CANTEL MEDICAL

**Visual Studio - 2005 TOOL VALIDATION PLAN**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Project Revision History** | | | | | | | | | |
|  |  |  | |  |  | |  |  |  |
|  |  |  | |  |  | |  |  |  |
| **Date** | **Version** | **Author** | **Brief Description of Changes** | | | **Reason** | | | |
| **Oct 25th 2019** | **Rev 0.1D** | **Vishal Gajare** | **Draft Version** | | | **Client Suggested** | | | |
| **Nov 13th 2019** | **Rev 0.2D** | **Vishal Gajare** | **Moved to CG Template** | | | **Client Suggested** | | | |
|  |  |  |  | | |  | | | |

|  |  |  |
| --- | --- | --- |
|  | Name | Title |
| Rev. Authored By: | Vishal Gajare | Senior Consultant |
| Rev. Reviewed By: | Darshan | Manager |
| Rev. Approved By: | Abhijit Dixit | Program Manager |
| CANTEL R&D: |  |  |
| CANTEL QA: |  |  |

**Visual Studio - 2005 Tool Validation Protocol**

Table of Contents

[1. Introduction/Background 4](#_Toc22813146)

[2. Purpose/Scope 4](#_Toc22813147)

[3. Reference Documents 4](#_Toc22813148)

[4. Intended Use 4](#_Toc22813149)

[5. Responsibilities 4](#_Toc22813150)

[5.1 Quality Assurance 4](#_Toc22813151)

[5.2 Product Development Life Cycle Group 4](#_Toc22813152)

[6. Test Materials / Tools and Equipment 5](#_Toc22813153)

[7. Product Configuration 5](#_Toc22813154)

[8. Test Methods 5](#_Toc22813155)

[8.1 Installation Qualification 5](#_Toc22813156)

[8.2 Operational Qualification 5](#_Toc22813157)

[8.3 Performance Qualification 5](#_Toc22813158)

[9. Requirements Traceability 6](#_Toc22813159)

[10. Sample Size 7](#_Toc22813160)

[11. Acceptance Criteria 7](#_Toc22813161)

[12. Test Execution 7](#_Toc22813162)

[13. Deliverables 8](#_Toc22813163)

[14. Risk Evaluation 8](#_Toc22813164)

[15. Appendix A: IQ Validation Test Protocol 8](#_Toc22813165)

[16. Appendix B: OQ Validation Test Protocol 13](#_Toc22813166)

# Introduction/Background

**Visual Studio - 2005** is used to develop computer programs i.e. To Create, Save and Edit a software program code, compile a program code to an executable file, Run the program upon compilation, Debug the program code.

# Purpose/Scope

The scope of this document is limited to validation of Visual Studio - 2005 as per its intended use defined in this document.

# Reference Documents

Not applicable

# Intended Use

Following features of Visual Studio - 2005 are currently used by product development teams at CANTEL:

* Create, Save and Edit a multiple software program class file.
* Compile a program code.
* Run the program upon compilation.
* Debug the program code.

# Responsibilities

## Quality Assurance

* Develop validation protocol and generate validation report.

## Product Development Life Cycle Group

* Reviews and approves validation protocol and validation report.
* Execute the validation per this protocol and provide data to quality assurance team.

# Test Materials / Tools and Equipment

* Visual Studio – 2005 professional executable is available with a valid license key.
* The user has local administrator privileges.
* The system has following minimum hardware configurations:
* 1 GHz or faster processor or 1 GB RAM, 10 GB of available hard disk space
* Windows 7 Professional Operating System
* .Net Framework 2.0 or latest version of .Net Framework.

# Product Configuration

Not applicable

# Test Methods

## ­Installation Qualification

Validate installation of Visual Studio - 2005

## Operational Qualification

Validate following operations of Visual Studio – 2005

* Create, Save and Edit a multiple software program class file.
* Compile a program code.
* Run the program upon compilation.
* Debug the program code.

## Performance Qualification

Not applicable

# Requirements Traceability

Listed below is the traceability of the requirements to the test case:

| REQ ID | REQUIREMENTS | TEST CASE |
| --- | --- | --- |
| REQ\_001 | The user shall be able to install Visual Studio - 2005 tool successfully. | Appendix A: IQ Validation Test Protocol -TS\_001 |
| REQ\_002 | The tool shall be able to Create, Edit and Save software program code. | Appendix B: OQ Validation Test Protocol -TS\_001 |
| REQ\_003 | The tool shall be able to compile a program code. | Appendix B: OQ Validation Test Protocol -TS\_002 |
| REQ\_004 | The tool shall be able to run the program upon compilation. | Appendix B: OQ Validation Test Protocol -TS\_003 |
| REQ\_005 | The tool shall be able to Debug the program code. | Appendix B: OQ Validation Test Protocol -TS\_004 |

# Sample Size

From the FDA document titled “General Principles of Software Validation; Final Guidance for Industry and FDA Staff” issued on January 11, 2002.

“The vast majority of software problems are traceable to errors made during the design and development process. While the quality of a hardware product is highly dependent on design, development and manufacture, the quality of a software product is dependent primarily on design and development with a minimum concern for software manufacture. Software manufacturing consists of reproduction that can be easily verified. It is not difficult to manufacture thousands of program copies that functions exactly the same as the original; the difficulty comes in getting the original program to meet all specifications.” Therefore, it is reasonable to limit the sample size of software to 1.

# Acceptance Criteria

All the requirements listed above in this document should be validated after execution of Installation & Operational Qualification of Visual Studio – 2005.

All test steps requiring verification should “Pass”. If a test step “Fails”, it will be individually evaluated within the validation report to determine if the cause for failure is acceptable. One potential acceptable cause for test step failure is a “Test Case Error”.

# Test Execution

Execution of identified qualification protocols will be performed on below mentioned test environment to meet the defined Acceptance Criteria. Results will be captured along with evidences wherever applicable. Deviation if any from the planned test cases and observed anomalies / defects will be reported in validation report.

**Test Environment:**

A Computer System of following configuration with Visual Studio – 2005 professional installed on it:

* The system has following minimum hardware configurations:
* 1GHz or faster processor or 1 GB RAM, 10 GB of available hard disk space
* Windows 7 Professional Operating System
* .Net Framework 2.0 or latest version of .Net Framework

# Deliverables

Upon completion of the execution of this validation plan and protocol, test personnel will provide to CANTEL a comprehensive report including:

* Test execution results
* Validation Report along with deviations if any
* Identified anomalies / defects if any

# Risk Evaluation

Considering the intended use, as of now there is no risk involved.

# Appendix A: IQ Validation Test Protocol

|  |
| --- |
| **Visual Studio – 2005 Installation Qualification** |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **TESTER & TEST CASE REVIEW SECTION** | | | | |
| SUCCESSFUL TEST: YES [ ] NO [ ] | | | | |
| Tested by: | | Date Tested: | Signature: | |
| Reviewed by: | | Date Reviewed: | Signature: | |
| **TEST INFORMATION SECTION** | | | | |
| Purpose of Test: | This test validates the installation of “Visual Studio - 2005” | | | |
| **TEST EQUIPMENT & SUPPLIES SECTION** | | | | |
| **EQUIPMENT NEEDED: (Include where applicable Qty., PN, Rev., and Description)** | | | | **SN#'s or Cal ID#'s** |
| (1) OS Version | | | |  |
| (2) PC Number | | | |  |
| **PRE-REQUISITES**   * Visual Studio – 2005 professional executable is available with a valid license key. * The user has local administrator privileges * The system has following minimum hardware configurations: * 1 GHz or faster processor or 1 GB RAM, 10 GB of available hard disk space * Windows 7 Professional Operating System * .Net Framework 2.0 or latest version of .Net Framework. | | | |  |

The instructions below detail the procedure to the installation of “Visual Studio, Ver 2005”. Please follow each step carefully and check “Pass” if expected result matches the actual result or check “Fail” for mismatch. All “Fail” must have a comment in the “Tester comments” section and reference to the comment under the “Pass/ Fail” checkboxes (additional page can be attached as necessary)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TS \_001** | **Install Visual Studio - 2005 successfully** | | | | |
| **Step #** | **Operator Action** | **Expected Result** | **Actual Result** | **Disposition** | **Tester Comments** |
|  | Navigate to Visual Studio - 2005 and double click Setup file.  Select “Install Visual Studio – 2005” | Setup should get load for installation |  | Pass [ ]  Fail [ ] |  |
|  | Select the check box to accept the License Agreement and enter the Product Key and name. | The user should be able to enter the details. |  | Pass [ ]  Fail [ ] |  |
|  | Select “Default” radio button from “Select feature to install:” in “Microsoft Visual Studio 2005 setup – Option Page” and click next | The user should be able to select the default feature and should navigate to next page. |  | Pass [ ]  Fail [ ] |  |
|  | Check the progress of Installation.  Click next. | Installation should be completed successfully |  | Pass [ ]  Fail [ ] |  |
|  | Navigate to Visual Studio – 2005 from Windows Start menu to launch the tool. | Visual Studio – 2005 should get launch. |  | Pass [ ]  Fail [ ] |  |

# Appendix B: OQ Validation Test Protocol

|  |
| --- |
| **Visual Studio - 2005 Operational Qualification** |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **TESTER & TEST CASE REVIEW SECTION** | | | | |
| SUCCESSFUL TEST: YES [ ] NO [ ] | | | | |
| Tested by: | | Date Tested: | Signature: | |
| Reviewed by: | | Date Reviewed: | Signature: | |
| **TEST INFORMATION SECTION** | | | | |
| Purpose of Test: | This test validates the tool “Visual Studio - 2005” for its following intended use:   * Create, Save and Edit a software program code. * Compile a program code to an executable file. * Run the program upon compilation. * Debug the program code. | | | |
| **TEST EQUIPMENT & SUPPLIES SECTION** | | | | |
| **EQUIPMENT NEEDED: (Include where applicable Qty., PN, Rev., and Description)** | | | | **SN#'s or Cal ID#'s** |
| (1) OS Version | | | |  |
| (2) PC Number | | | |  |
| **PRE-REQUISITES:**   * Visual Studio - 2005 professional executable is available with a valid license key. * The user has local administrator privileges. * The system has following minimum hardware configurations: * 1 GHz or faster processor or 1 GB RAM, 10 GB of available hard disk space * Windows 7 Professional Operating System * .Net Framework 2.0 or latest version of .Net Framework. | | | |  |

Please follow each step carefully and check “Pass” if expected result matches the actual result or check “Fail” for mismatch.

All “Fail” must have a comment in the “Tester comments” section and reference to the comment under the “Pass/ Fail”

checkboxes (additional page can be attached as necessary).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TS\_001** | **Create, save and edit a software program code** | | | | |
| **Step #** | **Operator Action** | **Expected Result** | **Actual Result** | **Disposition** | **Tester Comments** |
|  | Launch Visual Studio - 2005 from the Windows START menu. | It should be possible to launch the visual studio. |  | Pass [ ]  Fail [ ] |  |
|  | Create new project in Visual Studio - 2005 by selecting options File > New > Project.  Select Project Type “Visual C++” and Template “Win32 Console Application”. Mention Project Name as “ConsoleApplication” and browse for the desired location and select Ok. | New project window should get displayed on the screen and the user should be able to fill Project name and browse to the desired location. |  | Pass [ ]  Fail [ ] |  |
|  | Click Next in “Welcome to the Win32 Application Wizard” Window and select checkbox “Precompiled Header” from Additional options menu in Application Settings window and click Finish | New Project “ConsoleApplication” should get successfully created. |  |  |  |
|  | Go to solution explorer, select file “ConsoleApplication.cpp” and rename file to “TestSample.cpp” | It should be possible to rename the source file “ConsoleApplication.cpp” to “TestSample.cpp”. |  | Pass [ ]  Fail [ ] |  |
|  | Delete the default code from TestSample.cpp file and add the following code.  /\* \* C++ Program to Add two number \*/  // ConsoleApplication.cpp : Defines the entry point for the console application.  //  #include "stdafx.h"  #include <iostream>    int main ()  {  int l\_Sum\_1, l\_Number\_a, l\_Number\_b;    std::cout << "Enter two integers to add\n";  std::cin >> l\_Number\_a >> l\_Number\_b;    l\_Sum\_1 = l\_Number\_a + l\_Number\_b;  std::cout <<"Sum of the numbers: " << l\_Sum\_1 << std::endl;  system("PAUSE");  return 0;  } | Code should get successfully created in TestSample.cpp file. |  | Pass [ ]  Fail [ ] |  |
|  | Save the file.  Go to File>Save TestSample.cpp | File TestSample.cpp should get successfully saved. |  | Pass [ ]  Fail [ ] |  |
|  | Close the file.  Go to File>Close | File TestSample.cpp should get successfully closed. |  | Pass [ ]  Fail [ ] |  |
|  | Go to solution explorer and double click on TestSample.cpp, then  verify that the contents are correctly saved. | The contents are correctly saved in TestSample.cpp file. |  | Pass [ ]  Fail [ ] |  |
|  | Delete the code from TestSample.cpp file and add following edited code.  /\* \* C++ Program to Add two number \*/  // ConsoleApplication.cpp : Defines the entry point for the console application.  //  #include "stdafx.h"  #include <iostream>    int main ()  {  int l\_Sum\_2, l\_Number\_c, l\_Number\_d;    std::cout << "Enter two integers to add\n";  std::cin >> l\_Number\_c >> l\_Number\_d;    l\_Sum\_2 = l\_Number\_c + l\_Number\_d;  std::cout <<"Sum of the numbers: " << l\_Sum\_2 << std::endl;  system("PAUSE");  return 0;  } | Code should get successfully edited. |  | Pass [ ]  Fail [ ] |  |
|  | Save the file.  Go to File>Save TestSample.cpp | Edited File TestSample.cpp should get successfully saved. |  | Pass [ ]  Fail [ ] |  |
|  | Close the edited file.  Go to File>Close | Edited File TestSample.cpp should get successfully closed. |  | Pass [ ]  Fail [ ] |  |
|  | Go to solution explorer and open TestSample.cpp, then  verify that the edited contents are correctly edited and saved. | The contents are correctly edited and saved in TestSample.cpp file. |  | Pass [ ]  Fail [ ] |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TS\_002** | **Compile a program code.** | | | | |
| **Step #** | **Operator Action** | **Expected Result** | **Actual Result** | **Disposition** | **Tester Comments** |
|  | For Compiling the code, go to menu and select Build > Build Solution | Program should get build successful with 0 errors and 0 warnings. |  | Pass [ ]  Fail [ ] |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TS\_003** | **Run the program upon compilation.** | | | | |
| **Step #** | **Operator Action** | **Expected Result** | **Actual Result** | **Disposition** | **Tester Comments** |
|  | To Run the program, click F5 from keyboard. | Command window file: C:\Windows\system32\cmd.exe showing the input fields should get displayed on the screen. |  | Pass [ ]  Fail [ ] |  |
|  | Enter integers 2 and 3 as input for the required fields  i.e.,  Enter two integers to add  2  3    Press Enter after each input. | Fields should accept the entered values. |  | Pass [ ]  Fail [ ] |  |
|  | Verify exact output after addition of two integers 2 and 3 is displayed as Sum of the numbers: 5 | Should display the additional value of two integers 2 and 3 as Sum of the numbers: 5 |  | Pass [ ]  Fail [ ] |  |
|  | Close the running program by selecting close button on Console Application. | Running Program should get stop. |  |  |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TS\_004** | **Debug the Program code to remove coding errors.** | | | | |
| **Step #** | **Operator Action** | **Expected Result** | **Actual Result** | **Disposition** | **Tester Comments** |
|  | In the TestSample.cpp code, set the cursor on line#14 and add Breakpoint by pressing F9 or go to Debug>>Toggle Breakpoint.  Verify that round red circle is present on line#14. | Breakpoint on line#14 should get added successfully. |  | Pass [ ]  Fail [ ] |  |
|  | For Debugging the code, go to Debug>Start Debugging | Command window file: d:\users\default user\desktop\vs2005\consoleapplication\debug\ ConsoleApplication.exe showing the input fields should get displayed on the screen. |  | Pass [ ]  Fail [ ] |  |
|  | Enter integers 2 and 3 as input for the required fields  i.e.,  Enter two integers to add  2  3    Press Enter after each input. | Fields should accept the entered values. |  | Pass [ ]  Fail [ ] |  |
|  | Verify that the input value given by user is stored in respective variable by placing the cursor to line#14 at variable l\_Number\_c and l\_Number\_d. | It should display value “2” at variable “l\_Number\_c” and “3” at “l\_Number\_d”. |  | Pass [ ]  Fail [ ] |  |
|  | To run the program “F5” from keyboard. | Should display the addition of two integers “2” and “3” as “Sum of the numbers: 5” |  |  |  |
|  | Stop debugging by selecting close button on Console Application and by selecting “Delete Breakpoint” through right click on round red circle present on line#14. | Program debugging should stop. |  | Pass [ ]  Fail [ ] |  |
|  | Close the Visual Studio 2005 by clicking on close button on Console Application – Microsoft Visual Studio window | Visual Studio should get closed. |  | Pass [ ]  Fail [ ] |  |