steps 3.3.1.3– 3.3.1.14 when receiving a HomeCareObservation. Regarding attached files:Describe and demonstrate how SUT clearly displays the attached files, including the required ID and title in the HomeCareObservation. Name of the author and time of creation for the attached files must also be displayed if enclosed in the HomeCareObservation.Demonstrate that the user can access the attached files. *It is a requirement that SUT clearly displays in the user interface when SUT has received attached files as part of the HomeCareObservation.*  |  | The test steps 3.3.1.3– 3.3.1.14 has been completed and a HomeCareObservation with attached files has been received. SUT clearly displays the attached files for the user and the user can access the attached files.  |  | Choose |
|  | Describe and demonstrate how SUT clearly displays the attached files, received as part of the HomeCareObservation, in the laboratory chart. Demonstrate that the user can access the attached files from the laboratory chart.  |  | SUT clearly displays the attached files in the laboratory chart for the user and the user can access the attached files.  |  | Choose |
| **HomeCareObservation with attached files (without clinical comment and analysis comment)** |
|  | Load a HomeCareObservation test example which contains attached files (and no clinical comment and analysis comment).  | *In preparation* | The HomeCareObservation test example is loaded. |  | Choose |
|  | Complete the test steps 3.3.1.3– 3.3.1.14 when receiving a HomeCareObservation. Regarding attached files:Describe and demonstrate how SUT clearly displays the attached files, including the required ID and title in the HomeCareObservation. Name of the author and time of creation for the attached files must also be displayed if enclosed in the HomeCareObservation.Demonstrate that the user can access the attached files. *It is a requirement that SUT clearly displays in the user interface when SUT has received attached files as part of the HomeCareObservation.*  |  | The test steps 3.3.1.3– 3.3.1.14 has been completed and a HomeCareObservation with attached files has been received. SUT clearly displays the attached files for the user and the user can access the attached files.  |  | Choose |
|  | Describe and demonstrate how SUT clearly displays the attached files, received as part of the HomeCareObservation, in the laboratory chart. Demonstrate that the user can access the attached files from the laboratory chart. |  | SUT clearly displays the attached files in the laboratory chart for the user and the user can access the attached files.  |  | Choose |

### R1.A1: Receive a HomeCareObservation with refused consent to share observation results

| **Test step #** | **Action** | **Test data** | **Expected result** | **Actual result** | **MedCom assessment** |
| --- | --- | --- | --- | --- | --- |
|  | Load a HomeCareObservation test example which contains refused consent to share observation results (and no clinical comment and analysis comment).  | *In preparation* | The HomeCareObservation test example is loaded. |  | Choose |
|  | Complete the test steps 3.3.1.3– 3.3.1.14 when receiving a HomeCareObservation. Regarding refused consent to share observation results:Describe and demonstrate how SUT clearly displays that the patient has refused consent to share observation results received in the HomeCareObservation.*It is a requirement that SUT clearly displays in the user interface when refused consent has been received.*  |  | The test steps 3.3.1.3– 3.3.1.14 has been completed and a HomeCareObservation with refused consent to share observation results has been received. SUT clearly displays the refused consent for the user.  |  | Choose |

## Test of general technical requirements

The purpose of these test steps is to ensure that the technical receipt of HomeCareObservation is implemented with satisfactory quality, i.e. supports governance for message communication at a general level.

| **Test step #** | **Action** | **Test data** | **Expected result** | **Actual result** | **MedCom-assessment** |
| --- | --- | --- | --- | --- | --- |
| **E-CPR** |
|  | Load a HomeCareObservation test example which contains a test patient with an E-cpr (a replacement person identifier) and no clinical comment or analysis comment. Complete the test steps 3.3.1.3– 3.3.1.14 when receiving a HomeCareObservation with an E-cpr.  | *In preparation* | The test steps 3.3.1.3– 3.3.1.14 has been completed and a HomeCareObservation, with an E-cpr, has been received.  |  | Choose |
| **Use of terminology** |
|  | Explain how SUT uses terminology from MedCom’s terminology server. |  | For example: “SUT *has a local copy of relevant ValueSets. This is retrieved for SUT via MedCom’s terminology server*.” |  | Choose |
|  | Explain how terminology in SUT is updated. For example, if the list of analysis short names is updated. |  | For example: “*It requires an update of the analysis short names, which can be published with a new release*” |  | Choose |
| **Loading of FHIR-message** |
|  | Describe how FHIR-messages are loaded into SUT. For example: How is data loaded into SUT – via mapping to internal format or to local FHIR infrastructure? |  | For example: FHIR messages are used directly or processed.  |  | Choose |
| **Format of the HomeCareObservation** |
|  | Demonstrate that SUT can handle af HomeCareObservation as an XML and JSON file. Load the test file with HomeCareObservation in XML format. Load the test file with HomeCareObservation in JSON format.  | *In preparation* | SUT loads correctly test files with a HomeCareObservation |  | Choose |
| **Use of terminology – unknown observation codes (Not relevant in production trial)**In the production trial to be realized, updates of the observation codes will not occur and therefore it is not appropriate or necessary to check handling when receiving unknown observation codes. |