



**Re: GTS Validation** 📎

**Tetiana Morse** to: Raymond Cribbin, Emma Pierce  
Cc: HuaZhen Luo, "Edwin Koh", Sadiq Mohsin, Jaaffar Ismail

06.10.2018 04:48

Raymond, Luo,

As a Milford Validation Process rep, I would like to clarify the validation deliverables that has been incorrectly identified.

Since this GTS fixture is technically a new piece of Test equipment, we do not require VAF (validation submission form).

The purpose of the VAF is to assess the change to the legacy or already qualified equipment and determine the minimal qualification requirements specific to the change.

In our case, we would need to initiate Submission Form (730004131) for a new piece of equipment. The purpose of Submission form is to identify the new system information and simply record it in the Milford VMP (Validation Master Plan).

To the Raymond's point, we qualify the GTS fixture as a hardware, excluding the Design and Test Method validation activities.

Only the Test Fixtures, used for the specific PCB products will have to go through the higher scrutiny of validation against Product's Critical parameters and ability to pass the conforming and reject non-conforming product.

Being a new system, the GTS would have to go through the scrutiny of full IQ.

The acceptance criteria for the test scripts IQ-01 through IQ-05 (scripts verifying the utilities, safety, PM/CAL and documentation) could be found in the following Design Engineering files:

[attachment "GTS Site Prep\_Rev 5.pdf" deleted by Edwin Koh/Waters] [attachment "TE82988 Assembly Procedure\_Rev 16.docx" deleted by Edwin Koh/Waters]

The IQ-06 (Functional verification) can be performed via self-test fixture.

Let me know if you have additional questions or concerns.

Regards,

Tanya

**Tetiana Morse**  
Sr.Process Validation  
Engineer

[T] 508-482-3552  
[F] +1 508 482 3373  
[M] 508-330-7348  
[W] [www.waters.com](http://www.waters.com)  
[E] [tetiana\\_morse@waters.com](mailto:tetiana_morse@waters.com)



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Waters  
Corporation  
34 Maple Street  
Milford  
MA 01757  
USA

Raymond Cribbin

Please see answers in RED Below. Regards,

10/02/2018 09:55:47 AM

From: Raymond Cribbin/Waters  
To: HuaZhen Luo/Waters@WATTS WATERS SALES  
Cc: "Edwin Koh" <Edwin\_Koh@waters.com>, Sadiq Mohsin/Waters@WATTS Waters Sales, Tetiana Morse/Waters@WATTS Waters Sales  
Date: 10/02/2018 09:55 AM  
Subject: Re: GTS Validation

Please see answers in RED Below.  
Regards,  
Ray.

**Ray Cribbin**  
Electronic Manufacturing & Test  
Engineering Manager

[T] +44 (0)161 946 2435  
[F] +44 (0)161 946 2480  
[M] +44 (0)7826 872 573  
[W] [www.waters.com](http://www.waters.com)  
[E] [raymond\\_cribbin@waters.com](mailto:raymond_cribbin@waters.com)

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Waters Corporation  
Stamford Avenue  
Altrincham Road  
Wilmslow  
SK9 4AX  
UK

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Registered Office: Stamford Avenue, Altrincham Road, Wilmslow, SK9 4AX

WATZIP

HuaZhen Luo      Hi Sadiq, Basically the questions from Tetiana (es...      01/10/2018 08:46:49

From: HuaZhen Luo/Waters  
To: Sadiq Mohsin/Waters@WATTS WATERS SALES  
Cc: Raymond Cribbin/Waters@WATTS Waters Sales, Tetiana Morse/Waters@WATTS WATERS SALES, "Edwin Koh" <Edwin\_Koh@waters.com>  
Date: 01/10/2018 08:46  
Subject: Re: GTS Validation

Hi Sadiq,

Basically the questions from Tetiana (especially those related to EDV and TMV), which are beyond my knowledge, that's why I'm looking for the assist.  
Please kindly share with us if this modified GTS has it's own acceptance criteria? Something we can qualify this system against?

List if changes identified during gap analysis between original design GTS and current system:

First thing I would like to get clear. Are you trying to Validate the GTS system or the test sequence for testing our products?

**Major Issues:** The -12 system has been modified and is no longer technically a TE82988 system

- Hardware changes- some hardware added and some has been removed (power supply specifically)
- User interface- not using the GTS UI provided by Milford TE but running test on TestStand, through which changes to the sequence (intentional or otherwise) are far more accessible to the operator
- Software download- unknown software (and/or software with unknown affects) has been downloaded to the computer

| 4.1.2. Software/Firmware                                                                                                                | No                                  | Yes                                 |
|-----------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|-------------------------------------|
| Is the change a software modification that affects the way the system controls, and/or measures a test specification and/or PSC result? | <input type="checkbox"/>            | <input checked="" type="checkbox"/> |
| Is the change due to firmware downloaded to the UUT by a test system?                                                                   | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |
| Is the change a flash file update?                                                                                                      | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |
| Is it a change to an existing, or the addition of a new, PCB Test Sequence?                                                             | <input type="checkbox"/>            | <input checked="" type="checkbox"/> |

Need your help to answer above questions. Will this UI change affect the system control and/or measure a test spec and PSC result?

Point 1. The UI has not changed from the original design which is the standard TestStand UI as installed when installing the TestStand software. The Milford team have added their own unique UI

which they have decided to use so this change should be controlled under their own verification documentation to describe that this change has not changed the original UI which is TestStand. I'm sure we could change our programs to fit into the UI developed by Milford but would need to have information on how they control this UI and the programs called up on it. Until then we will continue to use the system as designed with the Test stand UI. There should be no verification of this UI required as it is still as designed.

Point 2. We have added a new Test Sequence which we have verified using a gold brick assembly to verify the results are consistent with an existing report from another GTS. This test sequence is independent to other test sequences already developed on the system. This should be the same as any other test sequence added by Milford so you should be able to document the same. We are not part of this process and have not been given any information of what requirements they are trying to fulfil but the process we currently use by verifying the test program using a gold brick assembly has been approved by external auditors as conforming to ISO13485. Again I don't see that there is any requirement to provide WPPL with any further information on the verification of the individual test programs.

#### VAF Specifics:

- 4.1.3. Hardware should be checked "yes"

| 4.1.3. Hardware (Mechanical, Electrical, Pneumatic, Hydraulic, etc.)                                                                                                              | No                       | Yes                                 |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-------------------------------------|
| Is the change a mechanical, electrical, pneumatic, and/or hydraulic modification that alters the way the system controls, and/or measures a test specification and/or PSC result? | <input type="checkbox"/> | <input checked="" type="checkbox"/> |

What are the hardware changed? Do those hardware change alter the way the system controls, and/or measure a test spec/PSC result?

What does PSC stand for?

The only change we have made to the GTS system from its initial design is the addition of a 1Ghz ethernet port. I don't believe that the current validation checks ethernet ports so the addition of this has made no change to the current validation you do. If they do please let me know how and we will look at repeating this step with the 1 GHz port. The new port will not affect any programs previously created to work on the GTS as the port has not been called with these programs. This information was provided to the Milford team when we first integrated it into the GTS in 2011 to add it to the Bill Of Materials going forward.

As we are on this subject we would like to understand the risk assessment on the changes made to the PC and Lambda Power Supplies made by Milford as this has had a significant impact on the programs we have previously written to work on a GTS. These changes have not been communicated to the users of these systems and we are finding that OEM VIs within Labview have been modified by the Milford team to allow their programs to work with this new hardware and are causing existing test programs to malfunction. Again we would like to get copies of the risk assessments for these changes to get an understanding of how these fundamental changes have been implemented excluding the Wilmslow team.

- 6.1. EDV should be done as the changes to the test system almost certainly have affected the test method and system (no longer using the legacy "fit for use" design)

#### 6. VERIFICATION, QUALIFICATION AND/OR VALIDATION:

| 6.1. Equipment Design Verification (EDV)                                                                                                                            | No                       | Yes                                 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-------------------------------------|
| Based on the Risk Assessment, does an EDV Protocol need to be created or revised due to this change?                                                                | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| Based on the Risk Assessment, does an EDV Protocol need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.) | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| <b>Comments/Justification</b><br>EDV should be done as the changes to the test system almost certainly have affected the test method and system                     |                          |                                     |

We don't have EDV for this system right now. Need your help on this part.

If you don't have an EDV for this system you need to discuss this with Milford. Why would WPPL

require to do this as this is a design requirement not an end user requirement.

- 6.3. TMV should be checked "yes" and a TMV done for each measurement component in the GTS (the whole thing is external measurement devices)

| 6.3. Test Method Validation (TMV)                                                                                                                         | No                       | Yes                                 |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-------------------------------------|
| Based on the Risk Assessment, does a TMV need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.) | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| <b>Comments/Justification</b><br>A TMV done for each measurement component in the GTS (the whole thing is external measurement devices)                   |                          |                                     |

We don't have TMV for this system too. Can you please help?

If you don't have an TMV for this system you need to discuss this with Milford. Why would WPPL require to do this as this is a design requirement not an end user requirement.

#### IQ Specifics:

- IQ-01 needs the GTS TSP and CAL (or does it? If the system has been modified not to follow these documents are they necessary? Which documents replace these?)

| IQ Test name: Associated Documentation Verification                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                       | Test Script No.: IQ-01             |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|------------------------------------|----------------|
| Equipment No./ID: TE82988-12                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                       | Equipment Name: Global Test System |                |
| Installation Site: Venture: WPPL, Singapore                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                       |                                    |                |
| <b>Purpose:</b><br>To verify that supporting documentation is available prior to the completion of qualification.                                                                                                                                                                                                                                                                                                                                                                                        |                                       |                                    |                |
| <b>Test execution:</b><br>List all applicable documents (Preventive Maintenance, Calibration, Operating Procedures, Test Specification Procedures, Manufacturing Procedures, etc.) under the Document type header and then complete the table below. If applicable documents are unavailable state why in the comments section. All applicable documents must be in either Ready, Pre-Rel-Prod, or Release General state in SAP. Enter N/A for any parameter or cell that is not used or not applicable. |                                       |                                    |                |
| <b>Objective evidence:</b><br>Completed Test Script Data Sheet<br>SAP Screen shot of below available document(s)                                                                                                                                                                                                                                                                                                                                                                                         |                                       |                                    |                |
| Document Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Title; Doc. No.; Revision/Version No. | Status in SAP                      | Initial & Date |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                       |                                    |                |

Do we have a TSP and CAL document for this modified GTS?

As I have said above the only change to the "as designed" system is the addition of a 1Ghz ethernet port. I don't believe that the current GTS TSP and CAL requirements call out the ethernet ports as require testing. If this is not the case please provide me with details of exactly how it is being done on the existing TSP and CAL and we can request getting the same test repeated for the 1GHz output. This is controlled by Milford so we cant make any changes to this.

- IQ-02 acceptance criteria does not align to the GTS Installation Guide- where have these values come from and why are they different from the guide?

| <b>IQ Test name:</b> Site Verification                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                            | <b>Test Script No.:</b> IQ-02             |           |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|-------------------------------------------|-----------|----------------|
| <b>Equipment No./ID:</b> TE82988-12                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                            | <b>Equipment Name:</b> Global Test System |           |                |
| <b>Installation Site:</b> Venture: WPPL, Singapore                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                            |                                           |           |                |
| <p><b>Purpose:</b><br/>To verify the location in which the test equipment is to be installed is suitable for use.</p> <p><b>Test execution:</b><br/>List any additional applicable environmental parameters in the Parameters column. Using the applicable equipment documentation, define the specifications in the Acceptance Criteria column, as appropriate. Verify and/or measure the applicable parameters and complete the table below. Do not delete any of the listed defined parameters. Enter N/A for any parameter or cell that is not used or applicable.</p> <p><b>Objective evidence:</b><br/>Completed Test Script Data Sheet.<br/>Photo(s) of the work area, if applicable.<br/>Copies of calibration certificates for gauges or meters used for measurement, if applicable.</p> |                                                                                                            |                                           |           |                |
| Parameters                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Acceptance criteria                                                                                        | As found                                  | Pass/Fail | Initial & Date |
| Ambient Temperature                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 59-86° F (15-30° C)                                                                                        |                                           |           |                |
| Relative Humidity                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 20%-80%, Non-Condensing                                                                                    |                                           |           |                |
| Workspace                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Adequate space for testing and service                                                                     |                                           |           |                |
| Test Station Bench                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Large and strong enough to support all equipment                                                           |                                           |           |                |
| Electrical Supply                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 50-60 HZ,<br>85-132 or 180-350 VAC                                                                         |                                           |           |                |
| Electrical Outlets                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | >= 1                                                                                                       |                                           |           |                |
| Network Available                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | >= 1                                                                                                       |                                           |           |                |
| Vacuum                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 40 cfm (1.13 cubic meters/min) minimum vacuum flow and a minimum vacuum pressure of 23 inches Hg (78 kPa). |                                           |           |                |

Previously I use the values from GTS Site Prep for this section, but it seems different from Installation Guide. Do you have Installation Guide or equivalent acceptance criteria for this section?

Again we have no input to this as this is controlled by Milford. We have never seen either a Installation Guide or Site Prep Guide.

- IQ-04 is missing- should have the UI software version (but if they aren't using that to run tests is that why they took this script out? Shouldn't we still be verifying the version of whatever software they do use?)

| IQ Test name: Test Software and Instrument Firmware Version                                                                                                                                                                                                                                                                                                                                                                                                                                       |                     | Test Script No.: IQ-04 |           |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|------------------------|-----------|----------------|
| Equipment No./ID:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                     | Equipment Name:        |           |                |
| Installation Site:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                     |                        |           |                |
| <b>Purpose:</b><br>To verify that the installed firmware/software is correct per the applicable design/operational documents (TSP, ASP, MPR, BOM, and/or other Design documents).                                                                                                                                                                                                                                                                                                                 |                     |                        |           |                |
| <b>Test execution:</b><br>List all critical instruments/components and/or sub-systems that require software and/or firmware in the Description column. List the associated required software/firmware version, as defined in the applicable design/operational documents, in the Acceptance criteria column. Verify that the software/firmware version on the Test Equipment match the acceptance criteria and are identical. Enter N/A for any parameter or cell that is not used or applicable. |                     |                        |           |                |
| <b>Objective evidence:</b><br>Completed Test Script Data Sheet<br>Identify the applicable design/operational document that defined the required software/firmware version(s) in the associated Installation Qualification Report.                                                                                                                                                                                                                                                                 |                     |                        |           |                |
| Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Acceptance criteria | As found               | Pass/Fail | Initial & Date |
| Test Equipment Software                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Version:            | Version:               |           |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Version:            | Version:               |           |                |

I have added this IQ-04 but need your help on those questions in this part.

Don't understand what you are asking here.

- IQ-06 specific boards shouldn't be used to test the functionality as that will not provide a full functionality test
- How to cover a full functionality test? Any other way to complete this functionality?
- Again the functionality of the GTS or the test solution? The functionality of the GTS is the same as you have always done as ethernet ports are not tested. The test solution can only be tested by using UUTs.

With the QDa ramping up in the coming Q4 and next year, please help to accelerate this

Qualification for the 2<sup>nd</sup> GTS.

And please see the updated draft copy of VAF, IQR and IQ script below. Please let me know if you have any questions.

The documentation should be the same as GTS-3 as it is exactly the same. All being that it is using new PC and power supplies which should have their own validation documents.

Thanks

[attachment "730001938 Validation Assessment Form\_GTS Venture.docx" deleted by Raymond Cribbin/Waters] [attachment "TE82988-12-IQR\_Iteration 00 Script.docx" deleted by Raymond Cribbin/Waters] [attachment "TE82988-12-IQR\_Iteration 00.docx" deleted by Raymond Cribbin/Waters]

**Luo HuaZhen**  
Senior Test Engineer

[T] +65 6590 7044  
 [F] +65 6873 0820  
 [W] [www.waters.com](http://www.waters.com)  
 [E] [huazhen\\_luo@waters.com](mailto:huazhen_luo@waters.com)

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Waters Pacific Pte Ltd  
 1 Science Park Road  
 #02-08 The Capricorn  
 Singapore Science Park II  
 Singapore 117528



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|-----------------|--------------------------------------------------------|---------------------|
| Sadiq Mohsin    | Sorry for the late reply but I'm not sure what Huaz... | 28.09.2018 17:36:34 |
| Edwin Koh       | Hi Sadip, We need advice on the GTS validation...      | 26/09/2018 14:37:23 |
| Sadiq Mohsin    | Hi, Jason was doing tests on the GTS 12 on Mond...     | 26.09.2018 18:48:39 |
| Raymond Cribbin | Hi Sadiq, Can you update Luo HuaZhen on progr...       | 26/09/2018 11:20:05 |
| HuaZhen Luo     | Hi Ray, Do you have any input about this GTS Val...    | 26/09/2018 11:05:33 |
| HuaZhen Luo     | Hi Ray/Sadip, As shared with you previously, I dra...  | 20.09.2018 17:04:10 |