WinWedge Pro Validation Report

Software: *WinWedge Pro 4*

Developer: *TAL Technologies Inc.*

Initial Date: *July 1996*

Last Updated: *April 2015*

Revision: *4.0*

Signatures

Prepared by: _____

Signature: _____   *Date:* _____

Approved by: _____

Signature: _____   *Date:* _____

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Table of Contents

1. Performance Validation Plan

1.1. Objective

This document describes the requirements for the validation of the WinWedge Pro v 4.0.

1.2. System Definition

The WinWedge Pro v 4.0 program allows users to import data from nearly any serial RS232 device (bar code reader, balance, caliper, measuring and laboratory instruments, etc.) and insert the data into any Windows application.

1.3. Responsibilities

1.3.1. Personnel

Personnel responsible for the preparation, review and approval of each required validation document are identified in the Plan Highlights.

1.3.2. Quality Control

The quality control unit for WinWedge Pro v4.0 will consist of the Main Application Developer, and the Assistant Software Developer.

1.3.3. Reviewer

For all validation documents, the reviewer's signature indicated that the content of the validation document is appropriate, accurate and correct.

1.4. Highlights

1.4.1. Purpose

The basic purpose of computer related system validation is to develop documented evidence that a specific computer-related system does what it purports to do in a reliable and consistent manner, and will continue to do so in the future. Key concerns in the validation include the performance and integrity of the computer-related system.

1.4.2. New releases

Whenever a new version of the WinWedge Pro v 4.0 is developed, the appropriate suite of functional tests, as defined by the WinWedge Pro v 4.0 Software Validation Procedure, will be executed by the delegated tester.

1.4.3. Documentation of changes

All changes to the WinWedge Pro v 4.0 will be documented using established practices of change control.

2. Software Testing Procedure

2.1. Objective

This defines a method of testing the WinWedge Pro v 4.0 software for functional performance and integrity.

2.2. Policy

It is divisional policy that all computer-related systems will be validated prior to routine use or commercial release to confirm each computer related system performs as intended and meets the functional requirements as defined in the system documentation. Established program development practices dictate that the requirements for validation should be considered throughout the entire development process. Appendix A identifies each required validation document and when it must be completed during the development process.

2.3. Scope

This divisional procedure applies to all application-specific computer related systems developed or modified by personnel within the division. This procedure does not apply to system software (i.e. operating systems, compilers, IDE's etc.) nor to purchased packages, which are intended for general-purpose use (packaged software such as Microsoft Office).

2.4. Responsibilities

It is the responsibility of the person who develops the computer-related system, in conjunction with the system's user, to assure that the required documents are completed at the appropriate time during the development process. The paragraphs in the Highlights Section specifically identify persons responsible for the preparation, review and final approval of each validation document. For all validation documents, the reviewer's signature indicated that the content of the validation document is appropriate, accurate and correct.

2.5. Testing Highlights

2.5.1. Testing Purpose & Concerns

The basic purpose of computer-related system validation is to develop documented evidence that a specific computer-related system does what it purports to do in a reliable and consistent manner, has done so in the past, and will continue to do so in the future. This documentation is generated throughout the life cycle of the system (as shown in Appendix A) and should be available for use during audits or inspections by company or regulatory officials. Key concerns in validation include the performance, integrity and accountability of the computer-related system.

2.5.2. Validation

New computer-related systems must be validated prior to implementation or release. Existing computer-related systems should normally have been validated prospectively, PRIOR to being installed for operational use. In some cases, existing computer-related systems may have to be validated retrospectively, by evaluation the PAST performance of the system to determine that the system does what it purports to do in a reliable manner. In other cases, existing systems may have to be validated concurrently, within their normal operating environment.

2.5.3.   Changes

The impact of changes to computer-related systems must be evaluated and appropriate re-testing performed. Changes to computer-related systems may be classified into one of three groups:

a. *Cosmetic Changes:* Changes which do not affect the operation of the computer-related system and are usually cosmetic in nature, such as a spelling correction. Cosmetic changes usually do not require re-validation.
b. *Minor Changes:* Changes which only affect one section of a computer-related system, or one module of one software program, such as a change in report layout. Minor changes require re-testing in accordance with the original test plan to insure that no bugs have been introduced.
c. *Major Changes:* Changes that impact large portions of the computer-related system, such as conversion from one version of a programming language to another. Major changes require that a complete re-validation be executed.

2.5.4.   Documentation of Changes

Whenever a change is made to a computer-related system, or software program, that change must be documented using established practices of change control. In addition, a decision must be made as to whether the change is Cosmetic, Minor or Major. This decision is made and documented by the person who makes the change. If necessary, changes must be made to the appropriate Qualification Protocols and recorded on the Protocol's Revision History page(s).

2.5.5.   Reporting

If a Qualification Protocol is executed and the result is unsuccessful, the person executing the protocol should record the discrepancy and report it to TALtech Quality Control immediately by phone 800-722-6004. The person who wrote/changes the software program will correct the problem, document the required modifications, and notify the person who was executing the protocol to continue the execution of the protocol at a certain point, or begin the entire protocol again.

2.5.6.   System Documentation

The **System Documentation** (i.e. the manual) is a description of what the computer-related system is and what it does. The System Documentation will contain:

1. A clear statement of the objective or purpose of the system.
2. The functional requirements of the system.
3. Descriptions of the systems inputs and outputs.
4. Other pertinent information, which further describes the computer-related systems.

   Functional Requirements, contained in the System Documentation are one of the most important elements of computer-related systems validation. They identify the functions to be performed by the computer-related system, and therefore they are the function to be validated. Functional requirements should be prepared in consultation with persons who will use the computer-related system.

   The preparation of System Documentation is the responsibility of the person who develops the computer-related system. It is to be reviewed and approved by the Chief Software Engineer.

2.5.7.   Project Validation Plan

The **Project Validation Plan** is a system-specific description of the requirements of validation of the entire computer-related system. It contains the strategy from which each phase of validation is planned, implemented and documented. It provides a clear statement of the objectives and approach to be used in performing the validation, and summarizes the documentation that is to be generated as part of the complete system validation effort. The clarity of a Project Validation Plan is often enhanced by the use of flow charts, tables, diagrams or other illustrative materials, which assist in presenting the overall plan.

The Project Validation Plan will identify all required validation documents, and will clearly define the persons responsible for the preparation, review and approval of each validation document. The meaning of signatures on each validation documents should be clearly defined in the Project Validation Plan. Because the Project Validation Plan is specific to a computer-related system currently under development, the responsible individuals may be identified by name. The quality control unit, which is the person(s) who will be responsible for the quality control duties related to the validation of this specific system, should be identified in the Project Validation Plan.

The preparation of Project Validation Plan is the responsibility of the person who develops the computer-related system. It is also to be reviewed and approved by the Chief Software Engineer.

2.5.8.   Qualification Protocol

A **Qualification Protocol** is a written description of the test plan to be followed for establishing documented evidence that a computer-related system does what it purports to do. There are three different types of qualification protocols that may be required for validation, based on the configuration and components of a specific computer system. The qualification protocols are:

1. *Installation:* Qualification which provides documented verification that all key systems components are properly installed.
2. *Operational:* Qualification which provides documented verification that the equipment-related system or sub-system performs as intended throughout all anticipated operating ranges.
3. *Performance:* Qualification which provides documented verification that the total system performs as intended throughout all anticipated operating ranges.

The preparation of Qualification Protocol is the responsibility of the person who develops the computer-related system. All protocols must be reviewed and approved by the Chief Software Engineer.

2.5.9.   Protocol Supplement

A Protocol Supplement is used to document changes to a Qualification Protocol. After a protocol has been approved, it is still subject to change due to inappropriate test data, inaccurate responses, etc. These supplements should be prepared, reviews and approved in like manner as the original protocol.

2.5.10.   Program Documentation

Program Documentation is a description of what one specific software program does and how it does it. The Program Documentation will contain:

1. A general description of the purpose of the software program.
2. The program processing logic, describing the software program and how it operates to satisfy the functional requirements.
3. Specifications for all of the systems inputs and outputs.
4. Other pertinent information that further describes the software program.

The preparation of the Program Documentation is the responsibility of the person who develops the computer-related system. The Program Documentation must be reviewed and approved by the Chief Software Engineer.

2.5.11. Task Summary Report

The **Task Report Summary** is a brief overview of the observations and conclusions upon execution of a Qualification Protocol.

The preparation of the Task Report Summary is the responsibility of the person who develops the computer-related system. The Task Report Summary must be reviewed and approved by the Chief Software Engineer and signed by a second user to ensure accuracy.

3. Performance Validation Report

3.1. Performance Qualification Overview

As a Microsoft Windows-based application, WinWedge responds to inputs from either the keyboard, the PC's mouse, or the PC's serial port. Validation of this application will be accomplished by following a script of keystrokes, mouse clicks, and serial input from several common devices (barcode scanners, balances, and measuring devices.) and visually comparing the resultant output of the application to a set of expected outputs. The person executing this qualification protocol is expected to make a copy of this document, perform each step of the script and initial/date each step indicating successful completion.

The WinWedge program validation is comprised of various performance tests. In the ideal situation, the tests will all succeed. If any of these tests diverge from the ideal, the tester is required to note the differences, contact TALtech Quality Control and proceed according to their directions. Throughout this validation effort, the tester is expected to compare the outputs of this application with the expected set of outputs in the appendices. Due to the variety of devices that support the Windows operating environment and the configurability of that environment, differences in window size, placement, video resolution, color, etc. may be observed. The tester is advised to compare outputs for content rather than for exact matches. In addition, it is expected that dates appearing on the appended documents will differ from those on the documents that are actually produced by the validation.

3.2. Setting up the Performance Qualification Test

	Action	Expected Output	Initials/Date
1.	Insert the disk labeled WinWedge Pro V 4.0 into your PC's CD drive.		
2.	The **Setup** Program for WinWedge Professional should automatically run allowing you to install the complete WinWedge program package onto your PC.	Compare to figure B1	
3	Type in the User Name, Company Name and WinWedge Serial Number.	Compare to figure B2	
4	Next, check the desired components for installation from the **Select Components** list and continue with the set up program, choosing the default options in all Windows to complete the installation of WinWedge Pro v4.0 onto your system.	Compare to figure B3	

3.3. Testing the Program's Main Menu

	Action	Expected Output	Initials/Date

1.	Launch the WinWedge program by highlighting, **Start** > **Programs** > **WinWedge Professional** > **WinWedge**. Use the mouse to **click** on WinWedge.	The WinWedge main window should be displayed - compare to figure C1.	
2.	Use the mouse to click on the **File** menu item.	Compare the list of the menu choices to the image in figure C2.	
3.	Use the mouse to click on the **Mode** menu item.	Compare the list of the menu choices to the image in figure C3.	
4.	Use the mouse to click on the **Port** menu item.	Compare the list of the menu choices to the image in figure C4.	
5.	Use the mouse to click on the **Define** menu item.	Compare the list of the menu choices to the image in figure C5.	
6.	Use the mouse to click on the **Activate** menu item.	Compare the list of the menu choices to the image in figure C6.	
7.	Use the mouse to click on the **Help** item.	Compare the list of the menu choices to the image in figure C7.	

3.4.   Testing the Mode Selection Windows

	Action	Expected Output	Initials/Date
1.	Use the mouse to click on the **Mode** Item. Then click on "**Send Keystrokes To…**"	The "**Send Keystrokes To…**" window should display. Compare window to figure D1	
2.	Use the mouse to click on the **Mode** Item. Then click on "**DDE Server…**"	The "**DDE Server…**" window should display. Compare window to figure D2	
3.	Use the mouse to click on the **Mode** Item. Then click on "**Log to Disk…**"	The "**Log to Disk…**" window should display. Compare window to figure D3	

3.5.   Testing the Port Selection Windows

	Action	Expected Output	Initials/Date
1.	Use the mouse to click on the **Port** menu Item. Then click on "**Settings…**"	The WinWedge **"Serial Port Settings…"** window should display. Compare window to figure E1	
2.	Use the mouse to click on the **Port** menu Item. Then click on "**Analyze…**"	The "**Port Analyze…"** window should display. Compare window to figure E2	

	Action	Expected Output	Initials/Date
3.	Use the mouse to click on the **Port** menu Item. Then click on "**Beep On Input**"	The "**Beep On Input**" item should now have a check mark next to it.	

3.6.   Testing the Define Menu Selection Windows

	Action	Expected Output	Initials/Date
1.	Use the mouse to click on the **Define** menu Item. Then click on "**Input Data Record Structure…**"	The "**Start and End of Record Events…**" window should display. Compare window to figure F1	
2.	Use the mouse to click on the **Define** menu Item. Then click on "**Pre Input Character Translations…**"	The "**Pre Input Character Translations…**" window should display. Compare to figure F2	
3.	Use the mouse to click on the **Define** menu Item. Then click on "**Pre Transfer Character Translations…**"	The "**Translation Table…**" window should display. Compare to figure F3	
4.	Use the mouse to click on the **Define** menu Item. Then click on "**Serial Output Strings…**"	The "**Output String Editor**" window should display. Compare to figure F4	
5.	Use the mouse to click on the **Define** menu Item. Then click on "**Hot Keys and Hot Key Actions…**"	The "**Hot Keys and Hot Key Actions…**" window should display. Compare to figure F5	
6.	Use the mouse to click on the **Define** menu Item. Then click on "**Command Source DDE Link…**"	The "**Command Source DDE Link** …" window should display. Compare to figure F6	
7.	Use the mouse to click on the **Define** menu Item. Then click on "**Output Buffer DDE Link …**"	The "**Output Buffer DDE Link …**" window should display. Compare to figure F7	

3.7.   Testing the Activate Menu Selection Windows

	Action	Expected Output	Initials/Date
1.	Use the mouse to click on the **Activate** menu Item. Then click on "**Test Mode…**"	The WinWedge **"Monitor Window"** should display. Compare window to figure G1	
2.	Use the mouse to click on the **Activate** menu Item. Then click on "**Normal Mode…**"	The WinWedge "**Monitor Window**" should display. Compare to figure G2	

	Action	Expected Output	
3.	Use the mouse to click on the **Activate** menu Item. Then click on "**Virtual Instrument Mode...**"	The "**Virtual Serial Device...**" window should display. Compare to figure G3	
4.	Use the mouse to click on the **Activate** menu Item. Then click on "**Minimize On Activation**"	The "**Minimize On Activation**" selection should now have a check mark next to it. Compare to figure G4	
5.	Use the mouse to click on the **Activate** menu Item. Then click on "**Always On Top...**"	The "**Always On Top...**" selection should now have a check mark next to it. Compare to figure G5	
6.	Use the mouse to click on the **Activate** menu Item. Then click on "**Display DTR Toggle Button**"	The "**Minimize On Activation**" selection should now have a check mark next to it. Compare to figure G6	
7.	Use the mouse to click on the **Activate** menu Item. Then click on "**Display Break Button**"	The "**Display Break Button**" selection should now have a check mark next to it. Compare to figure G7	
8.	Use the mouse to click on the **Activate** menu Item. Then click on "**Display Date/Time...**"	The "**Date/Time Format**" window should display. Enter "MM-DD-YY" and click "**OK**". Compare to figure G8 Now the "**Display Date/Time...**" selection should now have a check mark next to it. Compare to figure G9	

3.8.   Program Functionality Testing (Keystrokes Mode)

	Action	Expected Output	Initials/Date
1.	Launch the WinWedge program by highlighting, **Start** > **Programs** > **WinWedge Professional** > **WinWedge**. Use the mouse to **click** on WinWedge.	The WinWedge main window should be displayed - compare to figure C1.	
2.	Use the mouse to click on the **Mode** menu item. Select "**Send Keystrokes to...**"	The window "**Send Keystrokes to...**" should appear.	
3.	Enter the application title "**Notepad**", and the command line "**Notepad.exe**" then click "**OK**"	The window "**Send Keystrokes to...**" should disappear. The "**Send Keystrokes to...**" item should now be checked when the mouse is used to click on **Mode**.	
4.	Use the mouse to click on the **Port** menu item. Select "**Settings...**"	The "**Serial Port Settings**" window should be displayed.	

5.	Use the mouse to select the COM port and settings for the test device. (in this case, the test device is second PC running WinWedge connected to COM1 using the 9600 baud, even parity, 7 databits and one stopbit) Click "**OK**"	The "**Serial Port Settings**" window should disappear.	
6.	In the second PC running the second copy of WinWedge, use the mouse to click on the **Port** menu item. Select "**Analyze**". Send a test data string consisting of "**ABC.DEF.123**" followed by a carriage return character. Click "**Quit**".	The string ABC.DEF.123 followed by a carriage return should appear in the "**Input buffer**" box of the "**Port Analyze**" window in the first PC's copy of WinWedge. The carriage return will appear as a musical note.	
7.	In the copy of WinWedge on the first PC, use the mouse to click on the **Define** menu item. Select "**Input Data Record Structure...**".	The "**Start and End of Record Events**" window will be displayed.	
8.	Select "**Any Character Received**" as the start of record event. Select "**CR or CRLF received**" as the end of record event. Click the "**Continue**" button	The Beginning and End of Record structure will be defined. The "**Input Record Structure**" window will be displayed.	
9.	Select "**Single field data record**", then click "**Continue**"	The "**Input Record Definition Editor**" window will be displayed.	
10.	Click on the "**Field Postamble Keystrokes**", then click the "**Keystrokes List**" Button. Select "**Enter**" from the list. Click "**OK**"	The "**Field Postamble Keystrokes**" field will be defined as {**Enter**}, then the "**Input Record Definition Editor**" window will disappear.	
11.	Use the mouse to click on the **Define** menu item. Select "**Pre-Input Character Translations**".	The "**Pre-Input Character Translations**" window will appear.	
12.	In the "**Pre-Input Character Translations**" window select ASCII 46 (.) then click the "**Translate**" button. From the "**ASCII chart**" select ASCII 32 (space) then click "**OK**". Click the "**OK**" button on the "**Pre-Input Character Translations**" window	ASCII 46 (**.**) will be converted to ASCII 32 (**Space**) before the data is processed in **WinWedge.**	
13.	Use the mouse to click on the **Define** menu item. Select "**Serial Output Strings**".	The "**Output String Editor**" window will appear.	
14.	Use the mouse to click on the "**Acknowledgment String**" text box.	The "**Output String Editor**" window will close. When WinWedge	

	In the box enter "**OK**". Then click "**OK**".	receives data, it will send "**OK**" out the COM port.	
15.	Use the mouse to click on the **Define** menu item. Select "**Hot Keys and Hot Key Actions**".	The "**Hot Keys and Hot Key Actions**" window will appear.	
16.	Using the mouse click on the "**Hot Key Action**" combo box. Select "**Suspend WinWedge**".	The "**Hot Key Action**" combobox will read, **Suspend WinWedge**".	
17.	Using the mouse click on the "**Hot Key Keystroke**" text box. Press the "**ALT**" and the "**Z**" at the same time. Click the "**OK**" button.	The "**Hot Key Keystroke**" text box will have the following text, "**Alt+Z**". The "**Hot Keys and Keystroke**" window will close.	
18.	Using the mouse click on the **Activate** Menu item. Select "**Virtual Instrument Mode**"	The "**SoftwareWedge- Virtual Serial Device**" window will appear.	
19.	Click on the text box below "**Output - To WinWedge**" and enter the following text: "**ABC.DEF.123.**" then press the "**Enter**" key. Now click the "**Send**" button.	Notepad will open and display the following text: "**ABC DEF 123**". The "**Input Buffer - From WinWedge**" text box will have the following text: "**OK**".	
20.	Click on the "**Quit**" button	The "**SoftwareWedge- Virtual Serial Device**" window will close.	
21.	Using the mouse click the **Activate** menu item. Select "**Display DTR Toggle Button...**" item.	The "**Display DTR Toggle Button...**" menu item will be checked. When **WinWedge** is activated the "**Toggle DTR**" button will be displayed.	
22.	Using the mouse click the **Activate** menu item. Select "**Display Break Button...**" item.	The "**Display Break Button...**" menu item will be checked. When **WinWedge** is activated the "**Break**" button will be displayed.	
23.	Using the mouse click the **Activate** menu item. Select "**Display Date/Time...**" item.	The "**Display Break Button Display Date/Time...**"menu item will be checked. When **WinWedge** is activated The date and time will be displayed.	
24.	Using the mouse click the "**Activate**" menu item. Select "**Always On Top**" item.	The "**Always On Top**" menu item will be checked. When **WinWedge** is activated it will stay on top of all other windows.	
25.	Using the mouse click the **Activate** menu item. Select "**Minimize On Activation**" item.	The "**Minimize On Activation**" menu item will be checked. When **WinWedge** is activated it will be minimized.	

26.	Using the mouse select the **Activate** menu item. Select "**Test Mode**".	An icon titled "**Software Wedge - COM# (S)**" will be displayed.	
27.	Using the mouse click on the minimized "**Software Wedge - COM# (S)**" icon	The "**Software Wedge - COM# (S)**" window will be restored to regular size.	
28.	Using the mouse select the "**Quit**" menu item. Select the "**Resume for one Record**" item. Send the following text to the COM port: "**ABC.DEF.123<enter>**"	**WinWedge** will resume processing serial input for one record. When you send the text to **WinWedge,** Notepad will run and display the processed data. **WinWedge** will return to suspended mode. The window caption will again be "**Software Wedge - COM# (S)**".	
29.	Using the mouse select the "**Quit**" menu item. Select the "**Resume Software Wedge**" item. Send the following text to the COM port: "**ABC.DEF.123<enter>**"	The window caption of Software Wedge will change to "**Software Wedge - COM#**" When you send the text to the COM port Notepad will run and display the processed data.	

Revisions

Revision	Date	Change
1.0	July 1996	Original Issue
2.0	Nov 2004	WinWedge version update to 3.1
3.0	Sept 2007	WinWedge version update to 4.0
4.0	April 2015	Updated layout and styles

Appendices

Appendix A

Figure A1

	System development life cycle phases (After this phase...)	Required documentation (...these documents must be completed)
1	Project Conceptualization	NA
2	Functional Requirements and Objectives	System Documentation Project Validation Plan (if validation is required)
3	System Design	System Design Specifications
4	Program Construction	Qualification Protocol (if validation is required)
5	Program Testing	Program Documentation
6	System Integration and Installing	----
7	Performance Qualification	Task Report Summary (if validation is required)
8	System Release for Operational/ Production Use	----
9	On-going Support	----

Appendix B

Figure B1
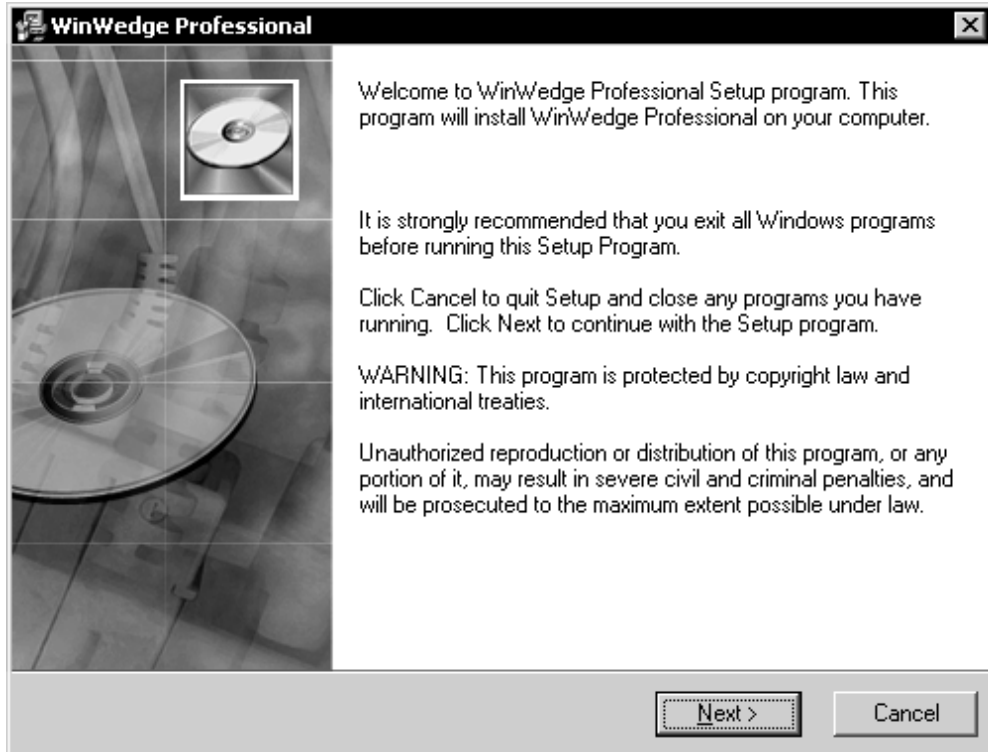
Figure B2
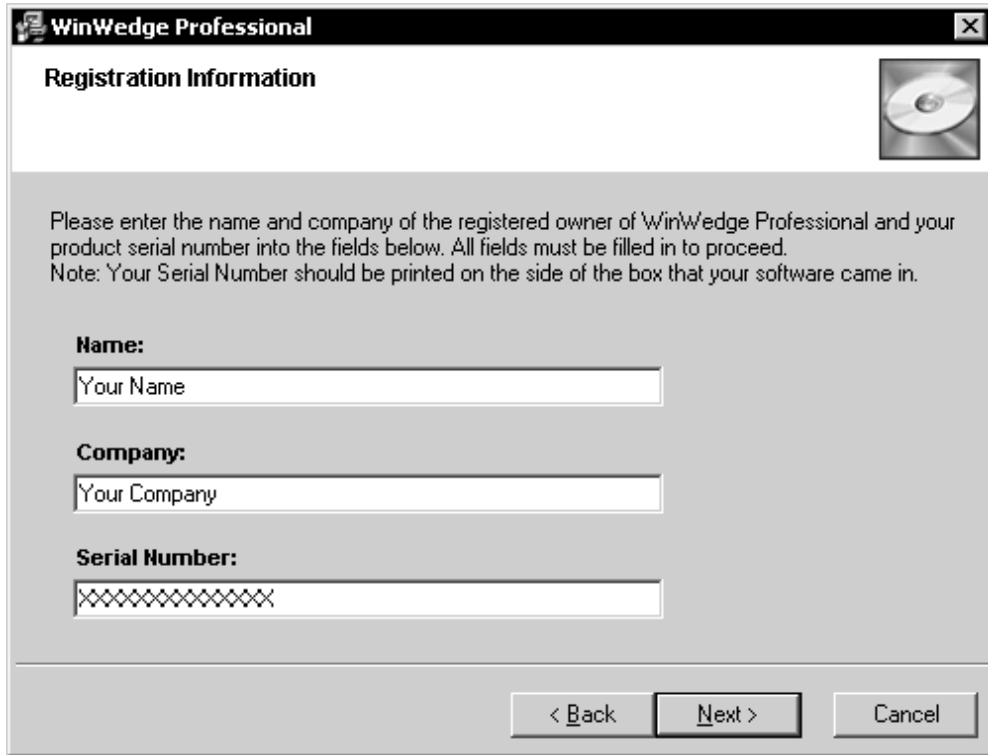
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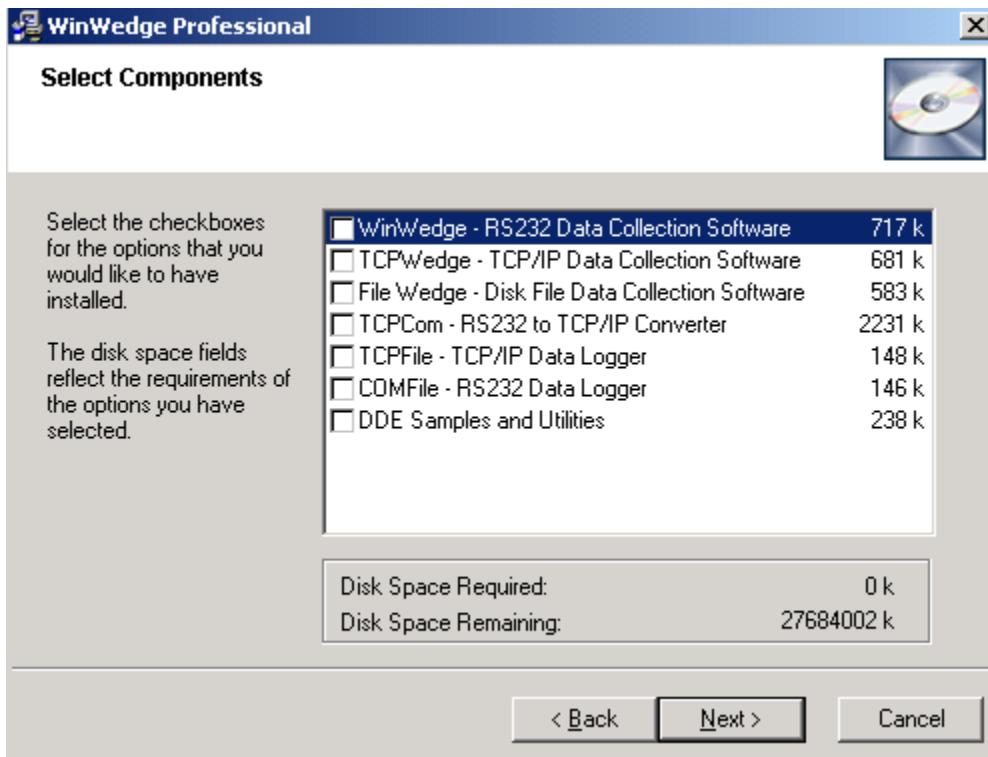
Appendix C

Figure C1
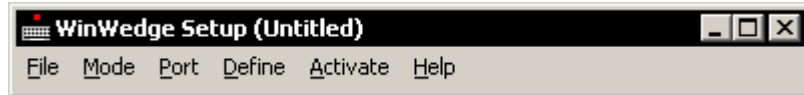
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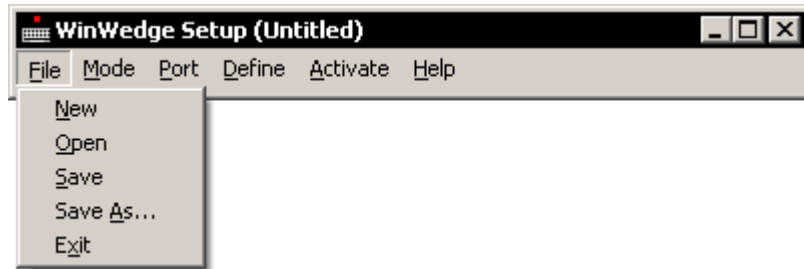
Figure C3

Figure C4

Figure C5
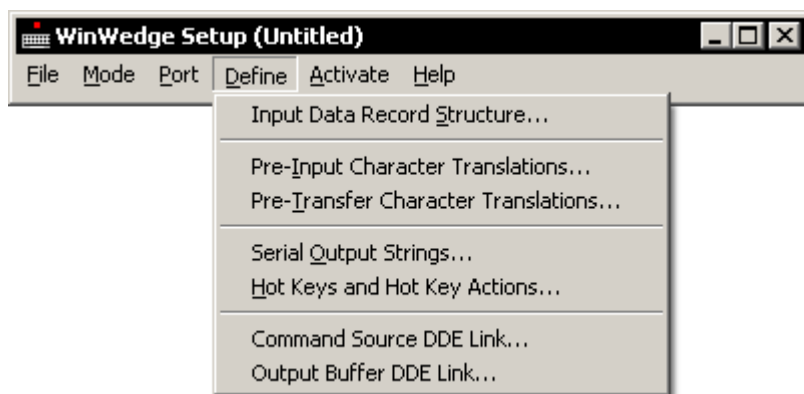
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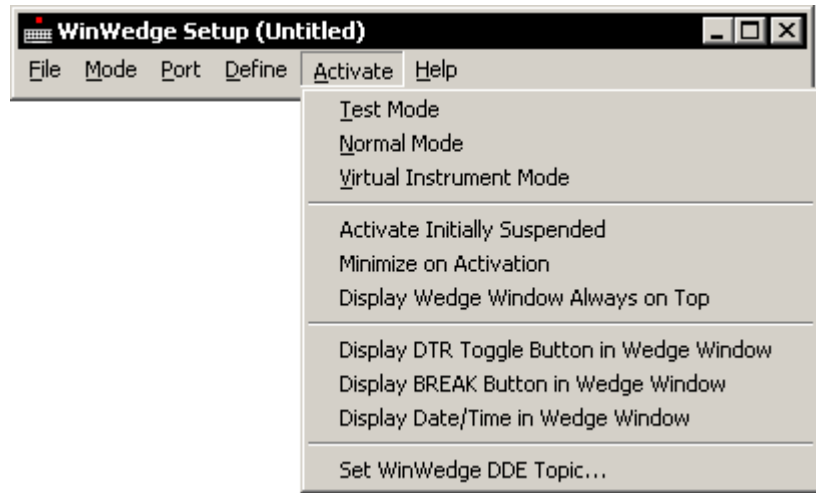
Figure C7

Appendix D

Figure D1
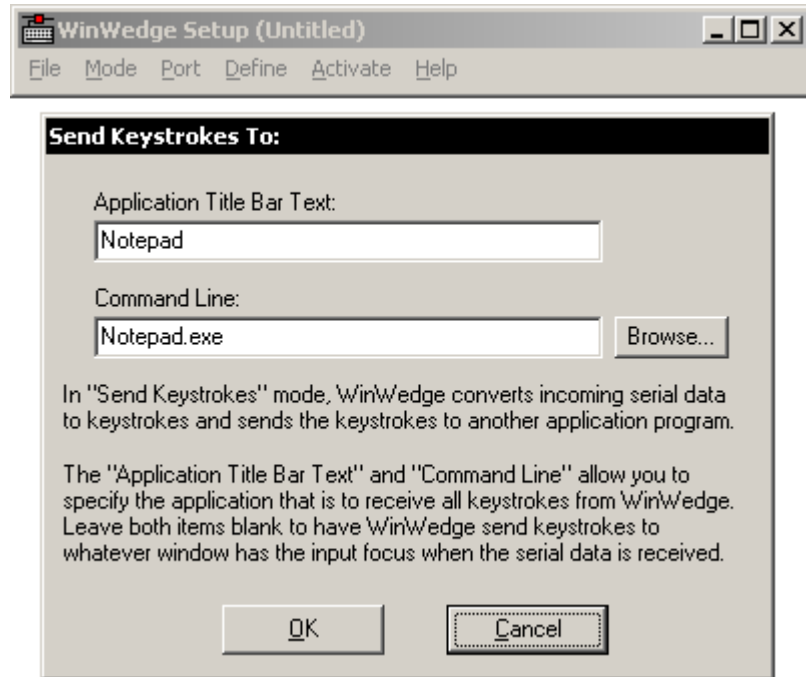
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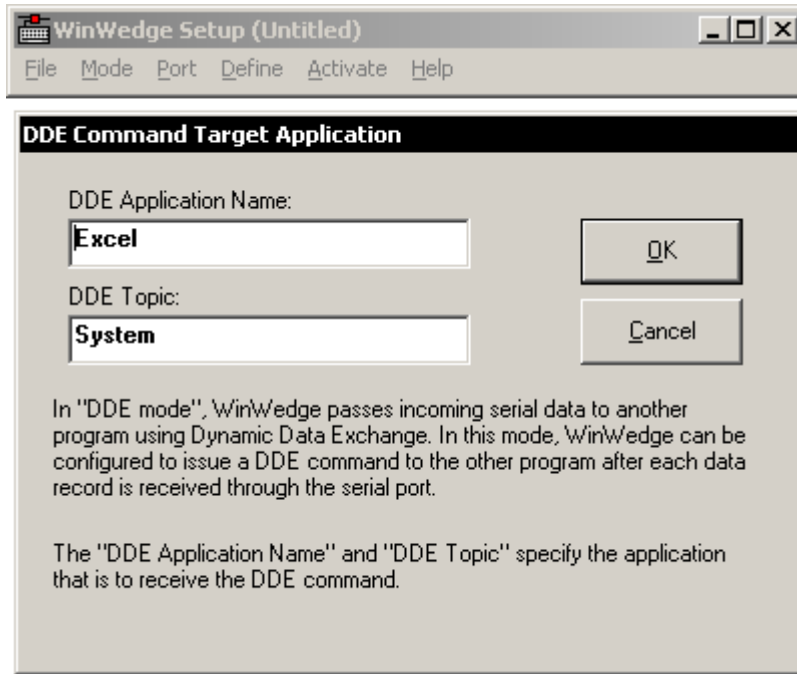
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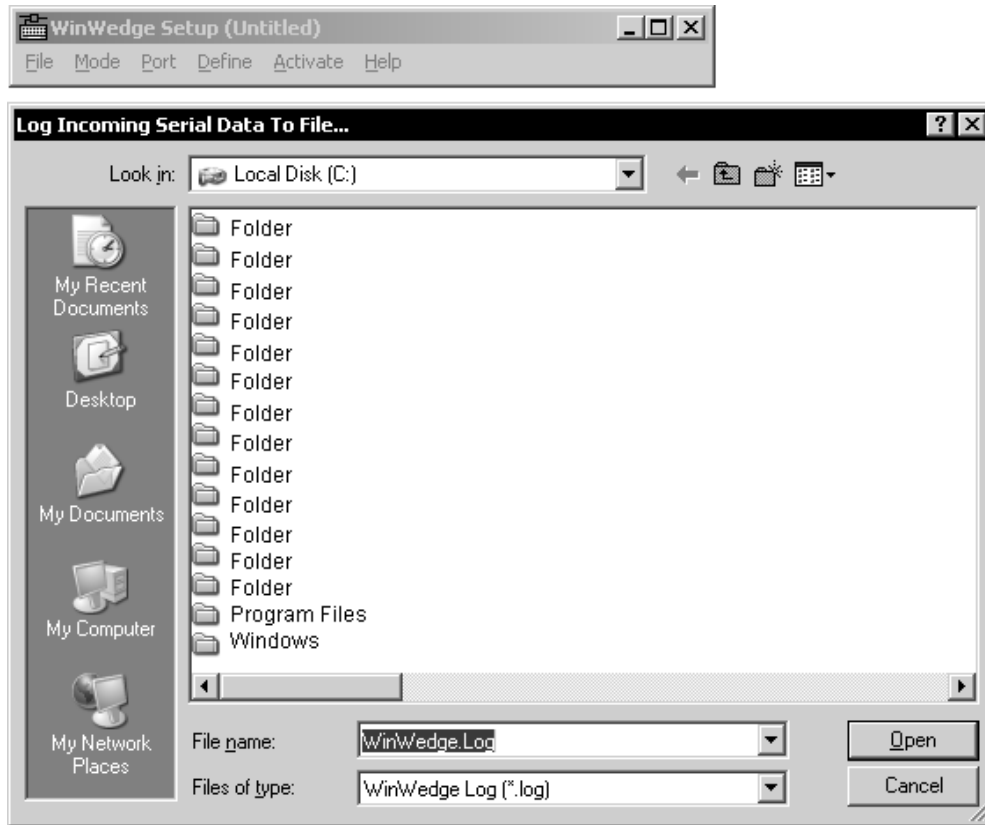
Appendix E

Figure E1
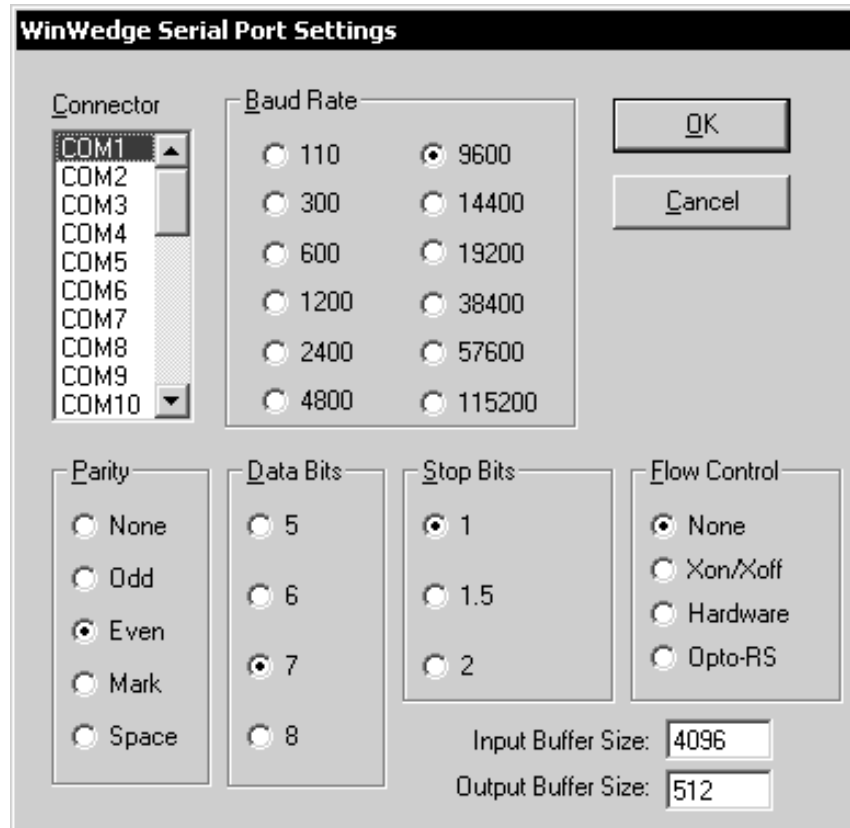
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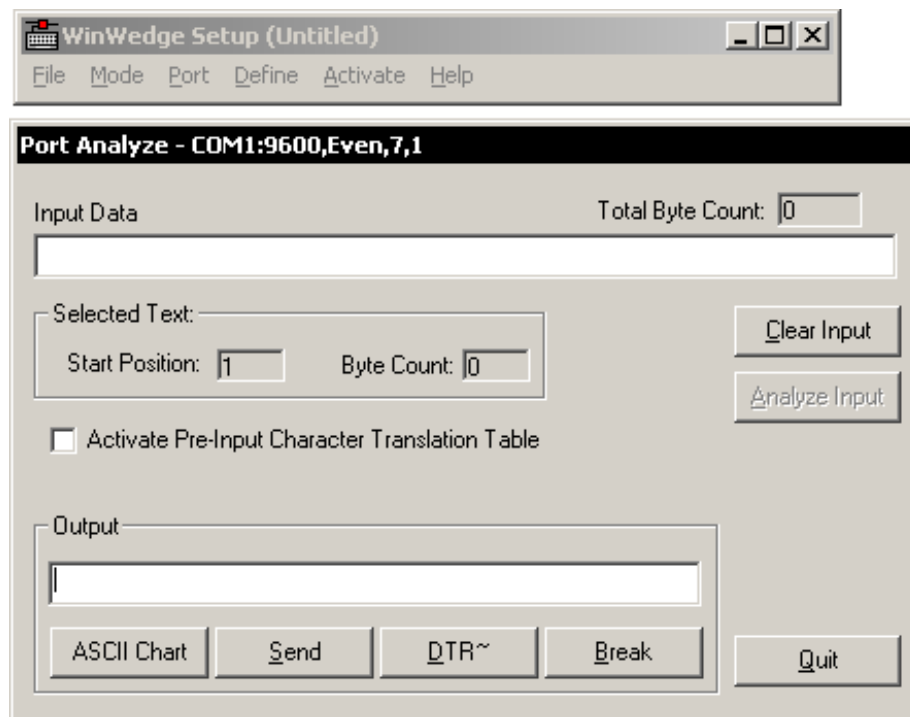
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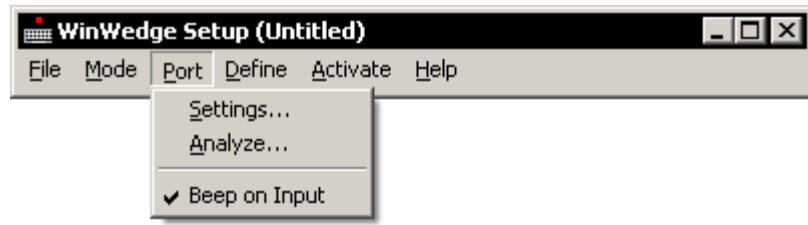
Appendix F

Figure F1
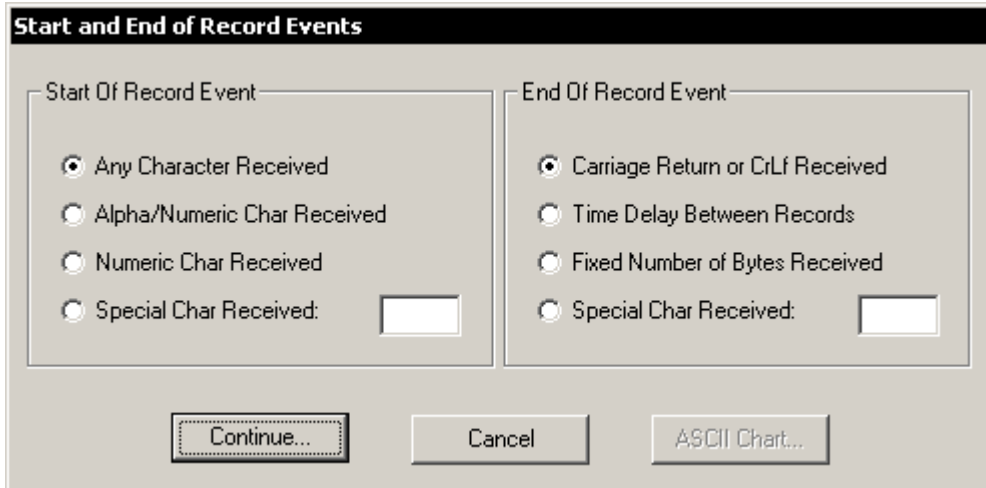
Figure F2
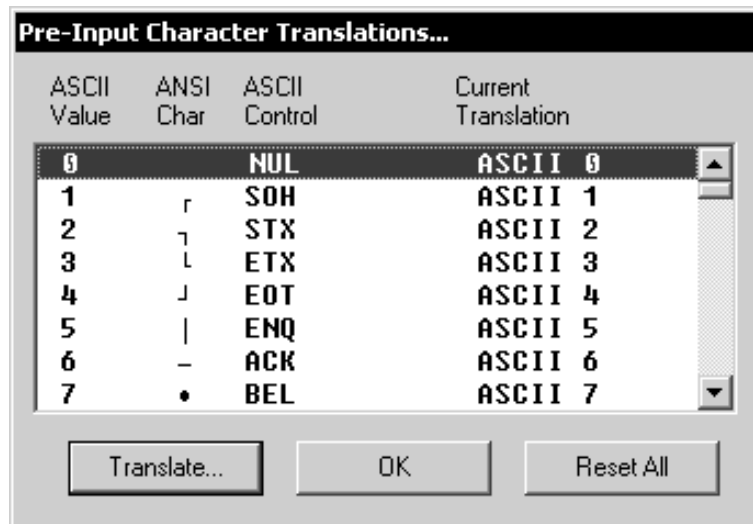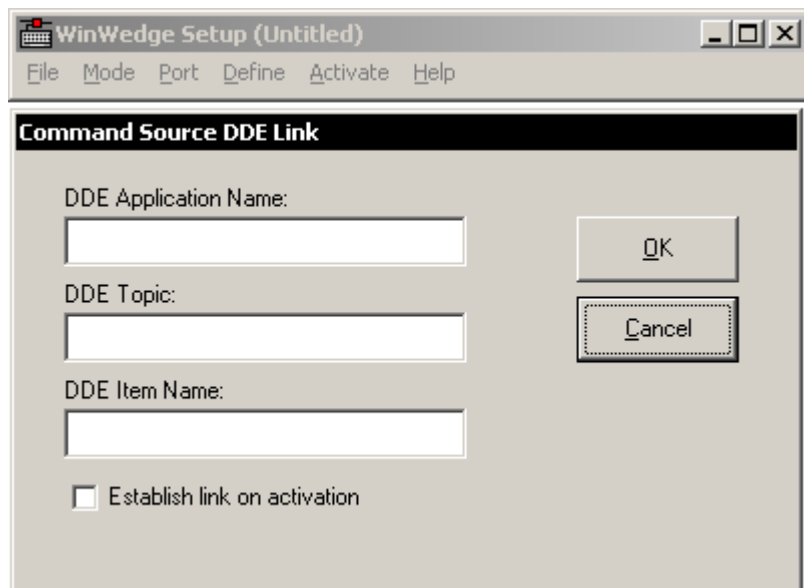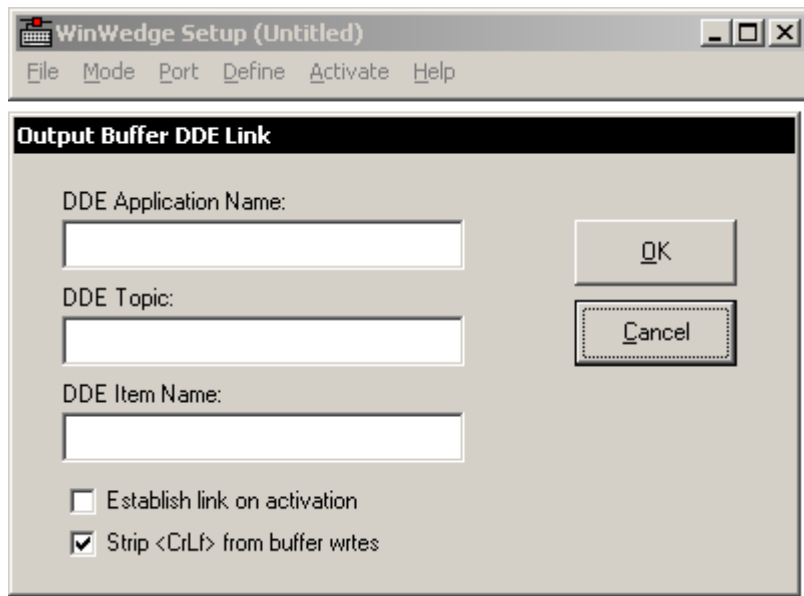
Figure F3
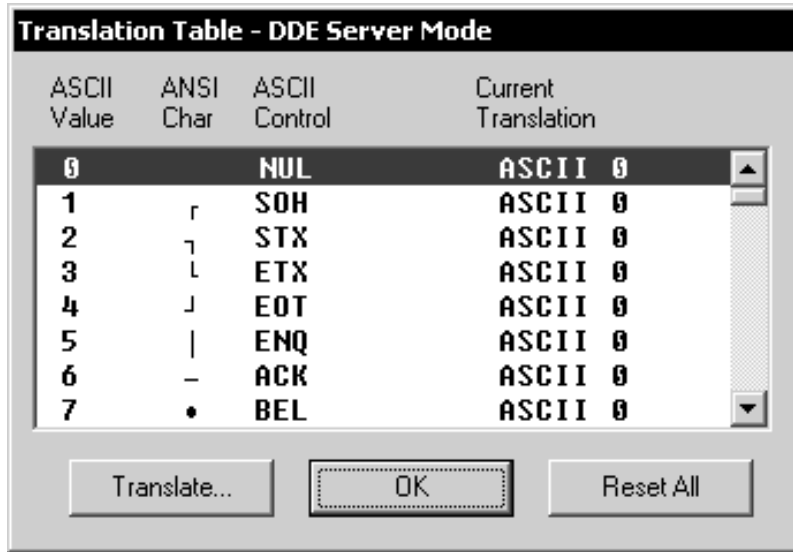
Figure F4
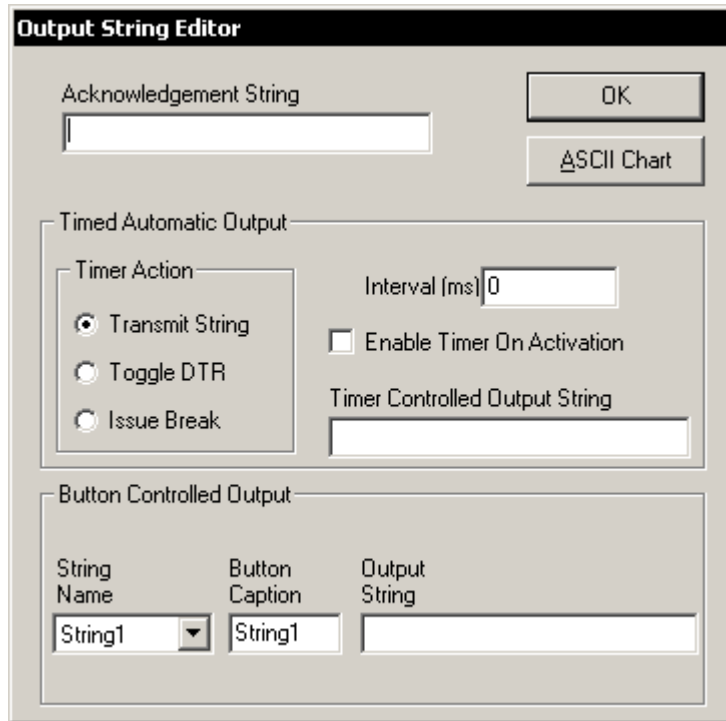
Figure F5

Figure F6

Figure F7

Appendix G

Figure G1
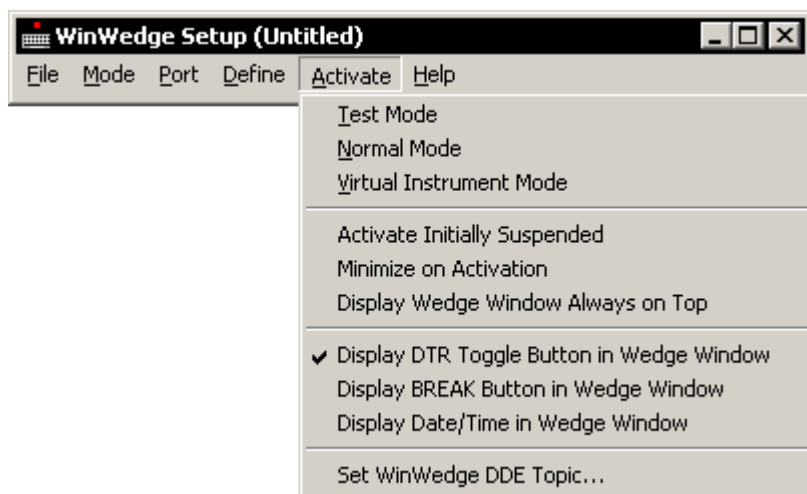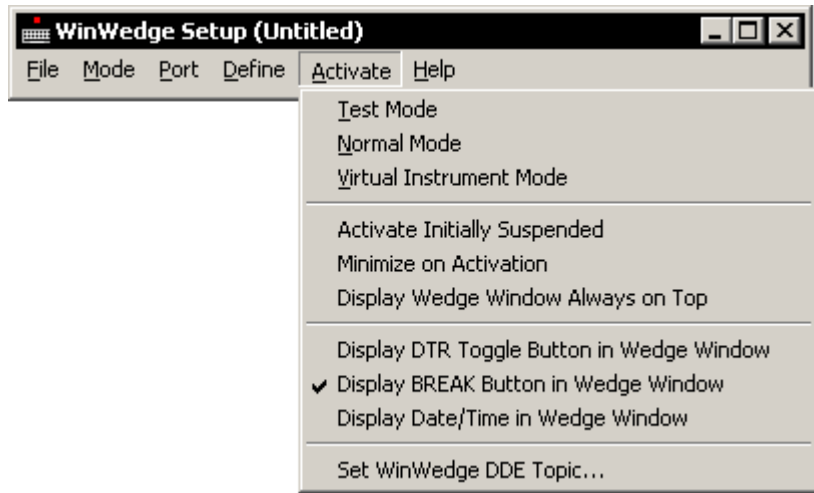

Figure G2

Figure G3
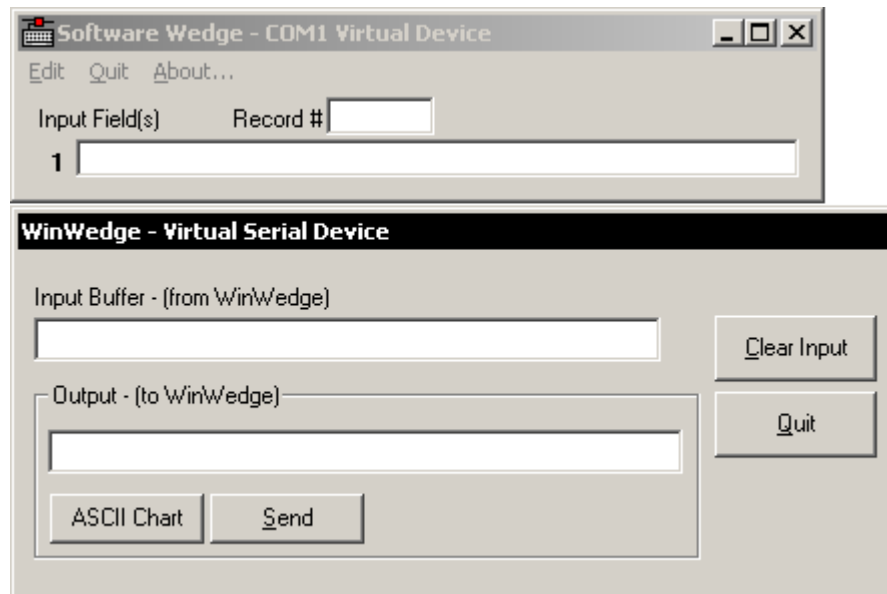
Figure G4
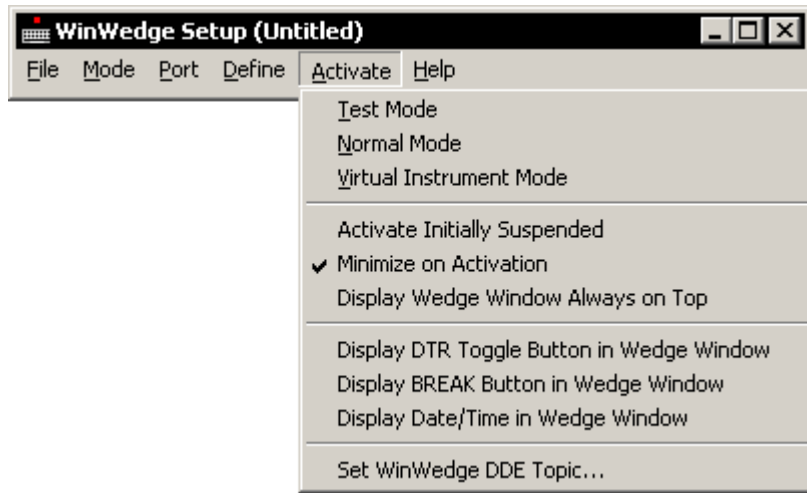
Figure G5

Figure G6

Figure G7

WinWedge Setup (Untitled)

File   Mode   Port   Define   **Activate**   Help

Test Mode
Normal Mode
Virtual Instrument Mode

Activate Initially Suspended
Minimize on Activation
Display Wedge Window Always on Top

Display DTR Toggle Button in Wedge Window
✔ Display BREAK Button in Wedge Window
Display Date/Time in Wedge Window

Set WinWedge DDE Topic...

Figure G8

WinWedge Setup (Untitled)

File   Mode   Port   Define   Activate   Help

Date/Time Format:

Enter Format Expression for Date/Time Display   OK

                                                      Cancel

Figure G9

WinWedge Setup (Untitled)

File   Mode   Port   Define   **Activate**   Help

Test Mode
Normal Mode
Virtual Instrument Mode

Activate Initially Suspended
Minimize on Activation
Display Wedge Window Always on Top

Display DTR Toggle Button in Wedge Window
Display BREAK Button in Wedge Window
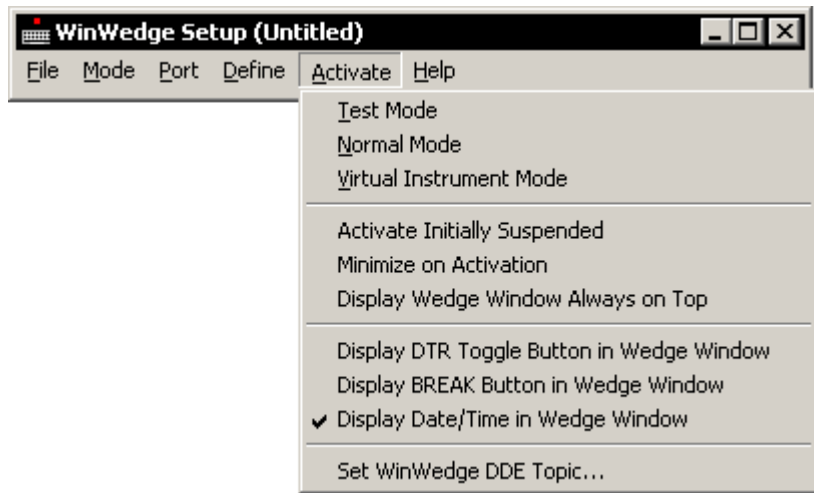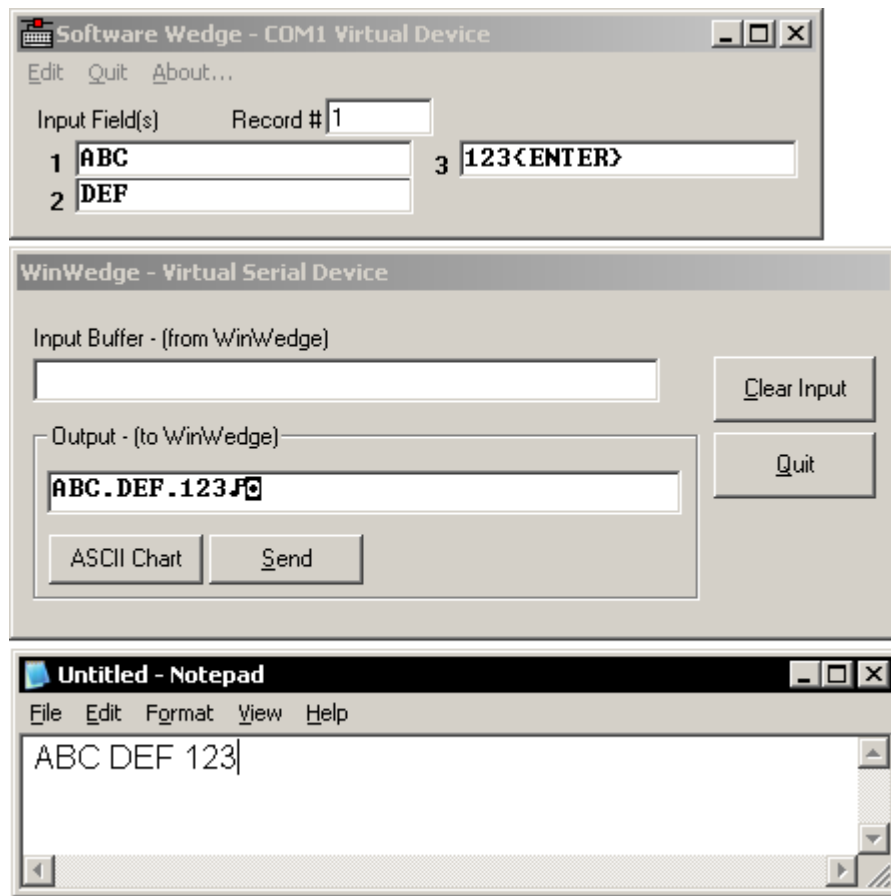✔ Display Date/Time in Wedge Window

Set WinWedge DDE Topic...

Appendix H

Figure H1

Figure H2

Figure H3

Figure H4

Figure H5