



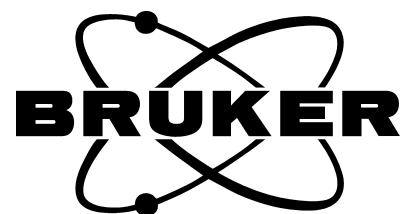
OPUS

Spectroscopy Software

Version 6

User Manual

OVP PhEur 2.2.24



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This manual is the original documentation for the OPUS spectroscopic software.

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1 Introduction

This manual describes the OPUS Validation Program (OVP) according to the guidelines set forth by the European Pharmacopoeia 5 (PhEur) for MIR spectrometers. OVP for PhEur 2.2.24 is an integral part of the OPUS spectroscopic software.

The tests and test criteria intend to check the Bruker line of spectrometers and modules according to the PhEur regulations. They are designed to follow the guidelines outlined in section 2.2.24 by the European Pharmacopoeia 5. According to section 2.2.24 a mid infrared spectrometer has to be qualified using a spectrum of a certified polystyrene foil in the mid infrared range. The polystyrene spectrum is used to test the wavelength accuracy and the spectral resolution of the spectrometer.

Certified standards (e.g. the BRM 1921) can be purchased from Bruker. For further details about the requirements refer to chapter 2.2.24 of the PhEur 5.

The PhEur 2.2.24 test protocol is intended to be run as part of the OQ test. The OQ (Operational Qualification) test protocol checks the instrument performance and compares this performance to the instrument specifications. OQ tests should be performed after each major repair, exchange of optical components which may influence the instrument performance, and on a regular yearly basis, e.g. after maintenance.

OVP for PhEur 2.2.24 acquires and evaluates a polystyrene spectrum. This kind of spectrum is measured in absorption, with a resolution of 2 in the range between 4000 - 400cm⁻¹.

1.1 PhEur 2.2.24 Tests

- Verification of Wavenumber Scale
- Control of Resolution Performance

For additional information on the different testing methods, refer to European Pharmacopoeia 5, section 2.2.24.

For further general information on OVP refer to the OPUS Reference Manual.

2 Test Setup

If you have already set up OVP for OQ and/or PQ, you can skip this chapter.

Before you can use OVP for PhEur 2.2.24 you have to set up the OVP test channels. Select the *OVP Setup* command from the *Validation* menu to open the following dialog:

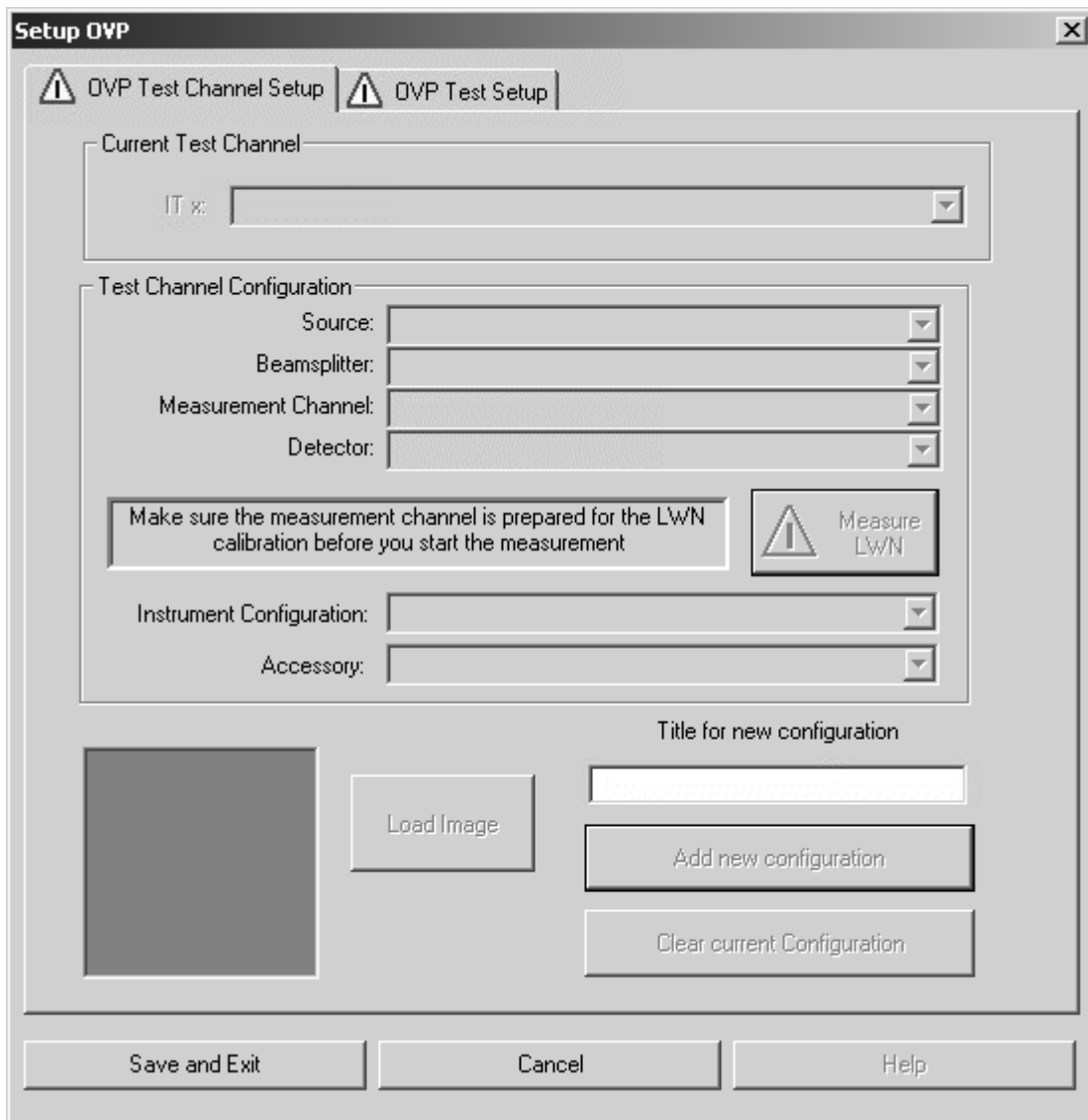


Figure 1: Setup OVP

Enter a title for the current configuration into the *Title for new configuration* entry field, to specify the current setup by a descriptive text.

Click on the *Add new configuration* button. Now, all the other selection fields will no longer be hidden and can be filled in.

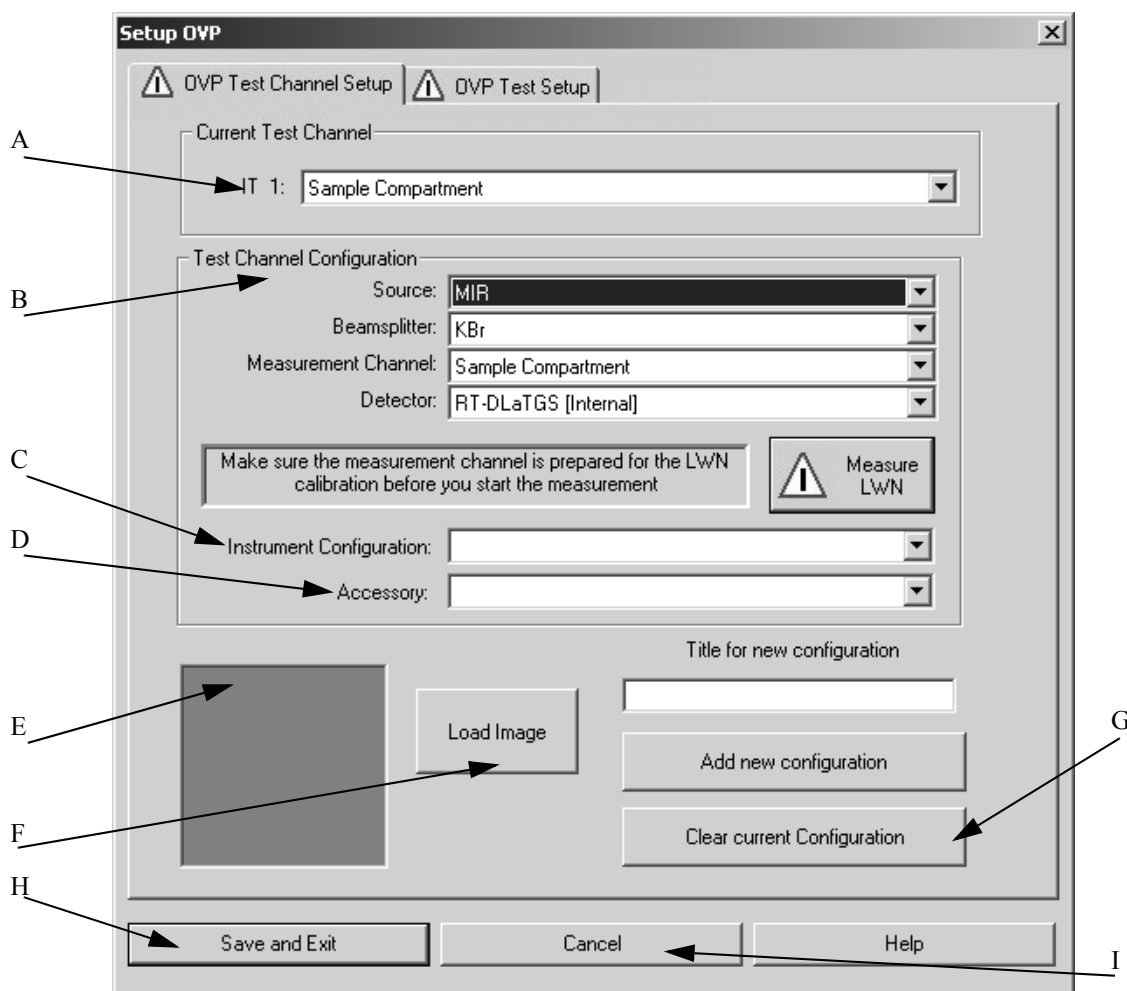



Figure 2: Setup OVP - Activated drop-down lists

- A) The drop-down list shows the test channel used by OVP.
- B) For each spectrometer test channel you have to assign a measurement configuration to be used during actual validation measurement. This is a valid combination of source, beam splitter, measurement channel and detector. As soon as you have selected all components the appropriate instrument configuration (C) and the bitmap (E) specified for the measurement channel will automatically be displayed.
- C) In general, the instrument configuration is automatically displayed as soon as you have selected all components.
- D) Depending on the test channel, the drop-down list contains appropriate accessories.
- E) Depending on the measurement channel selected a configuration-specific bitmap will be displayed.
- F) Use the *Load Image* button to load further instrument images available in OPUS. The bitmaps are stored in the *OPUS\VALIDATION\Bitmaps* directory. Select the *Thumbnail* option from the pop-up menu when clicking on the  button to be able to see at once

which bitmap belongs to which file name. For details on the bitmaps refer to the OPUS Reference Manual, chapter 13. You can also make your own photo with a size of 90 x 90 and store it into the bitmap directory using the *ITnn.bmp* file name (*nn* is a consecutive number).

- G) To delete the current configuration click on this button. Once deleted the settings cannot be reloaded. If you have accidentally deleted a channel, you have to repeat the complete setup again. OVP configurations are stored in the *OPUS\VALIDATION\Database* directory.
- H) To save the configuration click on the *Save and Exit* button.
- I) Click on this button to interrupt the setup without saving.

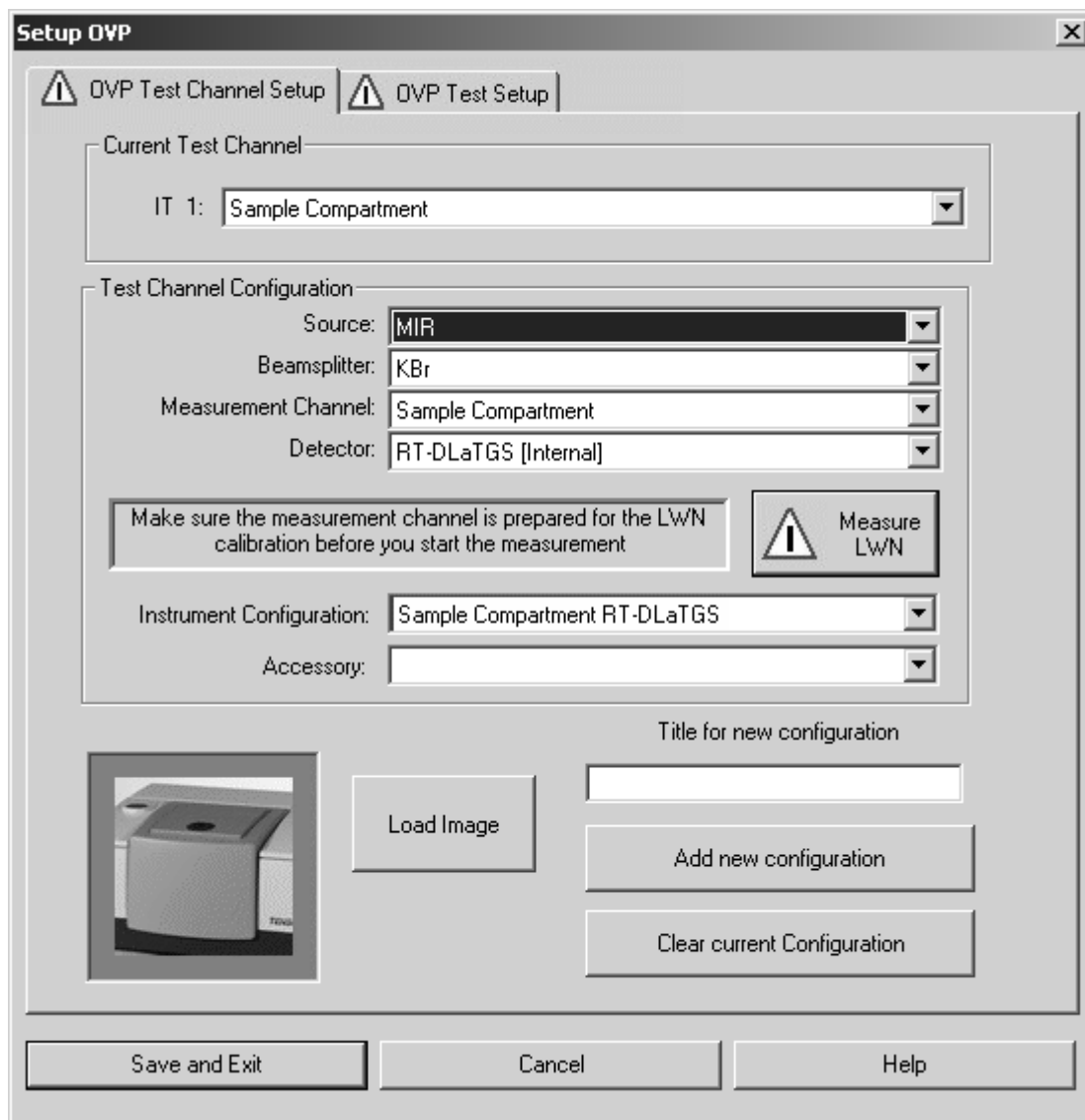


Figure 3: Setup OVP - Bitmap of instrument type

If you click on the *OVP Test Setup* tab, the following dialog opens:

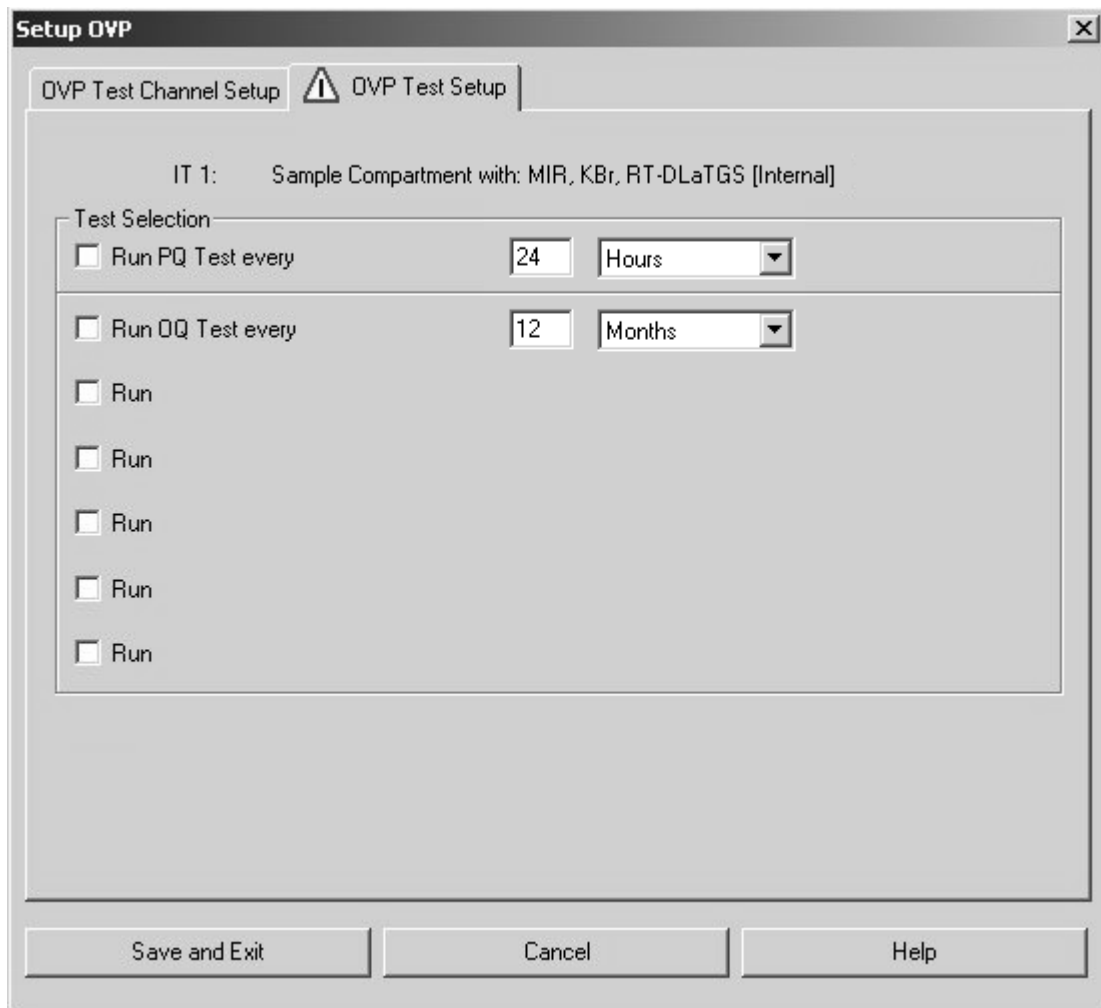


Figure 4: OVP Test Setup tab

The line on the very top shows the test channel selected on the *OVP Test Channel Setup* tab. Activate the *Run* check box on the *OVP Test Setup* tab.

Select *PhEur 2.2.24* from the first drop-down list and the *OQ* test category from the second. If the *OQ* test has not been setup, make sure that the expiration time for the test is properly defined in the *OQ* line. Type the interval period into the entry field and select the units from the drop-down list. Available units are hours, days, or months.

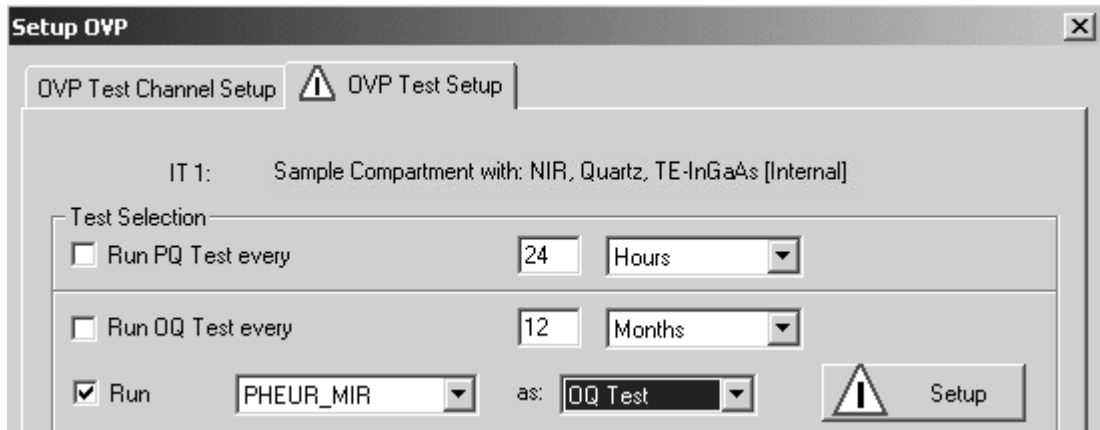


Figure 5: Configuring PhEur 2.2.24 test

Click on the *Setup* button to open the *PhEur 2.2.24 Test Protocol* dialog.

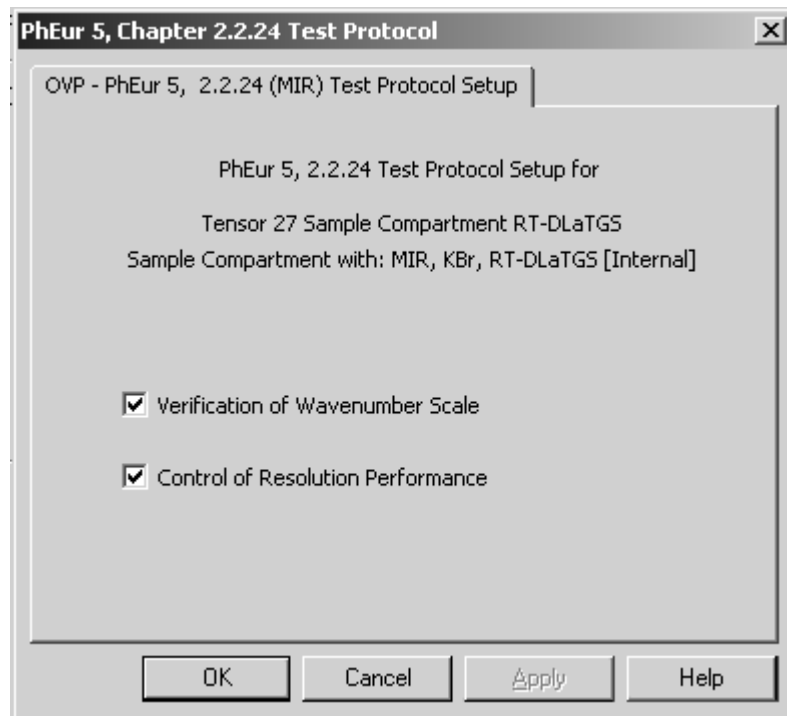


Figure 6: PhEur 2.2.24 Test Protocol

The two tests available for a particular type of spectrometer have already been selected. In exceptional cases (not recommended) you can deactivate a certain test by deleting the check mark.


The test protocol consists of the following single tests:

- **Verification of wavenumber scale**
Verifies the wavelength accuracy.
- **Control of resolution performance**
Verifies the spectral resolution performance of the spectrometer.

If the tests have been set up and you click on the *OK* button, the setup test status is indicated by a green check mark.



3 Run OVP Tests

There are two possibilities to run OVP tests. Either by selecting the Run *OVP Tests* command in the *Validation* menu or by clicking on the status light () and using the *Instrument Status* dialog. For details on the letter case refer to the OPUS Reference Manual, chapter 13.

To start running the tests click on the *Run OVP Tests* command in the *Validation* menu. The following dialog opens:

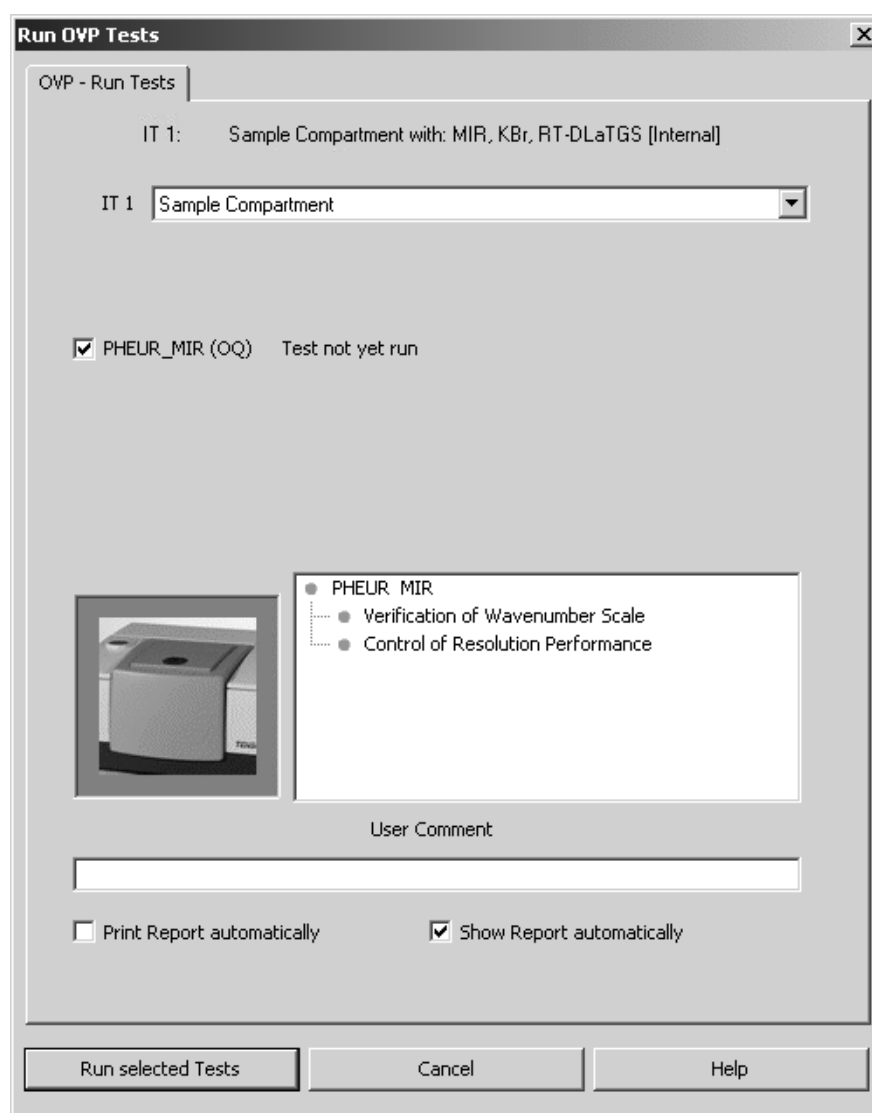


Figure 7: Run OVP Tests

The *ITn* drop-down list allows to select the appropriate IT test channel. The line below shows the tests set up for the IT test channel selected, as well as the test status. Tests which have expired, or which have not yet been performed are automatically activated for measurement. Tests which interval has not yet expired are not activated, and their remaining time is indicated as a reminder.

If a test has not expired, but the interval has only e.g. 2 hours left you can activate the check box for that test and run the test earlier.

If a test has expired, but you are not prepared to perform that test (external standards required), you can deactivate the check box for the corresponding test.

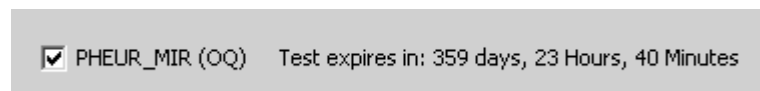


Figure 8: OVP test status

As soon as you have activated the check box for the respective test protocol you can see which test(s) will be performed by the browser-like display next to the bitmap.

All measurement results are stored in a report (PDF file) and in the *UserData* database. To append a comment to the current test protocol entry write a comment into the *User Comment* entry field.

Click on the *Run selected Tests* button to start the respective tests. If you do not want to perform any test, click on the *Cancel* button.

3.1 Printing Reports

The results of test measurements are stored in a report (PDF format). The test report contains a summarized test result page and subsequent pages for each test with all the test spectra displayed. Reports are stored in the separate *VALIDATION\REPORTS* directory and can automatically be displayed and/or printed. To have the report displayed and printed you require the Adobe Acrobat Reader which is available on the OPUS installation CD.

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