

Clinical Package Validator Installation Guide

22 December 2020 v3.2 Approved for external use Document ID: DH-3354:2020 Australian Digital Health Agency ABN 84 425 496 912, Level 25, 175 Liverpool Street, Sydney, NSW 2000 Telephone 1300 901 001 or email <u>help@digitalhealth.gov.au</u> www.digitalhealth.gov.au

Acknowledgements

Council of Australian Governments

The Australian Digital Health Agency is jointly funded by the Australian Government and all state and territory governments.

IHTSDO (SNOMED CT)

This material includes SNOMED Clinical Terms[™] (SNOMED CT[®]) which is used by permission of the International Health Terminology Standards Development Organisation (IHTSDO). All rights reserved. SNOMED CT[®] was originally created by The College of American Pathologists. "SNOMED" and "SNOMED CT" are registered trademarks of the <u>IHTSDO</u>.

HL7 International

This document includes excerpts of HL7[™] International standards and other HL7 International material. HL7 International is the publisher and holder of copyright in the excerpts. The publication, reproduction and use of such excerpts is governed by the <u>HL7 IP</u> <u>Policy</u> and the HL7 International License Agreement. HL7 and CDA are trademarks of Health Level Seven International and are registered with the United States Patent and Trademark Office.

Disclaimer

The Australian Digital Health Agency ("the Agency") makes the information and other material ("Information") in this document available in good faith but without any representation or warranty as to its accuracy or completeness. The Agency cannot accept any responsibility for the consequences of any use of the Information. As the Information is of a general nature only, it is up to any person using or relying on the Information to ensure that it is accurate, complete and suitable for the circumstances of its use.

Document control

This document is maintained in electronic form and is uncontrolled in printed form. It is the responsibility of the user to verify that this copy is the latest revision.

Copyright © 2020 Australian Digital Health Agency

This document contains information which is protected by copyright. All Rights Reserved. No part of this work may be reproduced or used in any form or by any means – graphic, electronic, or mechanical, including photocopying, recording, taping, or information storage and retrieval systems – without the permission of the Australian Digital Health Agency. All copies of this document must include the copyright and other information contained on this page.

OFFICIAL

Document information

Key information

Owner	Director, Connectivity & Informatics			
Contact for enquiries	Australiar	n Digital Health Agency Help Centre		
	Phone	<u>1300 901 001</u>		
	Email	help@digitalhealth.gov.au		

Product or document version history

Product or document version	Date	Release comments
2.0	22 Aug 2014	Major release.
2.1	20 Jan 2015	Feature and usability enhancements.
2.2	-	Not published.
2.3	17 Jul 2015	Software enhancements (see release note for details).
2.4	20 May 2016	Software enhancements (see release note for details).
2.5	29 May 2017	Support for ISO Schematrons and other software enhancements (see release note for details).
2.6.1	21 Nov 2017	Software enhancements (see release note for details).
2.7	16 Feb 2018	Software enhancements (see release note for details).
2.8	20 Jan 2020	Software enhancements (see release note for details).
2.9 - 3.1		Not published
3.2	08 Dec 2020	Configuration guide from previous version moved to User and Configuration Guide document

Table of contents

1	Intro	duction	. 5
	1.1	Purpose	5
	1.2	Intended audience	5
	1.3	Scope	5
2	Befor	e you begin	. 6
	2.1	Prerequisites	6
	2.2	Uninstall an earlier version of the Validator	7
	2.3	Install a NASH test certificate	9
3	Insta	ling the Validator and prerequisite software	15
	3.1	Install Microsoft SQL Server Compact Edition 3.5 Service Pack 2 for	
		Windows Desktop	15
	3.2	Installing the Validator	17
4	Trout	pleshooting	20
	4.1	Install the Validator in Administrator mode	20
	4.2	Validator states "Missing SQL CE Drivers"	20
Acron	nyms .		21

1 Introduction

1.1 Purpose

This document describes how to install the Clinical Package Validator (the Validator).

1.2 Intended audience

This document is intended for:

- Testers who use the Validator to assist them in assessing whether their healthcare software system produces clinical documents that conform to some clinical document specifications, and clinical packages that conform to some clinical package specifications;
- Developers who use the Validator to provide quick feedback during software development; and
- Administrators who need to install the Validator for other users.

The Validator does not test all conformance specifications and you must carefully read the Product Data Sheet for the Validator that indicates what is out of scope.

1.3 Scope

This document describes the system requirements, administrator rights, and supporting software needed for installing the Validator. It also describes how to install and configure the Validator.

2 Before you begin

2.1 Prerequisites

Before installing and configuring the Validator, you must have:

- administrator rights to your PC;
- Windows 8 or above;
- 4GB minimum memory;
- 8GB recommended memory; and
- 1GB minimum disk space free.

If the following software is not already installed on your computer, it will be automatically installed during the installation of the Validator (Section 3):

• .NET Framework 4.7.2 or a later version

Unfortunately, Microsoft SQL Server Compact 3.5 will need to be installed manually (Section 3.2).

The Validator allows more than one version of the software to operate on the same computer (Section 2.2) so it is no longer necessary for a user to uninstall previous versions of the Validator.

A NASH test certificate must be installed before a user can access template packages in the My Health Record software vendor test (SVT) environment (Section 2.3), though the installation does include a default set of the latest Template Packages should the user not have a NASH certificate.

You must also be aware that the Validator runs only a subset of the complete set of tests you must run to validate whether a document is conformant with the clinical document specifications.

2.2 Uninstall an earlier version of the Validator

The Validator allows more than one version of the software to operate on the same computer, so there is no need to uninstall earlier versions of the Validator.

Follow the steps below if an earlier version of the Validator is already installed and you want to remove it, otherwise go to Section 2.3.

1. If an earlier version of the Validator is already installed, select Uninstall a program from the Windows Control Panel.



2. Select the version of the Validator to be uninstalled and then select Uninstall.

E	Programs and Features			×
📀 ⋺ 🝷 ↑ 🔯 ト Control P	anel Programs Programs and Features	✓ C Search Programs	and Features	P
Control Panel Home View installed updates	Uninstall or change a program To uninstall a program, select it from the list and then	click Uninstall, Change, or Repair.		
off	Organize 🕶 Uninstall Change Repair		-	0
	Name	Publisher	Installed On	Size
	🛱 Clinical Package Validator	Australian Digital Health Agency	29/10/2020	
	C Microsoft Edge	Microsoft Corporation	29/10/2020	
	Microsoft Visual C++ 2008 Redistributable - x64 9.0.3	Microsoft Corporation	29/10/2020	
	Microsoft Visual C++ 2008 Redistributable - x86 9.0.3	Microsoft Corporation	29/10/2020	
	VMware Tools	VMware, Inc.	29/10/2020	8
	<			>
	Australian Digital Health Agency Product	version: 3.2 lelp link: https://www.digitalhealth	.gov.au/	

Note: The Uninstall option may be selected from the menu or found by right clicking on the mouse button.

3. If the following security screen appears, select Yes to allow the Uninstall process to proceed.

	Programs and Features	
	Are you sure you want to uninstall Clinical Package Validator?	
	In the future, do not show me this dialogue box Yes No	
4.	The uninstall process will continue to completion.	
End		

2.3 Install a NASH test certificate

1

2

As an alternative to importing template packages from the Agency website, the Validator allows a user to import template packages from the My Health Record software vendor test environment, provided a valid NASH organisation test certificate has already been installed.¹

Follow the steps below to install a NASH organisation test certificate, otherwise go to Section 3.

Navigate to the folder that contains your NASH test certificates. D 11 = Certificate 2 Home Share View \sim (\Rightarrow) v C Search Certificate p (ϵ) Name Date modified Size Type 🚖 Favorites 📃 Desktop 🏂 fac_sign 4/09/2018 11:45 AM Personal Informati... 4 KB Downloads 🖳 Recent places 🍓 Homegroup 🔍 This PC 📬 Network HE 🛋 1 item

Note: If you do not have any NASH organisation test certificates, contact the Department of Human Services Online Technical Support helpdesk: <u>otsliaison@humanservices.gov.au</u>.

Double-click the relevant certificate to launch the Certificate Import Wizard and select Next.

come to the Cortifi			
come to the certific	cate Import Wizard	d	
zard helps you copy certificate om your disk to a certificate st	es, certificate trust lists, and ore.	certificate revocation	
ficate, which is issued by a cer ntains information used to pro tions. A certificate store is the	tification authority, is a conf tect data or to establish sec system area where certifica	irmation of your identity ure network ates are kept.	
e Location Current User			
ocal Machine			
tinue, dick Next.			
			_
	izard helps you copy certificate om your disk to a certificate st ificate, which is issued by a cer ontains information used to pro- ctions. A certificate store is the e Location Current User Local Machine ntinue, dick Next.	izard helps you copy certificates, certificate trust lists, and om your disk to a certificate store. ificate, which is issued by a certification authority, is a conf ontains information used to protect data or to establish sec ctions. A certificate store is the system area where certifica e Location Current User Local Machine ntinue, click Next.	izard helps you copy certificates, certificate trust lists, and certificate revocation om your disk to a certificate store. ificate, which is issued by a certification authority, is a confirmation of your identity ontains information used to protect data or to establish secure network ctions. A certificate store is the system area where certificates are kept. e Location Current User Local Machine htinue, click Next.

¹ The Validator can apply any template package. A template package is something that meets the requirements in the PCEHR Template Service - Template Package Technical Specification v1.0, available from: https://www.digitalhealth.gov.au/implementation-resources/national-infrastructure/EP-1514-2012/NEHTA-1042-2012

2	
-	
-	

Select Next.

Spe	cify the file you want to import.
File	name:
C	Users\User\Desktop\DISK1\Certificate\fac_sign.p12 Browse
No	te: More than one certificate can be stored in a single file in the following formats:
	Personal Information Exchange- PKCS #12 (.PFX,.P12)
	Cryptographic Message Syntax Standard-PKCS #7 Certificates (.P7B)
	Microsoft Serialized Certificate Store (.SST)

4

Enter the password and select Next.

Private Te	e key protection
Т	ype the password for the private key.
P	assword:
	••••••
	Display Password
In	nport options:
	Enable strong private key protection. You will be prompted every time the private key is used by an application if you enable this option.
	Mark this key as exportable. This will allow you to back up or transport your keys at a later time.
	\checkmark Include all extended properties.

elect Next.		
	×	
📀 🔗 Certificate Import Wizard		
Certificate Store		
Cel uncare stores are system areas where cel uncares are kept.	_	
Windows can automatically select a certificate store, or you can specify a location for the certificate.		
$\textcircled{\sc opt}$ Automatically select the certificate store based on the type of certificate		
Place all certificates in the following store		
Certificate store: Browse		
Next Can	cel	

6 Select Finish.

	×	
🕤 🍠 Certificate Imp	ort Wizard	
Completing	the Certificate Import Wizard	
The certificate will be	e imported after you click Finish.	
You have specified t	he following settings:	
Certificate Store S Content	elected Automatically determined by the wizard PFX	
File Name	C:\Users\User\Desktop\DISK1\Certificate\fac_sign.p12	
		Certificate Import Wizard
		The import was successful.
	Finish Cancel	ОК

Note: If you are running the Validator you will need to restart it so it can detect the newly installed NASH test certificate.

7 If this is the first NASH certificate you have installed, you may need to also import the NASH Root and Organisation Certificates to complete the "trust chain" of the NASH Certificate which allows the computer to trust the NASH certificate.

These should have been provided when you received your NASH Certificate:



If you cannot locate them, request them from <u>devsupport@servicesaustralia.gov.au</u>.

8 To install the Root (tmarca.crt) and Organisation (tmaoca.crt) Certificates, Double click on the Root file, and select **Install Certificate** ...

Then select Next.

Welcome to the Certificate Import Wizard
This wizard helps you copy certificates, certificate trust lists, and certificate revocation lists from your disk to a certificate store.
A certificate, which is issued by a certification authority, is a confirmation of your identity and contains information used to protect data or to establish secure network connections. A certificate store is the system area where certificates are kept.
Store Location
To continue, dick Next.

9 Choose Place all certificates in the following store and then select Browse ... and choose the Trusted Root Certification Authorities Folder

X

Certificate Import Wizard	eas where certificates are kept.
Windows can automatically sel the certificate.	Select Certificate Store
O Automatically select the	Select the certificate store you want to use.
(Place all Certificates in to Certificate store:	Personal Trusted Root Certification Authorities Enterprise Trust Trusted Publishers Trusted Publishers Show physical stores OK Cancel
	Next Cancel

Now select Next.

10 Finally select Finish

Com	pleting the Certifi	cate Import Wizard	
The ce	tificate will be imported afte	r vou dick Finish	
ine ce	ancade vin be imported arte	you dider mish.	
You ha	ve specified the following se	ttings:	rition
Conte	icate Store Selected by Ose	Certificate	nues

- 11 If a Security Warning appears, select Yes Security Warning You are about to install a certificate from a certification authority (CA) claiming to represent: Test Medicare Australia Root Certification Authority Windows cannot validate that the certificate is actually from "Test Medicare Australia Root Certification Authority". You should confirm its origin by contacting "Test Medicare Australia Root Certification Authority". The following number will assist you in this process: Thumbprint (sha1): 48804E4F 62896C33 77FA722E AC98782F DEDBEC16 Warning: If you install this root certificate, Windows will automatically trust any certificate issued by this CA. Installing a certificate with an unconfirmed thumbprint is a security risk. If you click "Yes" you acknowledge this risk. Do you want to install this certificate? Yes No
- 12 The Certificate Wizard will then confirm the import was successful.



3 Installing the Validator and prerequisite software

3.1 Install Microsoft SQL Server Compact Edition 3.5 Service Pack 2 for Windows Desktop

The Microsoft SQL Server Compact 3.5 Service Pack 2 for Windows Desktop is the software used by the Validator to store terminology datasets. If it is not already present on the computer, the Validator when run, will detect this, and prompt the user to install the software (see Troubleshooting Section 4.2).

To install Microsoft SQL Server CE, you must install both the x86 and 64-bit versions in the following order:

1 Select the **SSCERuntime_x86-ENU.msi** installation script in the ISSetupPrerequisites\{B1165B38-CA52-11E0-A63D-7C004824019B} folder.



3 If you accept the license agreement terms, select I accept the terms in the license agreement and then select Next.

7	Microsoft SQL Server Compact 3.5 SP2 ENU	
License	Agreement	
Please agreem	read the following license agreement carefully. You must accept the license ent before continuing forward.	4
мтср	ROSOFT SOFTWARE LICENSE TERMS	
MICK		
MICR	COSOFT SQL SERVER COMPACT 3.5 WITH	I
MICR SERV These lic based or They app	COSOFT SQL SERVER COMPACT 3.5 WITH TICE PACK 2 tense terms are an agreement between Microsoft Corporation (or n where you live, one of its affiliates) and you. Please read them. of to the software named above, which includes the media on which	
MICR SERV These lic based or They app	COSOFT SQL SERVER COMPACT 3.5 WITH VICE PACK 2 cense terms are an agreement between Microsoft Corporation (or n where you live, one of its affiliates) and you. Please read them. by to the software named above, which includes the media on which we dit if any. The terms also apply to any Microsoft the terms in the kense argement	

4 To install the software select **Install**.

Setup is ready to begin installation. Click Install to begin the installation. If you want to review or change any of your installation settings, click Back. Click Cancel exit Setup. Installation Path C:\Program Files (x86)\Microsoft SQL Server Compact Edition\	Ready t	Install the Program	m		
Click Install to begin the installation. If you want to review or change any of your installation settings, click Back. Click Cancel exit Setup. Installation Path C:\Program Files (x86)\Microsoft SQL Server Compact Edition\	Setup is	ready to begin installa	ation.		
If you want to review or change any of your installation settings, dick Back. Click Cancel exit Setup. Installation Path C: \Program Files (x86)\Microsoft SQL Server Compact Edition\	Click In	stall to begin the installa	ation.		
Installation Path C:\Program Files (x86)\Microsoft SQL Server Compact Edition\	If you vexit Set	vant to review or chang sup.	ge any of your inst	allation settings, click Ba	ick. Click Cancel t
Installation Path C:\Program Files (x86)\Microsoft SQL Server Compact Edition\					
Installation Path C:\Program Files (x86)\Microsoft SQL Server Compact Edition\					
Installation Path C: \Program Files (x86)\Microsoft SQL Server Compact Edition\					
C:\Program Files (x86)\Microsoft SQL Server Compact Edition\					
C: Program Files (Xeo) (Victosorit SQL Server Compact Edution (Installatio	n Path			
· · · · · · · · · · · · · · · · · · ·	Installatio	n Path		ant Edition)	
	Installatio	n Path am Files (x86)Wicrosoft	t SQL Server Comp	act Edition \	

- 5
- If the following message is displayed select **Yes**.

2	Do yo softwa	u want to allow are on this com	the following puter?	g program '	to install
		Program name: Verified publisher: File origin:	SQL Server Com Microsoft Corp Hard drive on th	pact 3.5 SP2 oration iis computer	
•	Show deta	ils		Yes	No

6 To end the installation process, select **Finish**.

1 ¹	Micros	oft SQL Server Compact 3.5 SP2 ENU
		Completing the Microsoft SQL Server Compact Setup
	1	Setup has installed Microsoft SQL Server Compact successfully. Click Finish to exit.
		Finish

If the computer uses a 64-bit operating system, the additional 64-bit drivers need to be installed.
 Select the SSCERuntime_x64-ENU.msi installation script in the ISSetupPrerequisites\{B9E5C848-CA52-11E0-9D02-80004824019B} folder and follow the steps to complete the installation process.

End

3.2 Installing the Validator

This procedure requires that Microsoft .NET Framework 4.7.2 (or a later version) and Microsoft SQL Server Compact 3.5 Service Pack 2 for Windows Desktop are installed. The installer will detect if .NET Framework 4.7.2 is not installed and prompt the user to install. If Microsoft SQL Server Compact 3.5 Service Pack 2 software is not already installed on your computer it will need to be installed manually (Section 3.2).

To install the Validator, follow the steps below.

1 Locate the installer file (**Clinical Package Validator** x.y **Install.exe**, with "x.y" indicating the Validator's version number) and the **ISSetupPrerequisites** folder within the expanded .ZIP file that contained this guide.

Save the installer file and the ISSetupPrerequisites folder to a preferred location on a local drive (e.g. Desktop).

Note:

- The Validator installation may not work from a network drive.
- The installer file and the ISSetupPrerequisites folder must be co-located.
- The ISSetupPrerequisites folder contains prerequisite software that will be installed along with the Validator if the prerequisite software is not already installed on your computer.
- 2 Open Windows Explorer and navigate to the installer file. Double-click the file to install the software.

n i L3 mi ≠ i	DISK1					
File Home Shar	e View					\sim
€ 🦻 - ↑ 퉬 🕨	DISK1	¥	Ç	Search DISK1		J
🔆 Favorites	Name		Dat	e modified	Туре	
Desktop	퉬 Certificate		29/	10/2020 5:36 PM	File folder	
〕 Downloads	🌗 ISSetupPrerequisites		29/	10/2020 5:10 PM	File folder	
🕮 Recent places	Clinical Package Validator 3.2 Install		27/	10/2020 4:25 PM	Application	
🤣 Homegroup						
🌉 This PC						
辑 Network						
	<					
2.2						

- Note: Windows may mark files downloaded from the Internet as "Blocked". This prevents the Validator from running.
 To unblock a file, right-click on it and select Properties, then select Unblock in the 'General' tab, followed by OK.
- 4 Once the file is unblocked, continue installing the Validator by once again double-clicking the installer file.

5 If Microsoft .NET Framework 4.7.2 (or a later version) is not installed, this will be detected and prompt the user to go ahead and install. Select **Install**.

	Clinical Package Validator - InstallShield Wizard
نې ۲	Clinical Package Validator requires the following items to be installed on your computer. Click Install to begin installing these requirements.
Status	Requirement
Pending	Microsoft .NET Framework 4.7.2 Full
	Install Cancel

5

When the InstallShield Wizard opens, select Next.

0	Clinical Package Validator - InstallShield Wizard				
	5	Welcome to the InstallShield Wizard for Clinical Package Validator			
		The InstallShield(R) Wizard will install Clinical Package Validator on your computer. To continue, click Next.			
-		WARNING: This program is protected by copyright law and international treaties.			
		< Back Next > Cancel			

6 Select Install.

eady to Install the Progra	m
The wizard is ready to begin ir	istallation.
If you want to review or chan exit the wizard.	ge any of your installation settings, click Back. Click Cancel to
Current Settings:	
Setup Type:	
Typical	
Destination Folder:	
C:\DigitalHealth\CPV32\	
User Information:	
Name: User	
Company:	
IlShield	

7 If the following security screen appears, select **Yes** to allow the installation to proceed.



12 The Validator will start installing.

👸 🛛 Clin	nical Package Validator - InstallShield Wizard 💫 – 🗖 💌
Installing The prog	Clinical Package Validator ram features you selected are being installed.
1 7	Please wait while the InstallShield Wizard installs Clinical Package Validator. This may take several minutes.
	Status:
	Copying new files
TostallShield	
, הסנסונטרוופוט –	< Back Next > Cancel

13

Once the Validator installation is complete, select Finish.

🖞 Clinical Pack	age Validator - InstallShield Wizard	×
C.	InstallShield Wizard Completed The InstallShield Wizard has successfully installed Clinical Package Validator. Click Finish to exit the wizard.	
	< Back Finish Cancel	

The Validator is now installed.

End

4 Troubleshooting

4.1 Install the Validator in Administrator mode

The Validator may display unexpected behaviour if its installation was unsuccessful. If this happens, follow the steps below.

- 1 Uninstall any previous versions of the Validator (Section 2.2).
- 2 Delete the C:\DigitalHealth\CPVxx directory.
- 3 Ensure the **Installer** file is on the desktop or a local drive (e.g. C:\).
- 4 Right-click the **Installer** file and select **Run as administrator**.



- 5 Enter the admin password if requested.
- 6 Complete the installation of the Validator (Section 3).

End

4.2 Validator states "Missing SQL CE Drivers"

1 When the Validator is run for the first time, it may display a message about missing SQL CE Drivers. If so, follow Section 3.2 and install the necessary software.

 Missing SQL CE Drivers
 ×

 Image: No SQLCE 3.5 Drivers have been detected. Please check you have installed them, and then try again.
 OK

Acronyms

Acronym	Description
AMT	Australian Medicines Terminology
CDA	Clinical Document Architecture. CDA is a trademark of Health Level Seven International and is registered with the United States Patent and Trademark Office
CSS	Cascading Style Sheets
DVA	Department of Veterans' Affairs
IHTSDO	International Health Terminology Standards Development Organisation
NASH	National Authentication Service for Health
PBS	Pharmaceutical Benefits Scheme
SNOMED CT	Systematized Nomenclature of Medicine Clinical Terms
SNOMED CT-AU	Systematized Nomenclature of Medicine Clinical Terms – Australia
SVT	Software Vendor Test environment
XML	Extensible Mark-up Language