

## Ph21 Laboratory Automation System

# The Ph21 Development by Examples

Ph21(c) - A Pharmaceutical Production Control System  
for Solid Dosage Forms

This document is valid for the software revision:

Ph21 Rev. **R4.7**

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## Document Change Control Information

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## 2 COMPLAINT MANAGEMENT WINDOW

The screenshot displays a complaint management interface with the following components:

- Header:** A search bar containing 'List: F11003506' and navigation buttons (back, forward, search).
- Filter List for:** A text input field for filtering the list.
- Enduser:** A dropdown menu for selecting the end user.
- Reference:** Fields for 'Reference: F11003506', 'Customer: [redacted] GmbH', 'DueToResponse', 'DueToFinalize', 'Subject closed', and 'Incident Reference: 1559'.
- Subject:** A text field containing '[F11003506], [redacted], Dresden, [redacted], sporadischer Ausfall eines [redacted]'.
- Activity List:** A tree view showing activities for 'F11003506':
  - 3/12/2010 11:40:00 AM : annehmen
    - 001.Telnotiz.txt
  - 3/12/2010 11:50:00 AM : bearbeiten
    - 002.F11003506 [redacted] Dresden, [redacted], sporadischer Ausfall eines [redacted]
  - 3/13/2010 1:50:00 PM : bearbeiten
    - 003.AW Ph21 R4.7.htm
- Possible Activities:** A list of activities: annehmen, bearbeiten, abschliessen, Annahme bestätigen, kostenplf. Support.
- Expenses:** A section titled 'Expenses' with a 'Total Subject' field containing '1,1'.
- Select Transactions for Reporting:** Radio buttons for 'F-Number', 'Customer', and 'the actual transaction'. The 'F-Number' option is selected, with 'from: 03/1/2010' and 'to: 03/16/2010' fields.
- Filter Expenses:** Radio buttons for 'All', 'only the charged ones', and 'only the free ones'. The 'All' option is selected.
- Print:** A 'Print' button at the bottom right.

### 3 INCIDENT MANAGEMENT WINDOW

CC #

requested at  by  released:  by:

show ALL incidents  
 show only the APPROVED incidents  
 show only the NOT APPROVED incidents  
 show the incidents IN PROGRESS or DEFERRED

Problem Meldungen

Change Req. Incident No. reported by

components affected

documents affected

BN Access/Sql Server  Referenz Rekl.

priority

topic

**Problem Description**  
 when the Ph21 system is set-up for the first time and when Sysadmin creates all the user accounts, users can/will assign the initial passwords to themselves. This activity can also

**Suggestion for Resolution**  
 When Sysadmin creates new user accounts, Sysadmin will also assign a 'one-time' password to the newly created account. This password is handed over to the User. User creates his actual password using this 'one-time'

Scheduled

**Resolution**

**Test Method**

Processed

Tested

affected Component

Approved

Link1:

Link2:

Link3:

Link4:

Link5:

DRS	CI	Biomation	DRS-USA	J.Barnes	Copley	Kraemer	ABL+E	K+M	irl-intern	Manes	H.B.	
1	2	3	4	5	6	7	8	9	10	11	12	13
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

Comments

Record:  of 76

## 4 EXCERPT FROM THE CHANGE CONTROL REPORT

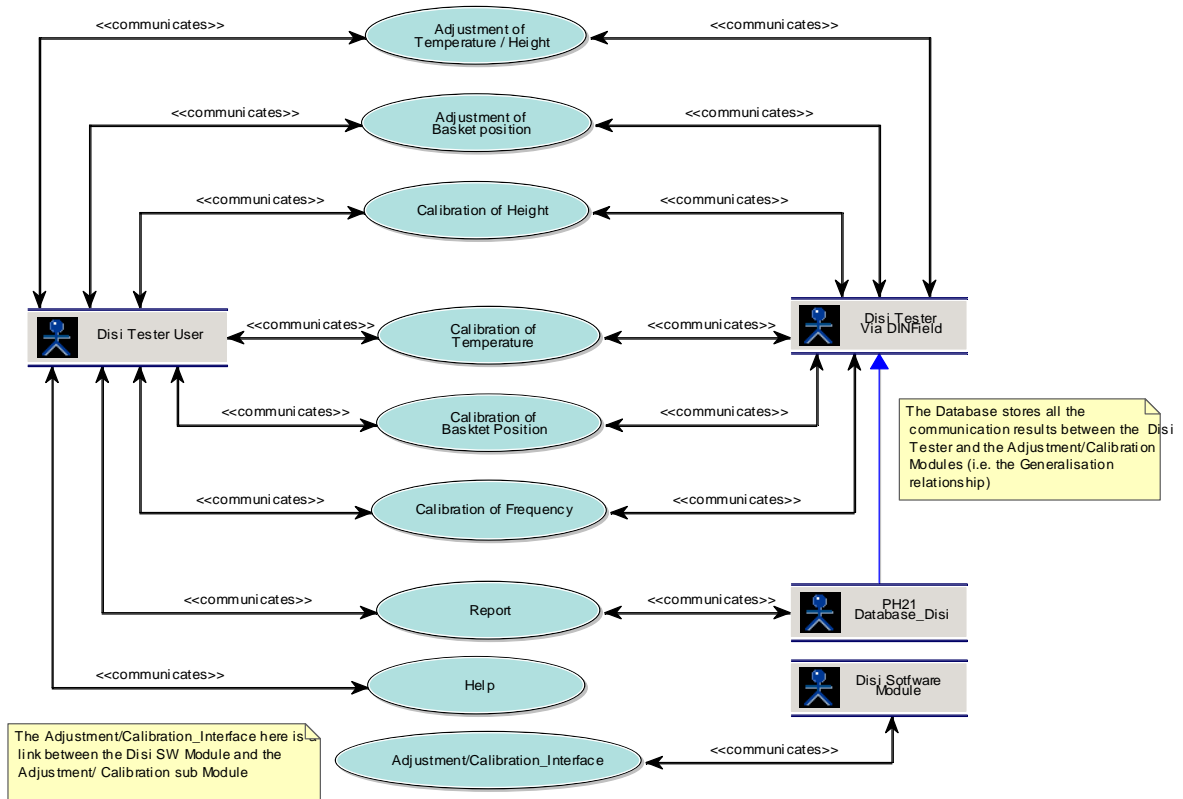
Change No.:	<b>1546</b>	BN DAO/ADO	/ 147k	F-Number:													
Topic:	<b>integrate additional alarm outputs</b>																
Problem Description			Resolution	Test Method													
for functional description see document 'PH21 data structures' chapter 'User supplied alarm function'			implement in sourcecode, provide external programs for digital output initiation.	define an alarm type using a user supplied alarm function simulate an alarm user supplied alarm function will be activated confirm the alarm user supplied alarm function will be deactivated													
<table border="1"> <tr> <td colspan="2">acquired</td> </tr> <tr> <td>Löffler</td> <td>11/24/2009</td> </tr> </table>		acquired		Löffler	11/24/2009	<table border="1"> <tr> <td colspan="2">processed</td> </tr> <tr> <td>Apostolou</td> <td>11-24-2009</td> </tr> </table>		processed		Apostolou	11-24-2009	<table border="1"> <tr> <td colspan="2">tested</td> </tr> <tr> <td>Löffler</td> <td>12-15-2009</td> </tr> </table>		tested		Löffler	12-15-2009
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PH21 (R), All Rights Reserved			Page 161 of 163														

## 5 PH21 SPECIFICATIONS

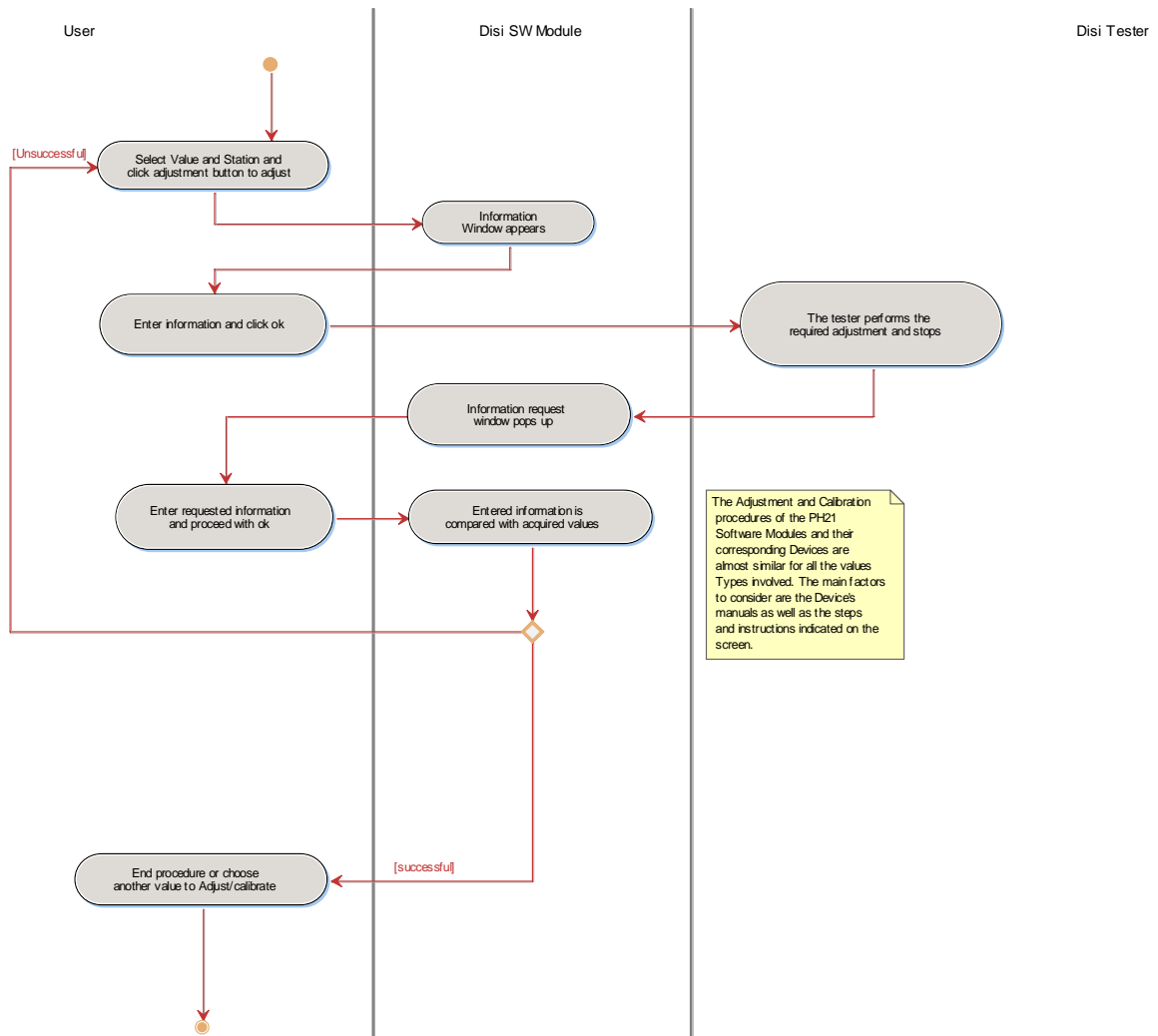
Ph21 specifications make use of the generally accepted UML system modeling environment. Some excerpts form user requirement specification and modul specification following.

### 5.1 DETAIL FROM AN USECASE DIAGRAM

The use case diagram of the Adjustment and calibration process. This diagram is part of PH21 Services Ltd's UML documentation method.

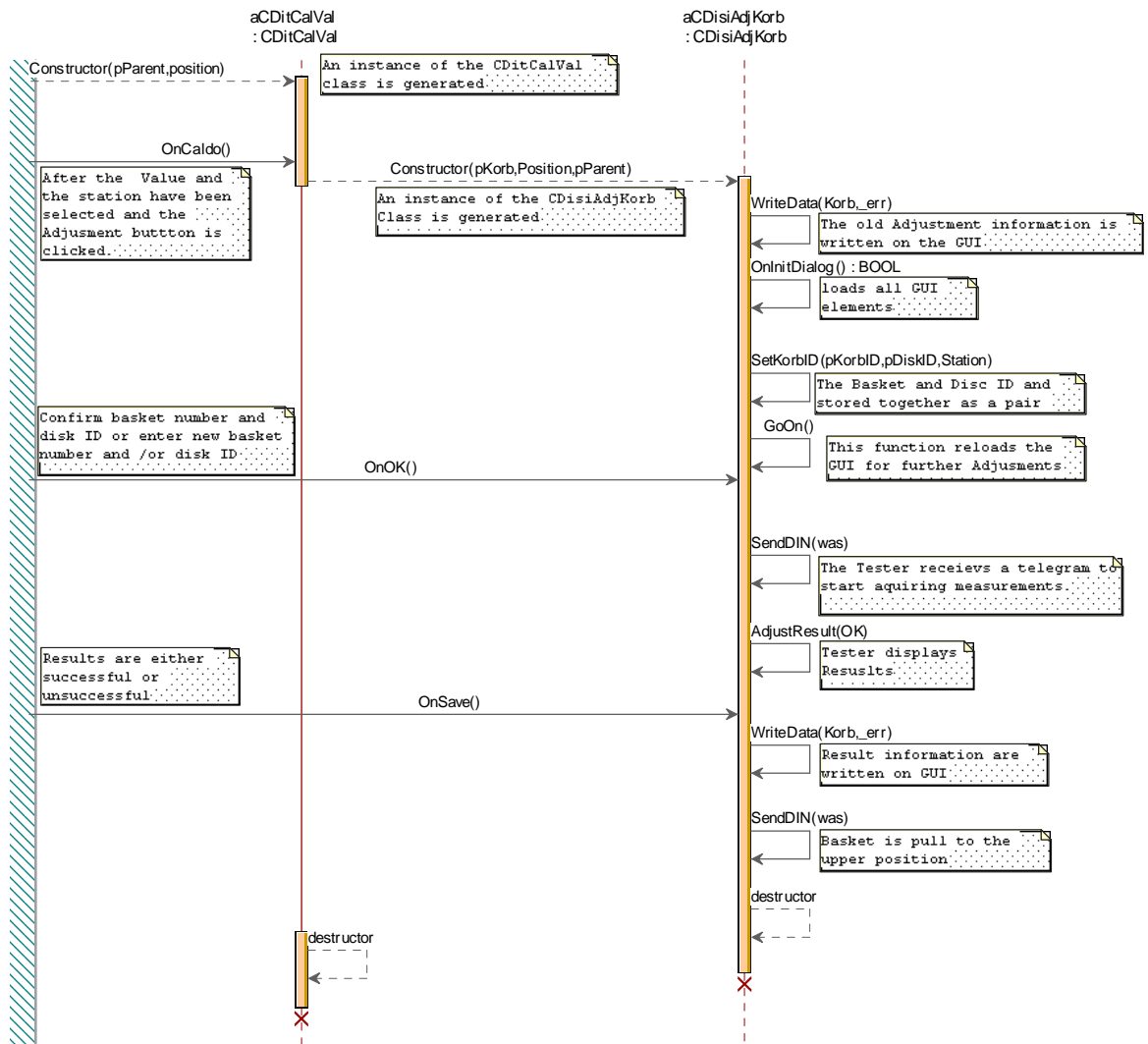


## 5.2 DETAIL FROM AN ACTIVITY DIAGRAM



The activity diagram of the Adjustment and calibration process. This diagram is part of PH21 Services Ltd's UML documentation method.

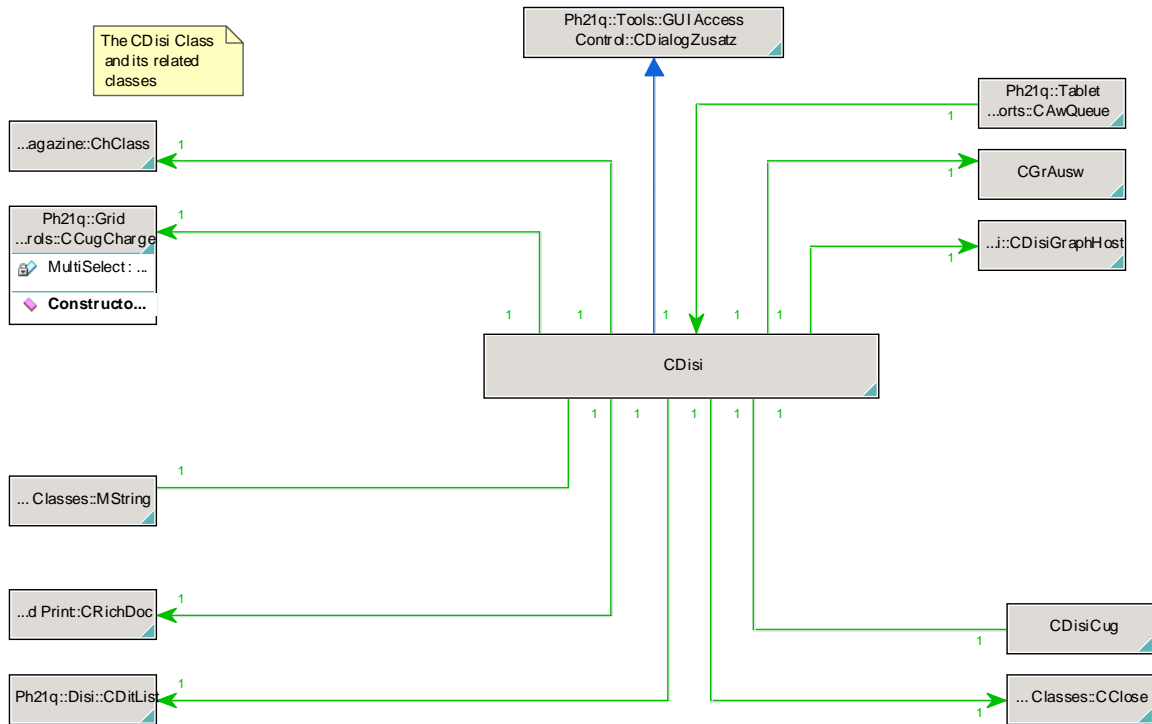
### 5.3 DETAIL FROM A SEQUENCE DIAGRAM



The sequence diagram defines and verifies the calling sequence of functions involved in the Adjustment of a Basket position. This sequence diagram belongs to the use case adjustment of the basket position (one of the use cases in the Use case diagram above).

This diagram is part of irl Team PH21's UML documentation method.

## 5.4 DETAIL FROM A CLASS DIAGRAM



Class diagram of the Adjustment and calibration use cases. This diagram is part of irl Team PH21's UML documentation method.

The function outlined in the sequence diagram in the previous chapter are now capsuled in their corresponding classes and the relationships between these classes are displayed on the diagram above with the line carrying direction arrows.

## 6 EXCERPT FROM THE SOURCECODE

```

class CDitCalVal :
    public CDialogZusatz
{
    //..begin "UserDefined"
    // put some additional code here
    //..end "UserDefined"
    //int PassiveBasketsKind;

private:
    CString ForceBasketC;
    CString ForceBasketV;
    int OneBasketSystem;
    int ScanStations (BOOL KorbIDcheck = true);
    int KorbAnzahl;
    //@access private
    CDisiAdjTemp * DisiTempCal;
    CDisiAdjKorb * DisiKorbCal;
    CDisiValKorb * DisiKorbVal;
    CDisiValHeight * DisiHeightVal;
    void InitValues ();
    char NextDate [ 20 ];
    //@member NextDate|Puffer zur Aufnahme des nächsten Kalibrierdatums
    CRichDoc Job;
    //@member Job|Objekt der Klasse <c CJob>. Wird benutzt um die Ausdrücke des
    Protokolls zusammenzustellen.
    void BuildCalValList (int DbSelID, int DbSelCou, BOOL Validat = false);
    //@member BuildCalValList|Low Level Funktion, die die Ausgabeliste des Protokolls
    //aus einer Datenbank-Selektion zusammenstellt.
    void GetCalValList (BOOL Validat, BOOL _last, const char * AbDatum, const char *
    pTstrName);
    //@member GetCalValList|Zusammenstellung des Protokolls.
    const char * GetCalValNext (long ID, int Korb, BOOL & NextValAktiv);
    //@member GetCalValNext|Funktion, die das Datum der nächsten Kalibrierung
    ermittelt.
    void BuildCalValListNext (int Korb);
    //@member BuildCalValListNext|Funktion, die das Datum der nächsten Kalibrierung
    als Liste darstellt.
    void PrintIt (BOOL _cal, BOOL _val, BOOL _last, const char * AbDatum = "");
    //@member PrintIt|Protokollausgabe auf dem Drucker.
    void SetLastVal (void );
    //@member SetLastVal|Diese Funktion aktualisiert der Daten der letzten Kalibrierung
    auf dem Dialog.
    void SetLastCal (void );
    //@member SetLastVal|Diese Funktion aktualisiert der Daten der letzten Justierung
    auf dem Dialog.

public:
    MString TstrName;
    CDisiValTemp * DisiTempVal;
    CDisiValFreq * DisiFreqVal;
    void AdjustResult (int OK);
    void AdjustTempResult (int OK, BOOL Upper);
    CDitCalVal (CWnd * pParent, int position);
    // standard constructor
    void SetRohrWerte (double * Akt);

```

```
void SetRohrWerte (double Akt, int Station);
void SetKorbID (char * pKorbID, char * pDiskID, int Station);
void SetNullPunkt (int Korb, int OK);
//@access public
CString Format;
//@member Format|Ausgabeformat der Einheit
CString Einheit;
//@member Einheit|Bezeichnung der Einheit
CString Messwert;
//@member Messwert|Bezeichnung der Messgrösse
double Praezision;
//@member Praezision|Eingestellte Präzision
CDit * Parent;
//@member Parent|Objektpointer auf das aufrufenden Disi-Dialogobjekt
```

The '//@' sequences designate code inline-comments which will be used for automated sourcecode documentation. Ph21 Services Ltd. uses the utility 'objectif' for this purpose.

## 7 AN EXCERPT FROM THE DISI TEST SUITE

### TEST No. 1 CONNECT EXTERNAL DEVICES - ASSIGN COM-PORT

Funct. Descript. Reference Disi Tablet Tester Reference Guide

#### Operation/Action

Click **[OK]**.

**Exit** PH21 system.

**Connect disi** tester or disi simulator to previously defined Com-Port.

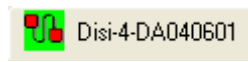
**Switch on disi** tester or disi simulator.

**Re-start** the PH21 system.

#### Expected Behaviour

Disi tester or disi simulator will identify itself as follows:

disi Tester icon on the left bottom part of the PH21 desktop window (example:



) will change from **gray to green/red** showing number of stations (Disi-1, -2, -3 or -4) and test device's serial number (Example: DA040601).

Disi identification message will appear in green letters on the audit trail line showing '**Device: Disi**', **disi Ser. No.** and **current EPROM version**.

#### Result

As expected

NOT as expected (annotate)

N/A (annotate)

#### Annotations

## 8 EXCERPT FROM THE FUNCTIONAL SPECIFICATION

According to Team Ph21 Ltd's development process, the user reference manual serves also as the functional specification. This is an excerpt:

.....

Report Disi-4 - DA040601

Presentation Output Layout

	Form	Production stage	Product Name	Product No.	Product Code	Batch Name
1	Tablet	uncoated	test product	001	tp-1	my test batch

Batch Comment

Layout: Standard

Method: Ph-Eur.

Procedure: Uncoated Tablets

Test

	Tube 1	Tube 2	Tube 3	Tube 4	Tube 5	Tube 6	Immersion fluid	Result
001	Run 1							
Step 1	00:01:5	00:02:0	00:02:0	00:01:40	00:02:22	00:02:26	Water R	Passed

Test Comment

Remaining height

Elapsed time

Temperature (°C)

39.0°

37°

35.0°

0:00:00 0:00:36 0:01:12 0:01:48 0:02:24

Modify comments

Do the report

Exit

The 'Report' window of the diski device is composed of the following elements:

- caption bar (for dragging the window around at the desktop)
- menu bar with options 'Presentation', 'Output' and 'Layout'.
  - via option 'Presentation' you may enable or disable printing of the graphical presentation of the disintegration curves
  - reports may be 'Output' directly to printer or printouts may be directed on screen at first from where they may be printed afterwards.
  - you may configure the appearance of the report by the 'Layout' applied to your report.

- batch selection list. A report may be printed for any test previously executed (single test report) or for all of the tests of the selected batch (batch report). Click the numbered button at right side of the batch row.
- in field **Test** all test numbers of the tests already executed for the selected batch will be displayed. Either leave the list alone, then a batch report will be printed including all individual tests executed, or select a particular test and print a report of this single test.

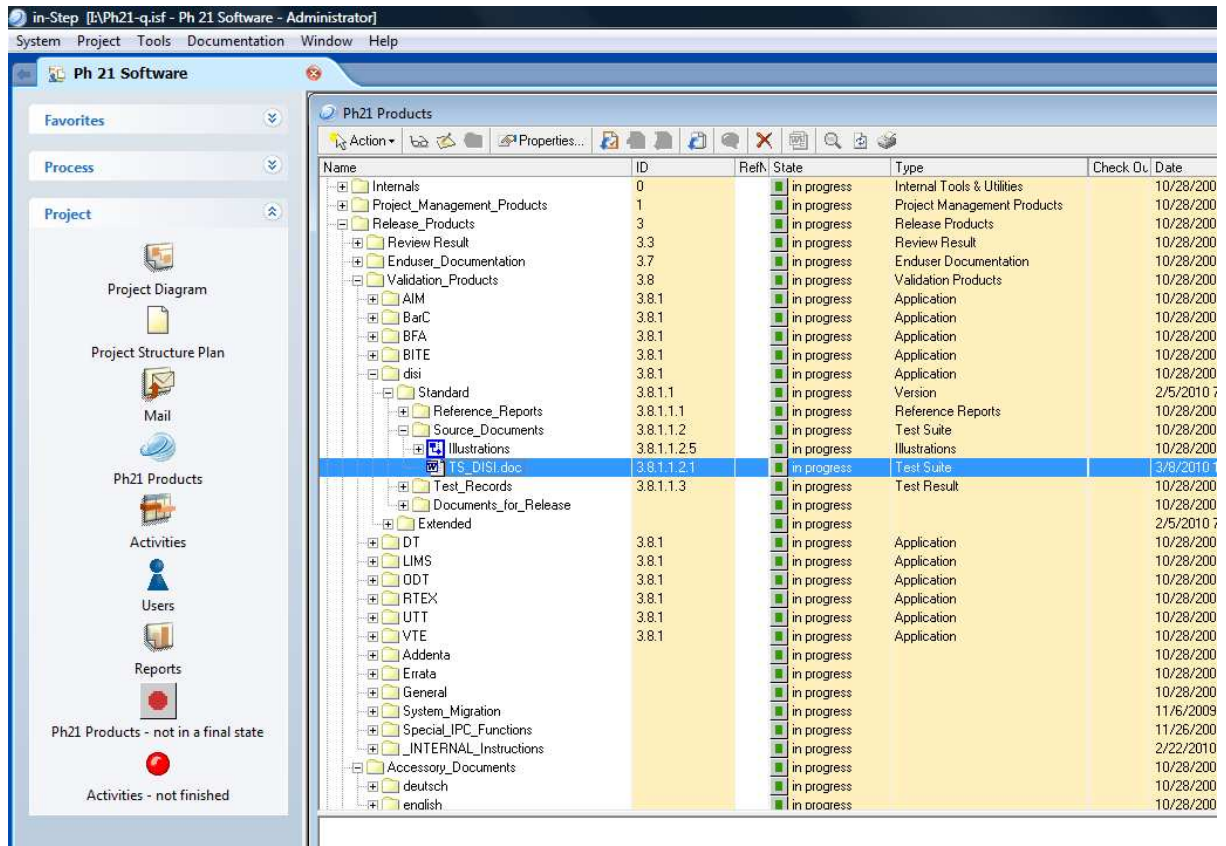
!

Test numbers shown in a strikethrough style (~~001~~) are tests which have been aborted and which carry no usable results.

- If a particular test has been selected from the list, then either the actual disintegration times of all objects will be displayed -or- the remaining heights will be displayed if the objects did not disintegrate within the specified time interval. The Result column shows if the test had been completed normally or if the test had been aborted prematurely.
- click button '**Do the report**' to start printing/previewing

.....

## 9 WINDOW OF THE WORKFLOW MANAGEMENT SYSTEM



Shown are the various products with their respective stadii.

end of document