

Ph21® Laboratory Automation System

Test Suite

for the

'disi' Disintegration Tester Application -Standard Features-



This document is valid for the software revision:

Ph21 Rev. **R4.7**

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1 DOCUMENT CHANGE CONTROL INFORMATION

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3 VALIDATION CONFIRMATIONS

3.1 PH21 INHOUSE VALIDATION CONFIRMATION

This is the confirmation of Ph21 Service Ltd's inhouse validation as part of the release procedure.

***** insert signed test confirmation here *****

3.2 VALIDATION CONFIRMATION

This is a blank template confirmation which may be used for customer on-site revalidation purposes.

Location of Execution of this Test Suite	
Company	
Branch	
Postal Address	
Building	
Validation Team Members	
Name	(capital letters)
Title	
Department	
Role in the validation process: Tester	
Signature	
Date start Testing (MM-DD-YY)	end Testing (MM-DD-YY)
Validation Team Members	
Name	(capital letters)
Title	
Department	
Role in the validation process: Reviewer	
Signature	
Date (MM-DD-YY)	
Validation Team Members	
Name	(capital letters)
Title	
Department	
Role in the validation process: Approver	
Signature	
Date (MM-DD-YY):	
Foreign validation team members (if applicable):	
Company	
Branch	
Street Address	
Foreign validation team members (if applicable):	
Name	(capital letters)
Title	
Department	
Role in the validation process	
Signature	
Date (MM-DD-YY)	
Foreign validation team members (if applicable):	
Name	(capital letters)
Title	
Department	
Role in the validation process	
Signature	
Date (MM-DD-YY)	

4 TEST PLAN

Usually the Ph21 Software system is made up of the Ph21 Desktop window and one or more test device applications.

Testing a complete system is divided into specific **test suites** for:

- the basic software system functions (also called 'The Ph21 desktop')
- applications of physical test equipment (universal tablet tester, disintegration tester, balances, electronic calipers)
- applications of virtual test environments (for entry of manually acquired values)
- accessory system options, if applicable

Every change control of this application requires the execution of this test suite or parts of it.

The execution of this test suite may also be used as a part of the installation qualification procedure at the customer's site.

4.1 INTENDED AUDIENCE

This document primarily addresses the QC and software validation staff at the system manufacturer's site. The document may also be used by the QC/validation personal at the customer's site for system qualification purposes.

4.2 PREREQUISITES

Good knowledge of the documentation which is included in the Ph21 release is required.

4.3 HOW TO USE THIS DOCUMENT

In order to keep this document's volume within reasonable limits, instructions for the tester are designed in a 'progressively simplified' way. This means that a complex operation is explained in full circumstance on its first occurrence and after this only is referred to briefly.

Example:

Starting a test may be a complex follow-up of operations like: selecting a product specification, selecting a batch designation, assigning accessory properties, several clicks of the '**[OK]**' button, click on the '**[Start]**' button.

In order to start a 2nd test of this kind the test suite may simply state: 'Start a second test'.

Notions which appear on the screen windows or printed on paper will be shown in **boldface**. Important hints will be printed in **bold italic typeface**.

Windows buttons will usually be shown in square brackets e.g. **[Store]**.

! **ALWAYS** use test suites only from **original Ph21 Quality Documentation Packs** (QDPs).

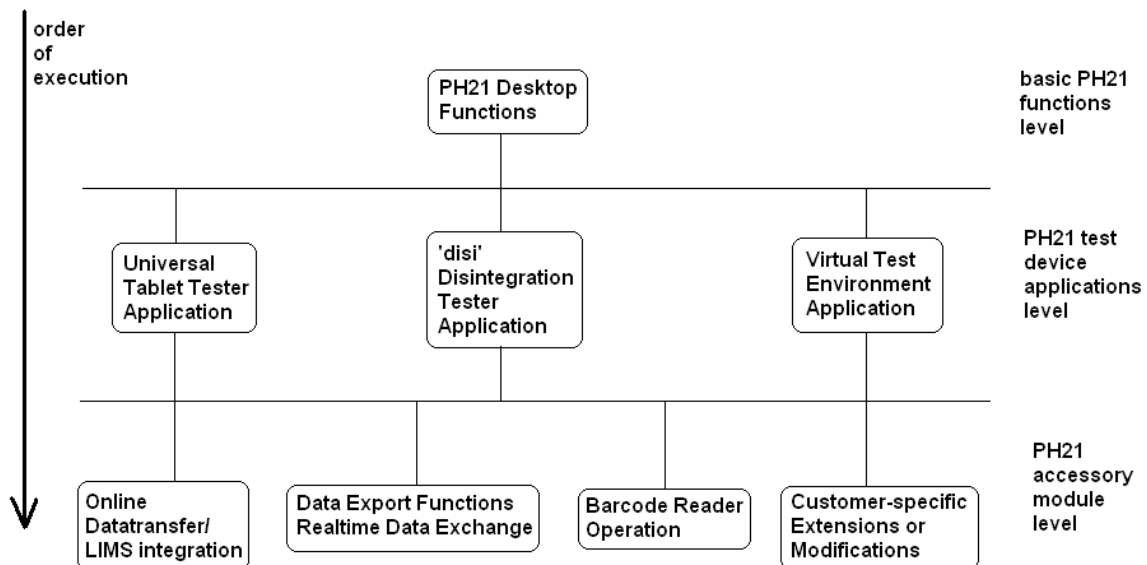
! **ONLY** use a QDP with the same **software license number** than the Ph21 runtime system.

The expression '**Monograph**' is an alias for expression '**Product**' and will designate a product specification. In order to conform to pharmacopoe terminology the expressions will be used interchangeably in the following chapters.

This test suite will be executed manually using keyboard and pointing device ('mouse'). This will take a considerable amount of time!

4.4 SUGGESTED ORDER OF EXECUTION

There are various dependencies between Ph21 components. For example, a disintegration tablet test can only be executed if a product specification has been previously set up. Setting up product specifications is a subject of the Ph21 desktop module, executing a tablet disintegration test is a subject of the tablet disintegration tester application module. The following is a suggestion in which order the test suites should be executed in order to have a smooth transition through the Ph21 features.



4.5 SUBJECT

4.5.1 SYSTEM NAME

Ph21 testing system for solid dosage forms as an integral component of the Ph21 laboratory automation system.

4.5.2 ORIGINAL MANUFACTURER

irl Industriesteuerungen GmbH, Seeheim, Germany is responsible for the hardware test equipment and Ph21 Services Ltd., Germany is the responsible owner of the PC software (Ph21 software system).

4.5.3 SYSTEM DESCRIPTION

Software system to support mechanical tablet testing, tablet disintegration testing and acquiring of test results of external devices as well as manually entered values.

4.5.4 SYSTEM CATEGORIZATION AND GAMP 5 RELEVANCE

More than Ph21 1000 licenses have been issued since 1993. From these 750 licenses of the software revision 4 have been shipped until March 2010 to major pharmaceutical corporations worldwide.

Therefore with some confidence the Ph21 software system can be regarded as an **COTS** (commercial, off-the-shelf) product. It can be run straight after setup from CD. There is no enduser-specific configuration work required. From the GAMP-5 point of view this software is to be regarded as a **'Non-Configured Product according to GAMP Category 3'**. Therefore according to GAMP 5 the supplier involvement for an purchase of the software is **'limited to the provision of documentation, training, support and maintenance'**.

4.6 TEST METHODOLOGY

Test datasets will be generated. The test application's menu options will be applied to these datasets. Simulated tests will be executed using a tablet tester simulator or a real tablet tester operating in simulation mode or simulated values will be acquired from prepared data files.

Reports will be generated. The generated reports will be compared to reference reports which are supplied together with this document.

Validation tests of this test suite may require a suitable hardware/test device. Special requirements for hardware configuration are mentioned in footnotes in the following tests. If certain hardware features are not available at the end-user's systems then this may be annotated in the test suite and the respective tests should be disregarded. Result in this case should be marked with '**N/A**'. This will **NOT** invalidate the validation result!

4.7 ACCEPTANCE CRITERIA

All tests of this test suite have to be carried out without errors. All tests have to be answered with '**As expected**' or '**N/A**' if the test is not applicable to the particular system under test.

If a test is answered with '**NOT as expected**' however the problem is already listed in the **known bugs list** and a **workaround** is made available by the manufacturer, then this '**NOT as expected**' answer does **NOT** invalidate the validation procedure. Annotate the application of the workaround in the test's comment field in that case.

In many validation tests there is an expected behaviour like 'Printed report corresponds to validation reference report' or 'Printed report is similar to validation reference report'. What actually this formulation mean may be best explained by the two examples following:

Example 1:

Due to a verification of a calibration function, reference values are compared to actually acquired values. You may acquire, for example, a value of 0.1mm, the reference report however lists a value of 0.2mm. Both values are well within the required precision limits. In this case the value printed in your report differs by 0.1mm to the value listed in the reference report. This difference is caused by mechanical properties of the devices being used and thus are **perfectly acceptable**.

Example 2:

due to a verification of a test abort function, the user is requested to run a test for about 1 minute and then click the [**Abort**] button. Because humans are not perfect machines, the operator may abort the test after 58 seconds or after one minute and three seconds. This deviation may appear if you compare your validation results with a validation reference report. Also this kind of deviations are **perfectly acceptable**.

The same applies to data and time information printed in reports. These will (obviously) always deviate from the validation reference reports

Page breaks in printed reports depend on the type of printer currently in use and also on the paper-size being used. Therefore page breaks on printed reports may (and will) be at different locations than on the reference reports. This does **NOT** invalidate the validation procedure!

! A conclusion of the two examples is, that validation results should be regarded in the context where the results have been created when comparing them to validation reference reports.

This test suite contains references to the application's reference guide. The reference guide serves the 'functional specification' in this validation. If all steps have been carried out successfully, also the reference guide will be regarded as 'accepted'.

! The Ph21 software system may be 'customized' by original equipment manufacturers who distribute the Ph21 system together with their mechanical test equipment as a 'bundled package'. This test suite

refers to the software system as it was initially configured by Ph21 Services Ltd. If OEM versions of the software system are to be validated using this test suite, then some expressions may be different from the expressions used in this test suite. Some features covered by this test suite may be absent. This has no impact on the functionality of the system and does **NOT** invalidate the result of the validation procedure

4.8 TESTDATASETS

A defined number of test datasets will be generated. In order to gain a maximum of coverage of internal program branches this data items may be permuted.

The following major test datasets will be applied:

- Products/Monographs
- Batches / Tests / Acquired Values
- Audit trail entries
- Operator data

4.9 PROVED FUNCTIONS

See table of contents.

4.10 PREPARATIONS

Have your hard lock key (WIBUKEY) with proper license content connected on the system to be validated. Have the user documentation at hand. For the 'Adjustment/Calibration' section have the required thermometer and stopwatch at hand. Have a current issue of **Ph-Eur** and **USP** pharmacopoe at hand.

Have test suite for the Ph21 Desktop, Standard features being executed before executing this test suite.

Enter Ph21 desktop's menu item 'Setup' | 'Setup the Ph21 Desktop' | 'Images'. Delete left and right Image fields. [Store] Setup.

!

When executing this test suite always use the **latest** EPROM Rev. of disintegration tester's embedded control logic.

4.11 VALIDATION ENVIRONMENT

Processor: Virtual Machine, VM-Ware 6.5.1, 1024MB Memory, 16GB Harddisk, USB-port, Serial port, Network connected, Screen resolution 1280x1024

Operating System: Windows 7 Ultimate, no Service Releases installed

Device and Firmware: disi tester/simulator, firmware 1.1013

5 TEST CASES

This test suite is divided into '**test cases**'. Every subchapter of this chapter is regarded as a test case. When a test case has been completed, it is good practice to copy the database files into a safety directory. This will enable you later on to start the test suite at any test case simply by restoring the database file generated by the previous test case.

Hint for executing this test cases:

On several occasions there will be an instruction like '**click Ok**'. However there are other controls like checkboxes, radiobuttons etc shown in this window which are NOT mentioned in the validation test step. In this case proceed **EXACTLY** as requested by the validation test. **DO NOT** touch any other control element, just leave it as it is.

Unless otherwise stated, all operations will be carried out by operator named '**Sysadmin**', ID-No. '**001**', having minimal access restriction (system administrator).

5.1 SYSTEM SETUP/INITIAL START

The following test step assumes the system has newly been set up. In case of an upgrade/extension of an already existing system some of the initial messages will not appear. However the functions can be selected nevertheless explicitly via Ph21's menu bar.

Setup the Ph21 software system as outlined in chapter System Installation in '**Ph21 Desktop Standard Features**' quick start reference guide. Have the Wibukey which contains the Ph21 software license properly set up and plugged on on the computer. Switch **OFF** the disi tester.

5.1.1 INITIAL START OF THE DISINTEGRATION TESTER APPLICATION

TEST NO. 1 INITIAL START – STATUS OF THE DATABASE

Funct. Descript. Reference User's Operating manual

Operation/Action

Start up¹ the Ph21 system for the first time.

Expected Behaviour

Window '**Status of the database**' or '**The database is healthy**'² will appear for a short period of time.

Result

- As expected
 NOT as expected (annotate)
 N/A (annotate)

Annotations

¹ usually the Ph21 system will start automatically after the computer is switched on.

² this message is only there if there are no batches and other records present in the current system. If other test suites or other activities have been performed before this test suite the message will list the database utilization

TEST NO. 2 INITIAL START – CONNECT EXTERNAL DEVICES

Funct. Descript. Reference Disi Tablet Tester Reference Guide

Operation/Action

Hint window '**Please connect the external devices before you start testing !**' will pop up. click '**[Ok]**'.³

Expected Behaviour

Window '**Connect external devices**' disappears.

Result

- As expected
- NOT as expected (annotate)
- N/A (annotate)

Annotations

³ The hint will only show up if no COM port is already assigned by former validation activities

TEST NO. 3 INITIAL START – ASSIGN PASSWORD

Funct. Descript. Reference Disi Tablet Tester Reference Guide

Operation/Action

On the **Ph21 Desktop [Sign On]** as user '**SYSADMIN/001**'.

Expected Behaviour

Window '**Sign On/Sign Off**' will pop up. Or Window '**Assign a new password**' will pop up⁴.

Result

- As expected
- NOT as expected (annotate)
- N/A (annotate)

Annotations

⁴ If other test suites or other activities have been performed before this test suite, this message will not appear. The sign-on enforcement happens only once after the system is freshly installed. However usually at least the test suite for the Ph21 Desktop features has been executed before, so a user password will already have been assigned.

TEST NO. 4 INITIAL START – ASSIGN PASSWORD

Funct. Descript. Reference Disi Tablet Tester Reference Guide

Operation/Action

If System asked for a new password than enter and **confirm** a **new password** of your choice of at least **six** characters in length, click **[Sign On]**. Otherwise use previously defined password.

Memorize the password for further use.

Expected Behaviour

User '**Sysadmin-001**' will be shown on Ph21 desktop's title bar, menu bar of Ph21 desktop will expand.

Result

- As expected
- NOT as expected (annotate)
- N/A (annotate)

Annotations