

Test Procedure for §170.302 (f) (1) Vital Signs

This document describes the test procedure for evaluating conformance of complete EHRs or EHR modules¹ to the certification criteria defined in 45 CFR Part 170 Subpart C of the Final Rule for Health Information Technology: Initial Set of standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology as published in the Federal Register on July 28, 2010. The document² is organized by test procedure and derived test requirements with traceability to the normative certification criteria as described in the Overview document located at http://healthcare.nist.gov/docs/TestProcedureOverview_v1.pdf. The test procedures may be updated to reflect on-going feedback received during the certification activities.

The HHS/Office of the National Coordinator for Health Information Technology (ONC) has defined the standards, implementation guides and certification criteria used in this test procedure. Applicability and interpretation of the standards, implementation guides and certification criteria to EHR technology is determined by ONC. Test procedures to evaluate conformance of EHR technology to ONC's requirements are defined by NIST. Testing of EHR technology is carried out by ONC-Authorized Testing and Certification Bodies (ATCBs), not NIST, as set forth in the final rule establishing the Temporary Certification Program (*Establishment of the Temporary Certification Program for Health Information Technology, 45 CFR Part 170; June 24, 2010.*)

Questions about the applicability of the standards, implementation guides or criteria should be directed to ONC at ONC.Certification@hhs.gov. Questions about the test procedures should be directed to NIST at hit-tst-fdbk@nist.gov. Note that NIST will automatically forward to ONC any questions regarding the applicability of the standards, implementation guides or criteria. Questions about functions and activities of the ATCBs should be directed to ONC at ONC.Certification@hhs.gov.

CERTIFICATION CRITERIA

This Certification Criterion is from the Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology Final Rule issued by the Department of Health and Human Services (HHS) on July 28, 2010.

§170.302 (f) Record and chart vital signs

- (1) Vital signs. Enable a user to electronically record, modify, and retrieve a patient's vital signs including, at a minimum, the height, weight, and blood pressure.

¹ Department of Health and Human Services, 45 CFR Part 170 Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, Final Rule, July 28, 2010.

² Disclaimer: Certain commercial products are identified in this document. Such identification does not imply recommendation or endorsement by the National Institute of Standards and Technology.

Per Section III.D of the preamble of the Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, Final Rule where the vital signs certification criterion is discussed:

- “We expect that Complete EHR and EHR Module developers will include the units of measure that their customers believe are necessary to meet their needs, which in many cases will include those that patients routinely request.”

INFORMATIVE TEST DESCRIPTION

This section provides an informative description of how the test procedure is organized and conducted. It is not intended to provide normative statements of the certification requirements.

This test evaluates the capability for a Complete EHR or EHR Module to enable a user to electronically record, modify, and retrieve a patient’s vital signs including the height, weight, and blood pressure.

The test procedure is not prescriptive about the method used to modify vital signs. For example, modifying vital signs does not require modifying an existing instance of vital signs. Modification may be accomplished through inactivating or deleting existing vital signs in the patient’s EHR and entering a new instance of vital signs.

This test procedure is organized into three sections:

- Record - evaluates the capability to enter vital signs data into the EHR system
 - The Tester enters the NIST-supplied height, weight, and blood pressure data
- Modify – evaluates the capability to modify vital signs data that have been entered previously into the EHR
 - The Tester displays the height, weight, and blood pressure data entered during the Record Patient Vital Signs test
 - The Tester modifies the previously entered vital signs data using NIST-supplied height, weight, and blood pressure data
- Retrieve – evaluates the capability to display the vital signs data that have been entered previously into the EHR
 - The Tester displays the height, weight, and blood pressure data entered during the test
 - The Tester validates that the displayed vital signs data are accurate and complete

REFERENCED STANDARDS

None

NORMATIVE TEST PROCEDURES

Derived Test Requirements

- DTR170.302.f.1 – 1: Electronically Record Patient Vital Signs
DTR170.302.f.1 – 2: Electronically Modify Patient Vital Signs
DTR170.302.f.1 – 3: Electronically Retrieve Patient Vital Signs

DTR170.302.e.1 – 1: Electronically Record Patient Vital Signs

Required Vendor Information

- VE170.302.f.1 – 1.01: Vendor shall identify a patient with an existing record in the EHR to be used for this test
- VE170.302.f.1 – 1.02: Vendor shall identify the EHR function(s) that are available to: 1) select the patient, 2) enter the patient's height, weight, and blood pressure, 3) modify these vital signs data, and 4) retrieve these vital signs data

Required Test Procedure:

- TE170.302.f.1 – 1.01: Tester shall select vital signs test data from one NIST-supplied test data set in TD170.302.f.1 – 1
- TE170.302.f.1 – 1.02: Using the EHR function(s) identified by the Vendor, the Tester shall select the patient's existing record and enter vital signs from the selected test data set in TD170.302.f.1 – 1 for
- the patient's height
 - the patient's weight
 - the patient's blood pressure
- TE170.302.f.1 – 1.03: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the vital signs test data have been entered correctly and without omission

Inspection Test Guide

- IN170.302.f.1 – 1.01: Using the data in the selected NIST-supplied test data set in TD170.302.f.1 – 1, Tester shall verify that the vital signs test data are entered correctly and without omission
- IN170.302.f.1 – 1.02: Tester shall verify that the units of measure appropriate for the height and weight display or are selected at the time each vital sign is entered
- IN170.302.f.1 – 1.03: Tester shall verify that the vital signs test data are stored in the patient's record, including
- the patient's height
 - the patient's weight
 - the patient's blood pressure

DTR170.302.f.1 – 2: Electronically Modify Patient Vital Signs

Required Vendor Information

- As defined in DTR170.302.f.1-1, no additional information is required

Required Test Procedure:

TE170.302.f.1 – 2.01: Tester shall select vital signs test data from one NIST-supplied test data set in TD170.302.f.1 – 2 that corresponds to the data set selected for DTR170.302.e.1 – 1: Electronically Record Patient Vital Signs

TE170.302.f.1 – 2.02: Using the EHR function(s) identified by the Vendor, the Tester shall select the patient's existing record, shall display each of the vital signs entered during the DTR170.302.e.1 – 1: Electronically Record Patient Vital Signs test, and shall modify each of the previously entered vital signs, including

- the patient's height
- the patient's weight
- the patient's blood pressure

TE170.302.f.1 – 2.03: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the patient vital signs data entered in TE170.302.f.1 – 2.02 have been entered correctly and without omission

Inspection Test Guide:

IN170.302.f.1 – 2.01: Using the data in the selected NIST-supplied Test Data set in TD170.302.f.1 – 2, Tester shall verify that the vital signs test data entered during the DTR170.302.e.1 – 1: Electronically Record Patient Vital Signs test are accessed and modified correctly and without omission

IN170.302.f.1 – 2.02: Tester shall verify that the units of measure appropriate for the height and weight display or are selected at the time each vital sign is modified

IN170.302.f.1 – 2.03: Tester shall verify that the modified vital signs data are stored in the patient's record, including

- the patient's height
- the patient's weight
- the patient's blood pressure

DTR170.302.f.1 – 3: Electronically Retrieve Patient Vital Signs

Required Vendor Information

- As defined in DTR170.302.f.1-1, no additional information is required

Required Test Procedure:

- TE170.302.f.1 – 3.01: Using the EHR function(s) identified by the Vendor, the Tester shall select the patient's existing record and shall display the data the Tester entered during the DTR170.302.e.1 – 2: Electronically Modify Patient Vital Signs test for
- the patient's height
 - the patient's weight
 - the patient's blood pressure
- TE170.302.f.1 – 3.02: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the vital signs test data display correctly and without omission

Inspection Test Guide

- IN170.302.f.1 – 3.01: Using the data in the NIST-supplied test data set in TD170.302.f.1 – 3 that corresponds to the data set selected for DTR170.302.e.1 – 1: Electronically Record Patient Vital Signs, Tester shall verify that the vital signs data entered during the DTR170.302.e.1 – 2: Electronically Modify Patient Vital Signs test display correctly and without omission, including
- the patient's height
 - the patient's weight
 - the patient's blood pressure
- IN170.302.f.1 – 3.02: Tester shall verify that the units of measure appropriate for the height and weight display or are selected for the height and weight

TEST DATA

Test data is provided by NIST in this Test Procedure to ensure that the functional and interoperable requirements identified in the criteria can be adequately evaluated for conformance, as well as to provide consistency in the testing process across multiple ONC-Authorized Testing and Certification Bodies (ATCBs). The NIST-supplied test data focus on evaluating the basic capabilities required of EHR technology, rather than exercising the full breadth/depth of capability that installed EHR technology might be expected to support. The test data is formatted for readability of use within the testing process. The format is not prescribing a particular end-user view or rendering. No additional requirements should be drawn from the format.

The Tester shall use and apply the NIST-supplied test data during the test, without exception, unless one of the following conditions exists:

- The Tester determines that the Vendor product is sufficiently specialized that the NIST-supplied test data needs to be modified in order to conduct an adequate test. Having made the determination that some modification to the NIST-supplied test data is necessary, the Tester shall record the modifications made as part of the test documentation.
- The Tester determines that changes to the test data will improve the efficiency of the testing process; primarily through using consistent demographic data throughout the testing workflow.

The Tester shall ensure that the functional and interoperable requirements identified in the criterion can be adequately evaluated for conformance and that the test data provides a comparable level of robustness.

Any departure from the NIST-supplied test data shall strictly focus on meeting the basic capabilities required of EHR technology relative to the certification criterion rather than exercising the full breadth/depth of capability that installed EHR technology might be expected to support.

The Test Procedures require that the Tester enter the test data into the EHR technology being evaluated for conformance. The intent is that the Tester fully controls the process of entering the test data in order to ensure that the data are correctly entered as specified in the test procedure. If a situation arises where it is impractical for a Tester to directly enter the test data, the Tester, at the tester's discretion, may instruct the Vendor to enter the test data, so long as the Tester remains in full control of the testing process, directly observes the test data being entered by the Vendor, and validates that the test data are entered correctly as specified in the test procedure.

TD170.302.f.1 – 1: Record Patient Vital Signs (Blood pressure may be entered as a single value into one blood pressure field or as two separate values – systolic and diastolic – each entered into its own part of a two-part blood pressure field)

Vital Signs Test Data - Set 1

Height: 5 ft 6 in OR 66 in OR 1.67 meters OR 167 centimeters

Weight: 135 lbs OR 134 lbs 15 oz OR 61.2 kg OR 6120 gm

Blood pressure: 120/80

Vital Signs Test Data - Set 2

Height: 6 ft 1 in OR 73 in OR 1.85 meters OR 185 centimeters

Weight: 200 lbs OR 199 lbs 15 oz OR 90.7 kg OR 9070 gm

Blood pressure: 110/70

TD170.302.f.1 – 2: Modify Patient Vital Signs

Vital Signs Test Data - Set 1

Modify the height from 5 ft 6 in OR 66 in OR 1.67 meters OR 167 centimeters to **5 ft 3 in OR 63 in OR 1.60 meters OR 160 centimeters**

Modify the weight from 135 lbs OR 134 lbs 15 oz OR 61.2 kg OR 6120 gm to **130 lbs OR 130 lbs 1 oz OR 59 kg OR 5900 gm**

Modify the blood pressure from 120/80 to **130/80**

Revised Vital Signs Data

Height: 5 ft 3 in OR 63 in OR 1.60 meters OR 160 centimeters

Weight: 130 lbs OR 130 lbs 1 oz OR 59 kg OR 5900 gm

Blood pressure: 130/80

Vital Signs Test Data - Set 2

Modify the height from 6 ft 1 in OR 73 in OR 1.85 meters OR 185 centimeters to **6 ft 2 in OR 74 in OR 1.88 meters OR 188 centimeters**

Modify the weight from 200 lbs OR 199 lbs 15 oz OR 90.7 kg OR 9070 gm to **210 lbs OR 210 lbs 2 oz OR 95.3 kg OR 9530 gm**

Modify the blood pressure from 110/70 to **116/80**

Revised Vital Signs Data

Height: 6 ft 2 in OR 74 in OR 1.88 meters OR 188 centimeters

Weight: 210 lbs OR 210 lbs 2 oz OR 95.3 kg OR 9530 gm

Blood pressure: 116/80

TD170.302.f.1 – 3: Retrieve Patient Vital Signs

Revised Vital Signs Data - Set 1

Height: 5 ft 3 in OR 63 in OR 1.60 meters OR 160 centimeters

Weight: 130 lbs OR 130 lbs 1 oz OR 59 kg OR 5900 gm

Blood pressure: 130/80

Revised Vital Signs Data -Set 2

Height: 6 ft 2 in OR 74 in OR 1.88 meters OR 188 centimeters

Weight: 210 lbs OR 210 lbs 2 oz OR 95.3 kg OR 9530 gm

Blood pressure: 116/80

CONFORMANCE TEST TOOLS

None

Document History

Version Number	Description	Date Published
0.7	Original draft version	February 26, 2010
1.0	Updated to reflect Final Rule	July 21, 2010
1.0	Updates include: <ul style="list-style-type: none">removed "Pending" from headerupdated test data to give option of entering height in inches	August 13, 2010
1.1	Removed "draft" from introductory paragraph In the Informative Test Description section <ul style="list-style-type: none">Added "The test procedure is not prescriptive about the method used to modify vital signs. For example, modifying vital signs does not require modifying an existing instance of vital signs. Modification may be accomplished through inactivating or deleting existing vital signs in the patient's EHR and entering a new instance of vital signs." In the Normative Test Procedures section <ul style="list-style-type: none">Added verbiage instructing Tester to select only one data set from the Test Data In the Test Data section <ul style="list-style-type: none">Recalculated all weight data starting with the metric kg weight, and changed standard weight to nn lbs or nn lbs nn ozAdded inches only to height dataChanged the word "change" to "modify"	September 24, 2010