**Installation Qualification Protocol for WireT / WireX3GLC Production Bench at SYNERGY/EDEVICE**

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| --- | --- |
| **Audience** | Qualité, Production, R&D, Support |

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| --- | --- |
| **Project Name** | WireT / WireX3GLC |
| **Protocol Name** | *Installation Qualification Protocol for WireT / Wirex3GLC Production Bench* |
| **Protocol Version** | 4.0 |

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| --- | --- | --- | --- |
| **Approved by** | **Department** | **Date** | **Signature** |
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# Version History

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| --- | --- | --- | --- |
| **Version** | **Author** | **Date** | **Description of Changes** |
| 1.0 | GNeny | 29Sep2015 | Initial Version |
| 2.0 | GNeny | 27Oct2015 | Update bench software version |
| 3.0 | G.Neny | 12Nov2015 | Update bench software version |
| 4.0 | G.Neny | 19Jan2016 | Update bench software version |
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# Purpose

This protocol establishes the performing and documenting Installation Qualification activities for the WireT / WireX3GLC production bench at Synergy or eDevice. The same test stations will be used for WireT delivery and WireX3GLC Manufacturing+Delivery.

# Scope

This document specifies the test station Installation Qualification for the control of both WireT and Wirex3GLC fabrication at Synergy or eDevice.

# Definitions

|  |  |
| --- | --- |
| **Abbreviation** | **Definition** |
| IQ | Installation Qualification |
| SOP | Standard Operation Procedure |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

# Relevant Documents

## Reference Documents

* Installation Qualification SOP (Rev 1.0)
* Processus FMEA WireT (Rev 1.0)
* Processus FMEA WireX (Rev 1.0)

## Attached Documents

# Responsibility

Production Manager (eDevice):

* Identifies “Bench Manager” as “Protocol Manager”
* Reviews and approves IQ protocol
* Ensures IQ protocol is executed
* Audits data, deviations, and other records for IQ final decision
* Documents deviations final decision
* Documents IQ final decision

Bench Manager (eDevice):

* Writes and maintains IQ protocol
* Verifies measurements or data collected meet acceptance criteria
* Documents resolution of deviations and non-conformances

Installation Technician:

* Executes IQ protocol
* Reports measurements, data collected, or any deviations

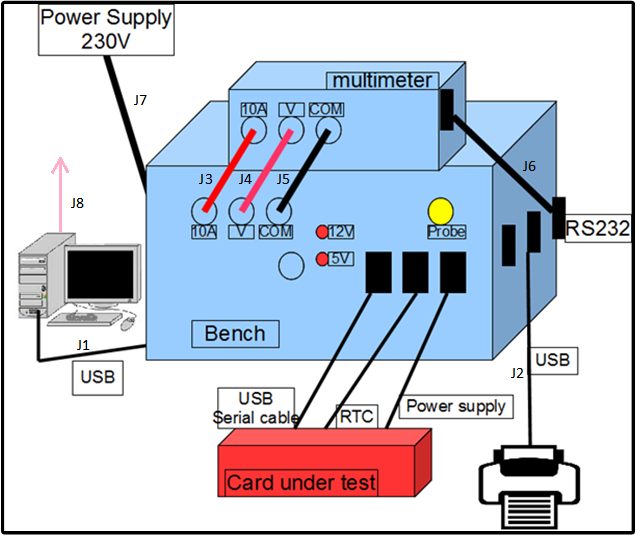
| **Title** | **Name (Printed)** | **Initials** | **Date** | **Signature** |
| --- | --- | --- | --- | --- |
| Production Manager | Michel GOMEZ | MG |  |  |
| Bench Manager | Gilbert NENY | GN |  |  |
| Installation Technician | Rémy AUMEUNIER | RA |  |  |

# Equipment Identification and Location

|  |  |
| --- | --- |
| ***WireT/Wirex3GLC Production Bench*** | |
| **Manufacturer** | edevice |
| **Serial number** | Pc test wirex3glc 1 |
| **Equipment location** | Edevice av ariane 33700 merignac |

# Equipment Description

## Equipment Design Features

**

## Installation conditions

The wiring installation is described in the Figure above.

The production bench should be connected to 220 V power supply.

The production bench should also be connected to a LAN network with Internet access.

## Controlled maintenance

The components that need regular calibration should be registered in the eDevice calibration schedule for measurement devices.

The multimeter must be verified every year.

## Documentation

The following documents related to production bench software should be available:

* The wiring procedure for connecting bench components
* The installation procedure for device drivers, python environment, bench software installation and configuration

## Environmental conditions

Ambient Temperature.

ESD workbench or table.

# Procedure

*This section describes the activities of the various stages of Installation Qualification.*

*The measurement devices used to perform tests during IQ should be registered in the calibration schedule for measurement devices. They are listed below:*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Instruments Used for IQ Tests and Measurements** | | | | | | |
| **N°** | **Instrument Name** | **Serial Number** | **Test Used For** | **Calibration Date** | **Calibration Due Date** | **Verified By / Date / Signature** |
| 1 | Voltmeter | 2217064 | Validation | 23/12/2015 | 20/12/2016 | RAumeunier  30Sep2016 |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

## Documentation Verification

**Reference Documents/Manuals/Procedures**

***Procedure:***

* *Verify that all the documents and manuals listed below are available.*
* *Check that procedures, guides or reference documents are approved. Approval is not applicable for user manuals and lists or any non-revised documents.*

| **N°** | **Expected Document Title / Number** | **Location (Physical location or attached)** | **Is Approved?**  (Y/N) | **Verified By / Date / Signature** |
| --- | --- | --- | --- | --- |
| 1 | *INSTALL PRODUCTION BENCH (Rev 4.0)* | *svn://192.168.200.6/Manufacturing/WireX3G/Procedures/InstallBenchProdIntech.pdf* | Yes | RAumeunier  30Sep2016 |
| 2 | eDevice measurement devices calibration schedule. | Manufactruring/suiviEdevice/suivi/appareilMesure | NA | RAumeunier  30Sep2016 |
| 3 | WireT\_DeliveryTest\_Bench .pdf (Rev1.0) | svn://192.168.200.6/Manufacturing/WireT/Procedures/WireT\_DeliveryTest\_Bench.pdf | Yes | RAumeunier  30Sep2016 |
| 4 | InstallationBaseDeDonneesMySqlBancProduction.docx (Rev1.0) | svn://192.168.200.6/Manufacturing/WireX3G/Procedures/InstallationBaseDeDonneesMySqlBancProduction.docx | Yes | RAumeunier  30Sep2016 |
| 5 | Maintenance Activities eDeviceWirex3GLC.pdf (Rev 1.0) | svn://192.168.200.6/Manufacturing/WireX3G/Procedures/Maintenance Activities Wirex3GLC.xlsx | Yes | RAumeunier  30Sep2016 |
|  |  |  |  |  |

### Acceptance Criteria (*eDevice part of the document*)

* *All the above documents are released in a controlled document area*
* *All procedure that need to be are approved*

*YES NO\* (Circle one) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Signature and date*

*\* If no indicate the discrepancy in the comments section below.*

*Comments:*

## Component(s) Verification

***Procedure:***

* *Verify that the components listed below have been supplied (spare parts being optional)*
* *Check (when required) that device calibration is OK, ie device has been calibrated before IQ and next calibration date is not reached.*

| **N°** | **Components / Spare Parts / Accessories** | **Calibration**  **Required? (Y/N)** | **Equipment Serial Number or Supplier reference if no Serial Number** | **Calibration Date / Next Cal. Date** | **Calibration OK?**  **(Y/N)** | **Verified By / Date**  **/ Signature** |
| --- | --- | --- | --- | --- | --- | --- |
| 1 | Multimeter Fluke | Y | 2217064 | 23/12/2015 | 23/12/2016 | RAumeunier  30Sep2016 |
| 2 | PC with screen, mouse and keyboard with (at least): 1GHz processor, 1Go RAM, 100 Go HD, 1 USB port, Windows XP or superior | N | *Windows10*  *eamsbx006054* | NA | NA | RAumeunier  30Sep2016 |
| 3 | TestBox | Y | 52347 | 27/09/2016 | 27/09/2017 | RAumeunier  30Sep2016 |
| 4 | Dongle | N | 784 | NA | NA | RAumeunier  30Sep2016 |
| 5 | Dymo Printer “Label Writer 450 Twin Turbo” | N | 2029717 | NA | NA | RAumeunier  30Sep2016 |
| 6 | Connector with device under test (Debug Card and/or TestJIG) | N | NA | NA | NA | RAumeunier  30Sep2016 |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

### Acceptance Criteria (*eDevice part of the document*)

* *All components listed above and their Serial Number are present*
* *Each component requiring calibration is calibrated.*

*YES NO\* (Circle one) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Signature and date*

*\* If no indicate the discrepancy in the comments section below.*

*Comments:*

## Hardware Configuration Verification

***Procedure:***

* *The different components must be wired following the instructions in the document* “INSTALL PRODUCTION BENCH” (Rev 4.0), chapter “Bench Hardware connection procedure” and “WireT\_Test\_Bench.docx (Rev1.0)”
* *Verify with the check list below that each connection is correctly established*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **N°** | **Installation Requirements** | **Criteria** | **Requirement Met (Y/N)** | **Verified By / Date / Signature** |
| J1 | Box / USB PC connector | USB Connection to PC | Yes | RAumeunier  30Sep2016 |
| J2 | Box / DYMO Printer USB connector | USB Connection to DYMO Printer | Yes | RAumeunier  30Sep2016 |
| J3/J4/J5 | Box / Multimeter connectors | * “V” box and “V” multimeter are connected * “A” box and “A” multimeter are connected * “COM” box and “COM” multimeter are connected | Yes | RAumeunier  30Sep2016 |
| J6 | Box / Multimeter RS232 cable | RS232 connection between Multimeter and Box DB9 | Yes | RAumeunier  30Sep2016 |
| J7 | Box / Power Supply | 220V cable connection between Box and power outlet | Yes | RAumeunier  30Sep2016 |
| J8 | PC / LAN connection | RJ45 Connection between PC and Ethernet Switch | Yes | RAumeunier  30Sep2016 |
| J9 | USB-RS232 FTDI/ Connector with device under test (Debug Card and/or TestJIG) | Pin to Pin Connection | Yes | RAumeunier  30Sep2016 |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

### Acceptance Criteria (*eDevice part of the document*)

* *Each of the visually inspected wiring connections listed above is mechanically sound*

*YES NO\* (Circle one) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Signature and date*

*\* If no indicate the discrepancy in the comments section below.*

*Comments:*

## Utilities Verification (equipment only)

***Procedure:***

* *Verify power supply source with a voltmeter*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **N°** | **Utility** | **Specified** | **Verification Method** | **As Found** | **Acceptable**  **(Y/ N)** | **Verified By / Date / Signature** |
| 1 | Electricity | Voltage (220V) +/- 20 V | Voltmeter | 238,3V | Yes | RAumeunier  30Sep2016 |
| 2 | TCP/ IP network | PC can access to MySQL database IP | Ping *127.0.0.1* | Reçu 4/4 <1ms | Yes | RAumeunier  30Sep2016 |

### Acceptance Criteria (*eDevice part of the document*)

* *Power supply source and TCP/IP network access are available.*

*YES NO\* (Circle one) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Signature and date*

*\* If no indicate the discrepancy in the comments section below.*

*Comments:*

## Software Verification

***Procedure:***

* *Install each software listed below following the corresponding installation procedure*
* *Check the version of the software installed thanks to Windows Configuration Panel or the installer file if not available in Windows Configuration Panel. For “scp.py”, edit the file to check version number.*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **N°** | **Installation Requirements** | **Installation Procedure** | **Required Software Version** | **Installed Software Version** | **Requirement Met**  **(Yes / No)** | **Verified By / Date / Signature** |
| 0 | Windows OS | Preinstalled at purchase | XP or superior | Windows10 | Yes | RAumeunier  30Sep2016 |
| 1 | Python software | “*Install production bench” (Rev 4.0), chapter* *Bench Software Installation (Windows XP/ 7 / 8) »* | V2.7.1150 | V2.7.1150 | Yes | RAumeunier  30Sep2016 |
| 2 | PyQt | “*Install production bench” (Rev 4.0), chapter Bench Software Installation (Windows XP/ 7 / 8) »* | V4.8.4 | V4.8.4 | Yes | RAumeunier  30Sep2016 |
| 3 | PySerial | “*Install production bench” (Rev 4.0), chapter Bench Software Installation (Windows XP/ 7 / 8) »* | V2.5 | V2.5 | Yes | RAumeunier  30Sep2016 |
| 4 | Phidget (driver + python lib) | “*Install production bench” (Rev 4.0), chapter Bench Software Installation (Windows XP/ 7 / 8) »* | V2.1.8  or latest | V3.1.227 | Yes | RAumeunier  30Sep2016 |
| 5 | Dymo driver | “*Install production bench” (Rev 4.0), chapter Bench Software Installation (Windows XP/ 7 / 8) »* | V8.3.0.443  or latest | V8.3.0.443 | Yes | RAumeunier  30Sep2016 |
| 6 | Dymo sdk | “*Install production bench” (Rev 4.0), chapter Bench Software Installation (Windows XP/ 7 / 8) »* | V8.3.1.1332  or latest | V8.5.1.1816 | Yes | RAumeunier  30Sep2016 |
| 7 | PyWin32 | “*Install production bench” (Rev 4.0), chapter Bench Software Installation (Windows XP/ 7 / 8) »* | V2.14 | V2.14 | Yes | RAumeunier  30Sep2016 |
| 8 | Xlwt | “*Install production bench” (Rev 4.0), chapter Bench Software Installation (Windows XP/ 7 / 8) »* | V0.7.2 | V0.7.2 | Yes | RAumeunier  30Sep2016 |
| 9 | MySQLdb | “*Install production bench” (Rev 4.0), chapter Bench Software Installation (Windows XP/ 7 / 8) »* | V1.2.3 | V1.2.3 | Yes | RAumeunier  30Sep2016 |
| 10 | Pycrypto | “WireT\_DeliveryTest\_Bench.docx (Rev1.0), chapter Mise à jour des bibliothèques python” | V2.3.0 | na | Yes | RAumeunier  30Sep2016 |
| 11 | Paramiko | “WireT\_DeliveryTest\_Bench.docx (Rev1.0), chapter Mise à jour des bibliothèques python” | V1.7.4 | na | Yes | RAumeunier  30Sep2016 |
| 12 | Scp.py | “WireT\_DeliveryTest\_Bench.docx (Rev1.0), chapter Mise à jour des bibliothèques python” | 0.10.0 | na | Yes | RAumeunier  30Sep2016 |
| 13 | MySQL database | Must be installed only once following «  InstallationBaseDeDonneesMySqlBancProduction.docx (Rev 1.0) ».  But must be available for all test stations. | V5.6  or latest | V5.6.10 | Yes | RAumeunier  30Sep2016 |
| 14 | Delivery Bench Software | “WireT\_DeliveryTest\_Bench.docx (Rev1.0), chapter Mise à jour des bibliothèques python” | 173290000X  (X=0 or 1) | 1733300000 | Yes | RAumeunier  30Sep2016 |

### Acceptance Criteria (*eDevice part of the document*)

* *Each software listed above is installed on the PC.*
* *For each installed software, version is correct.*

*YES NO\* (Circle one) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Signature and date*

*\* If no indicate the discrepancy in the comments section below.*

*Comments:*

## Operation / Safety Features / Requirements

***Procedure:***

* *Execute the built-in bench feature “Auto-Test” to check that the Bench Software can communicate with measurement devices, printer and database.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **N°** | **Functional Requirements**  **(functional step)** | **Criteria** | **Requirement Met**  **(Yes / No)** | **Verified By / Date / Signature** |
| 1 | MySQL database reachable | AutoTest successful | Yes | RAumeunier  30Sep2016 |
| 2 | Multimeter answers commands | AutoTest successful | Yes | RAumeunier  30Sep2016 |
| 3 | Dongle password is correct | AutoTest successful | Yes | RAumeunier  30Sep2016 |
| 4 | Dongle answers commands | AutoTest successful | Yes | RAumeunier  30Sep2016 |
| 5 | Dymo is able to print labels | AutoTest successful | Yes | RAumeunier  30Sep2016 |

### Acceptance Criteria (*eDevice part of the document*)

* *Each equipment listed above is reachable by the PC, based on AutoTest results.*

*YES NO\* (Circle one) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Signature and date*

*\* If no indicate the discrepancy in the comments section below.*

*Comments:*

# Installation Qualification Acceptance (*eDevice part of the document*)

*Installation Qualification is considered successful if for each stage of the IQ protocol:*

* *All acceptance criteria are met and there is no deviation,*

*or*

* *All acceptance criteria are not met but all deviations are justified, documented and accepted with appropriate approval signatures.*

|  |  |  |
| --- | --- | --- |
| **IQ Stage** | **All Acceptance criteria met ?**  **(Yes / No)** | **All Deviations accepted ?**  **(Yes / No / No Deviation)** |
| Document Verification |  |  |
| Component(s) Verification |  |  |
| Hardware Configuration Verification |  |  |
| Utilities Verification (equipment only) |  |  |
| Software Verification |  |  |
| Operation / Safety Features / Requirements |  |  |

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Signature and date*

# Deviation record template

**Deviation n°X**

***Deviation Identification:***

IQ procedure stage:

Number of the element at the origin of the deviation:

Description of the deviation:

*Signature and date*:

***Deviation Analysis:***

Analysis:

Corrective Action:

Deviation Accepted: *YES NO (Circle one)*

*Signature and date*:

***Deviation Acceptance:***

Conclusion:

Final Decision: *Accepted Not Accepted (Circle one)*

*Signature and date*: