

TM020 – 21 CFR pt 11

WiRE™ 5

This document shows the WiRE™ 5 user how to set up and use the integrated 21 CFR pt 11 functionality. It assumes suitable protocols are in place to correctly use Windows® XP or Windows® 7 limiting functionality relating to groups, users, and directories. Use of the 21 CFR pt 11 module of Renishaw's WiRE™ 5 software does not in itself ensure complete adherence to the regulatory requirements.

WiRE™ 21 CFR pt 11 compliance comprises;

- User restriction (permission defining)
- File signing (electrical signing)
- File integrity (check sum)
- History log

Compliance relates specifically to WiRE™ 5 file types with extension wdf.

System history

In addition to the compliance requirements listed above, the instrument history is recorded to ensure complete traceability of calibration, performance, and safety parameters.

This information is accessed through the tools menu (Tools.... System health....History)

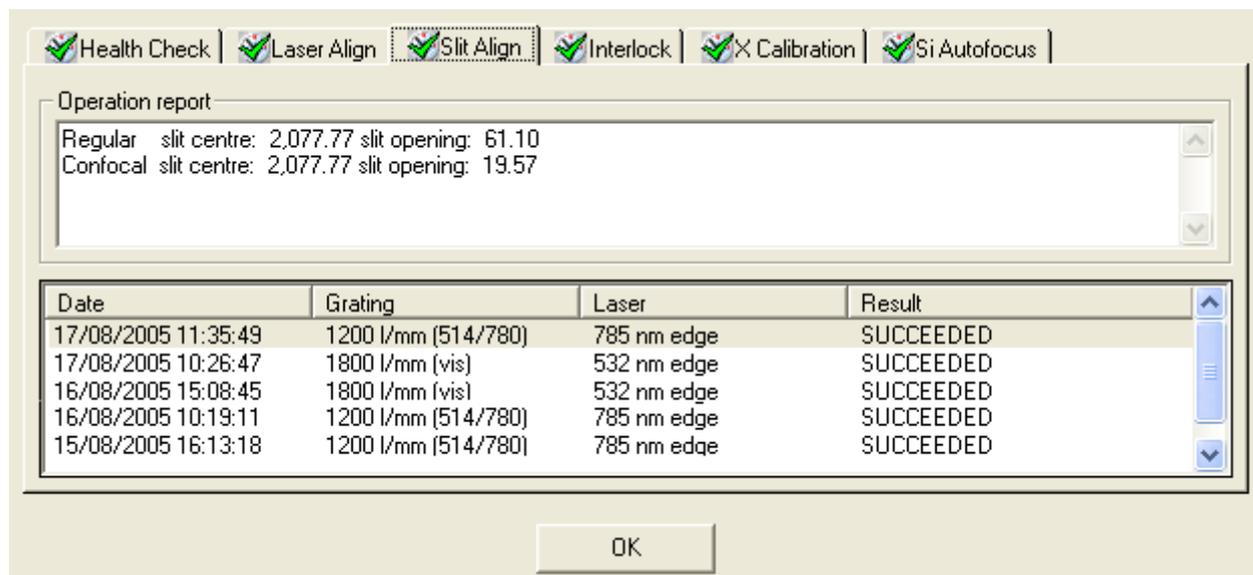


Figure 1. System history dialog

Figure 1 details the regular and confocal slit positions for the selected auto alignment. A complete history is stored for each of the parameters detailed in the history dialog

Set-up and definition of groups and users

Defining specific users to permission controlled user groups is an inherent requirement to allow user restriction in the WiRE™ interface. Users and groups can be defined through either a network, or local set-up. Either way, the restrictions apply to the specific PC used only. Therefore a network user can have different permissions on multiple PC's.

The WiRE™ security administration dialog is accessed through the start menu (Start...Programs...Renishaw Wire 5....Tools....WiRE security admin) or the desk top icon



WiRE Security Admin

The dialog allows groups and users to be defined, and settings to be imported / exported as XML. Also the dialog allows the relevant security features to be enabled / disabled as appropriate. Access to this dialog is set by the administrator, and should be restricted to administrators only.



Figure 2. WiRE security admin dialog

Note; the WIRE™ administrator does not need to have Windows® XP or Windows® 7 administrative privileges.

WiRE Users

The 'WiRE Users' button provides a list of current users, groups they belong to, and an editable description (Figure 3).

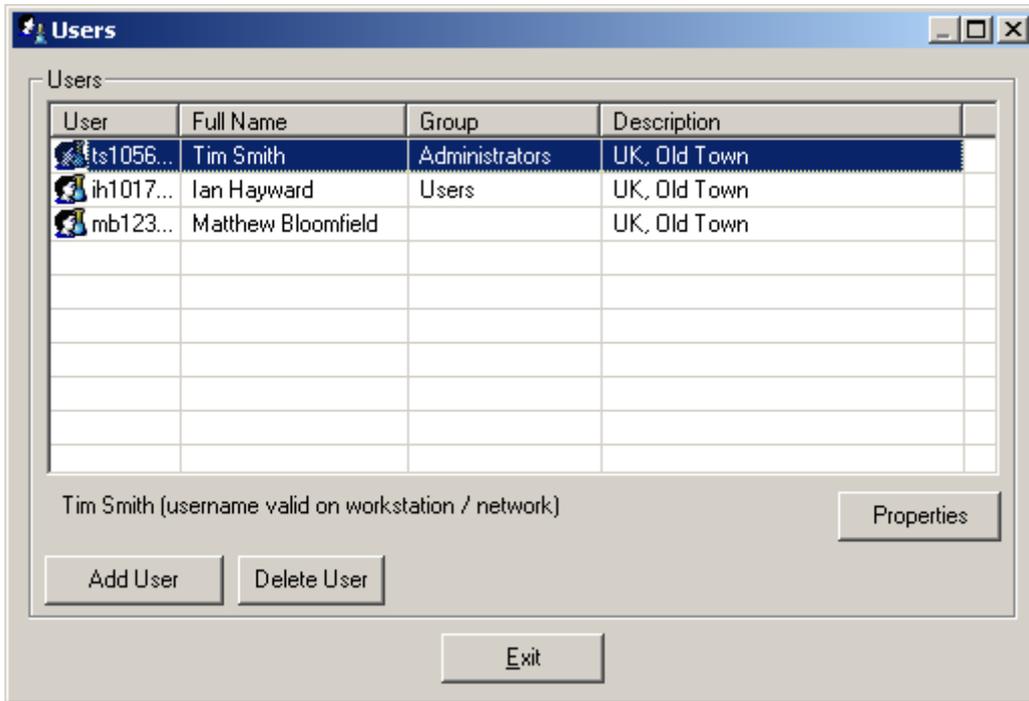


Figure 3. WiRE Users set-up dialog

Users are added and deleted using the appropriate buttons at the bottom of the dialog.

New users can be added by using either network, or local PC / WiRE set-up permissions.

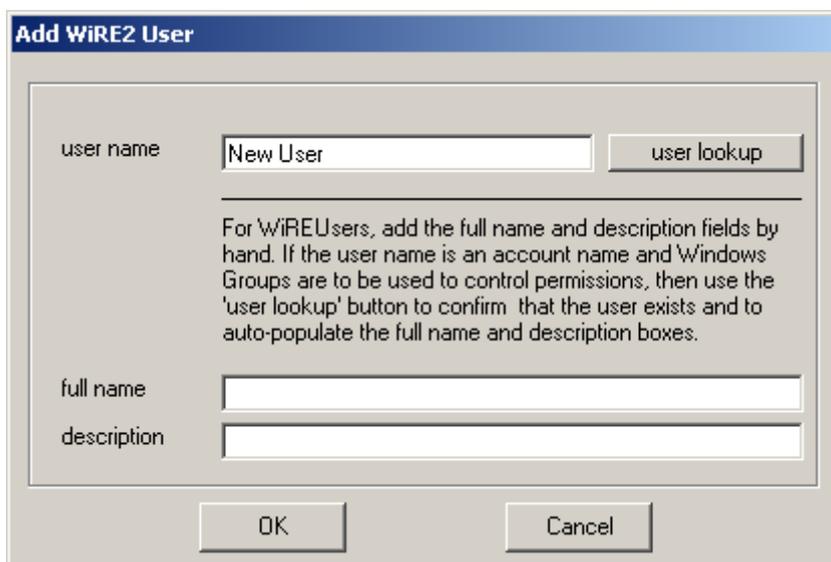


Figure 4. WiRE new user set-up dialog

To check a network user name simply chose the ‘user lookup’ option to populate the relevant fields. The user must verify correctly for the WiRE security to use the username. Local user names can be set-up, and the information added manually. This requires correct set-up of the Windows local users and groups settings.

Clearly a defined 21 CFR pt 11 working protocol is required to determine users and groups are controlled through local WiRE administration, or pre-defined through network administration (recommended). Network users and groups are controlled through the network administration, and is beyond the scope of the WiRE administrator.

Windows® XP also requires configuring to allow only one log in at a time.

WiRE groups

The WiRE groups button provides access to the group set-up and displays the available groups, number of denied permissions, and a description of the group.

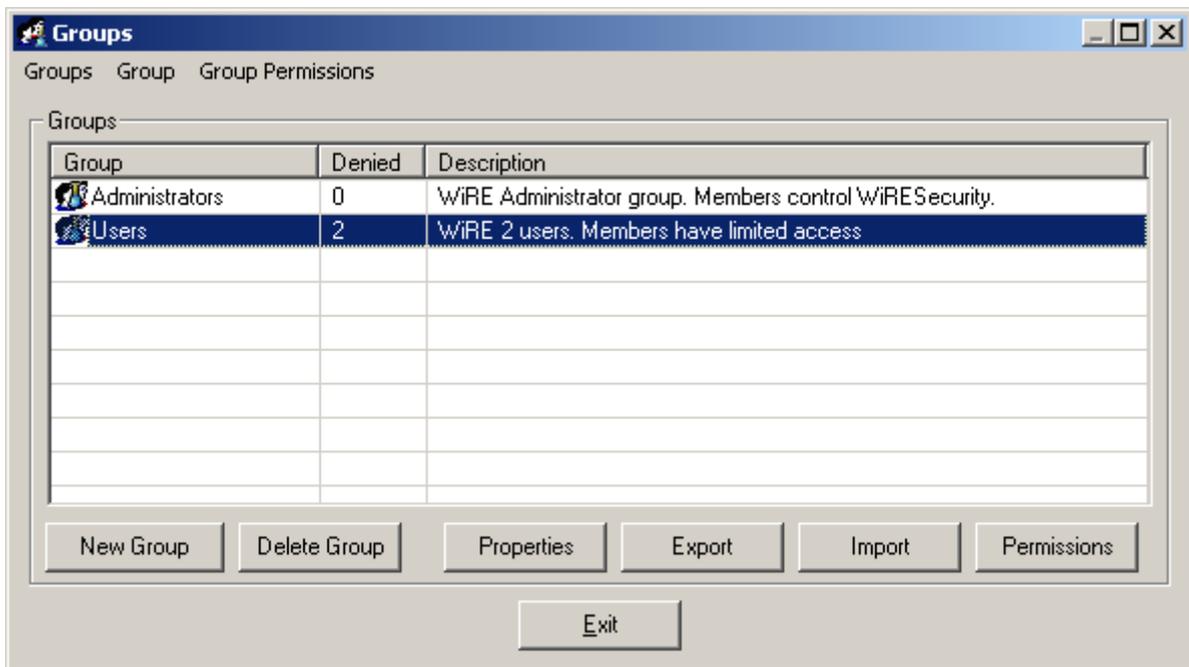


Figure 5. WiRE Groups set-up dialog

New groups can be set-up through WiRE (‘WiRE groups’), or verified from a network or local PC (both termed ‘Windows groups’ where groups have been pre-defined (Figure 6)).

The group properties allow users already defined to be added to a specific group. One user may be added to more than one group.



Figure 6. WiRE new group set-up dialog

A group also needs to be added to the local PC that will be used to set access permissions to the registry;

- Add a new group (called WiRE3AllUsers) to Windows using Computer Management
- Add all Windows groups that have WiRE users in them to the WiREAllUsers group
- If WiRE is configured to use 'WiRE groups' then the individual users will need to be added to the WiRE AllUsers group.
- Run regedit as an administrator
- Browse to HKEY_LOCAL_MACHINE\SOFTWARE\Renishaw, right-click and select permissions...
- Click on Add and add the WiREAllUsers group.
- Give this group FullControl permissions.

User restriction (permission defining)

Access permissions are set per group. Renishaw has provided default guide permissions based on group type. The exact nature of the permissions is detailed in appendix 1.

The default permissions are accessed through the group permissions menu of the groups dialog (Figure 7).

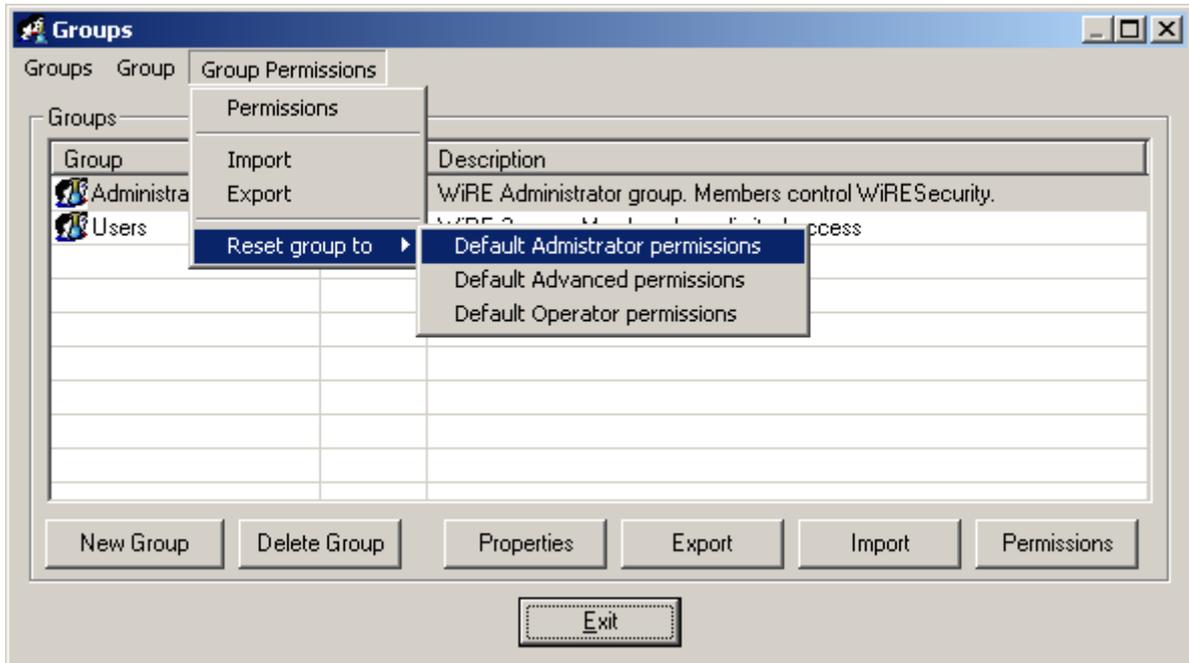


Figure 7. Default group permissions access

The exact permissions given per group should be decided as part of the overall 21 CFR pt 11 user protocol.

The permissions are displayed for each group selected, and take the form of a tree structure. Figure 7 shows the expanded CFR permissions for the selected 'Users' group.

Ticked boxes show where the group is permitted to use the relevant functionality.

When changes have been made to this, a save prompt will be displayed to ensure all changes are desired.

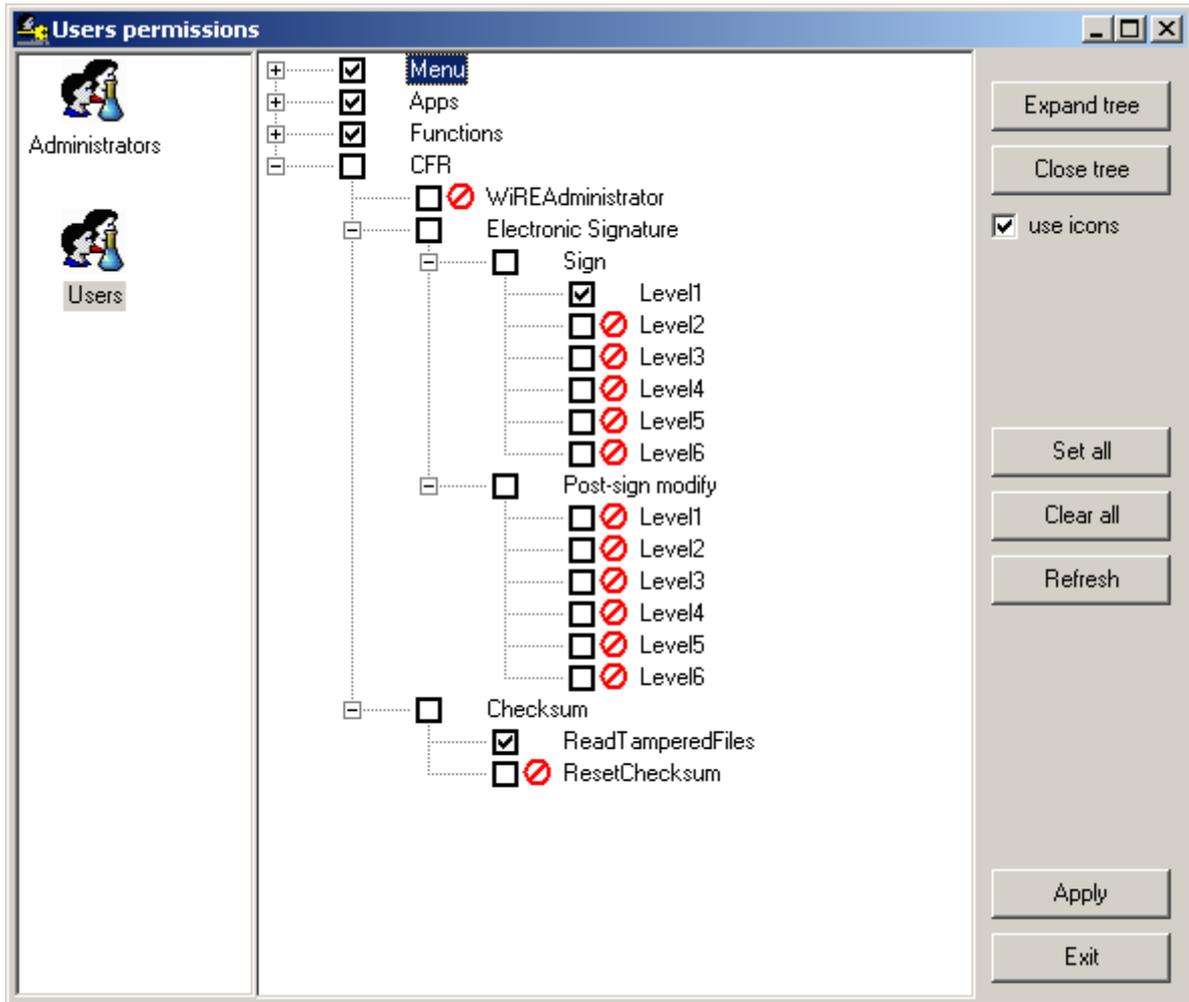


Figure 8. Permission setting dialog

Note; Any required restrictions on file usage (i.e. which user can access, modify, copy, or delete other users' files) need to be configured in Windows® XP and are beyond the scope of WiRE.

File signing (electrical signing)

To enable this functionality the relevant field should be ticked on the WiRE security admin dialog (Figure 2).

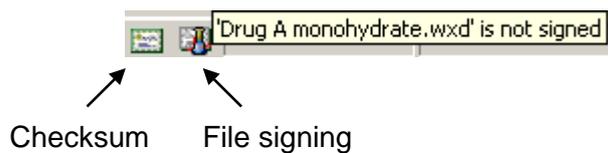


There are 6 configurable signing levels, the number of required levels should be set (ticked), with relevant meaning given appropriate to the specific level (Figure 9).



Figure 9. Electronic signature configuration dialog

The file signing status is displayed, for any loaded spectrum, in the statusbar at the bottom of the WiREInterface.



If electronic signature is off, the whole image is greyed.

If electronic signature is on, and the file is not signed, the certificate is greyed out, and the label text gives the current status information.

To sign a file, select 'File...Sign file' from the WiREInterface's menu. Select the appropriate responsibility to be signed (Figure 10), and fill in the description field.

Selecting 'sign file' will prompt the username and password of the user to be entered (it is a CFR requirement that the username be typed from scratch).

If a signing level is not available to that particular user it will be greyed out. However, the user can be briefly changed if higher signing authority is required. This option is located at the top right of the electronic signature dialogue, and will un-grey appropriate levels.

On exiting the electronic signature dialog, the file's electronic signature status is updated to reflect the new certification.

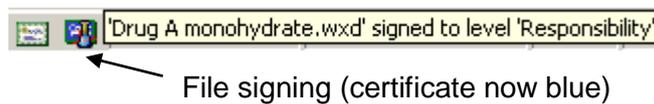


Figure 10. Electronic signing dialog

The file's electronic signature is stored in the file and therefore will only be saved if the file is saved. Subsequent file signing will have levels below the current level greyed out. Figure 11 shows an example of the signing options if the current level is set to 'responsibility'.

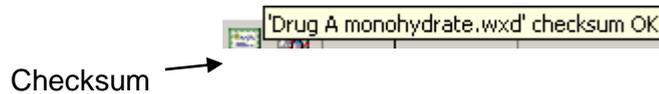
Passwords must not be zero length or the signing functionality will be disabled. Also the username must not be the full name (see Figure 3).



Figure 11. Electronic signing dialog after signing

File integrity (checksum)

The checksum status is used to determine if a file has been modified outside of WiREInterface, or within WiREInterface with WiRE file security turned off. It is therefore used to confirm the data validity.



On loading a wxd file, the checksum is automatically calculated. If this fails the user may have the option of resetting the value; this depends on the group permission settings the user belongs to. The act of resetting the checksum from an invalid state is recorded in the file history.

It is the intention that the checksum be used to determine if data has been externally modified in anyway, and to highlight this to the user.

History log

A log of all the processes applied to the loaded data are recorded as part of the CFR requirement. These can be viewed using the 'File history' option from the 'file' menu in the WiRE interface, and are also available in more detailed form in the Navigator data tree.

File history						OK
ID	Operation type	Date	Time	User	Source data	
1	ElectronicSignature	19/08/2005	10:24:08	ih10	All	
2	CurveFit	19/08/2005	11:14:22	ts10	DataSet0	Copy table
3	BackupDataList	19/08/2005	11:14:44	ts10	DataSet0	Print...
4	BaselineSubtraction	19/08/2005	11:14:44	ts10	DataSet0	
5	ElectronicSignature	19/08/2005	11:15:00	ts10	All	Filter types...

Figure 12. File history table

Filter types can be applied to the file history to display specific operation types if multiple operations have been performed.

The following information is also displayed within the summary information of the Navigator data tab (Figure 13);

- Measurement configuration (experimental parameters)
- Measurement status (file information)
- File security (checksum status)
- Electronic signature (history)
- File modification (users)
- History summary (all operation types)

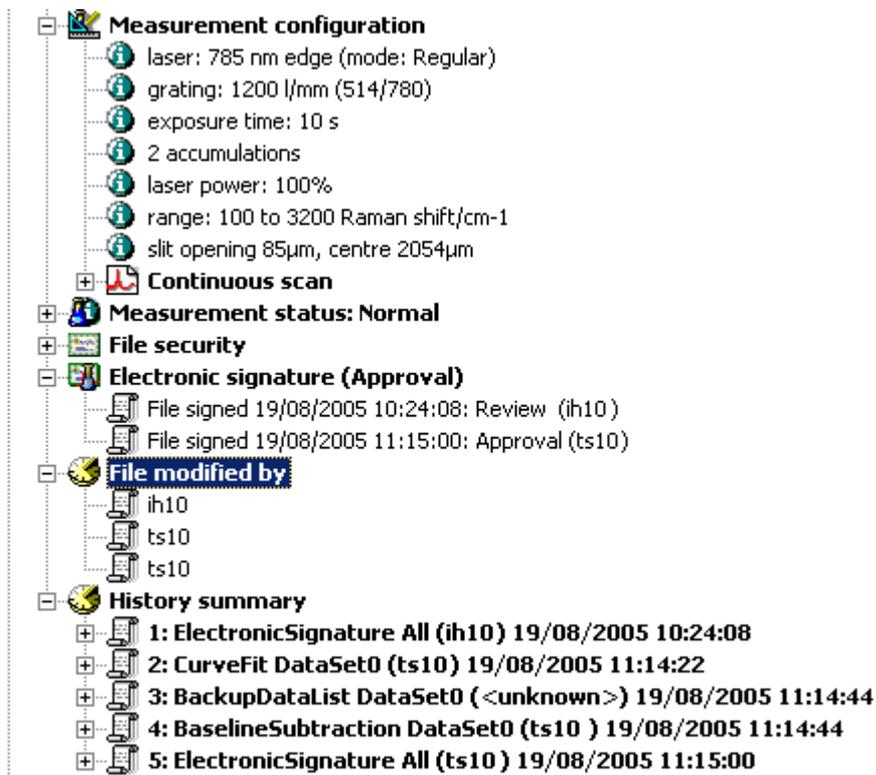


Figure 13. Navigator information example

Appendix 1 - Functional access restrictions

x: not allowed, 1: access allowed, 2: access allowed if customer purchased CFR module

ID	Title	Category	Admin	Advanced	Operator
1	File\Open	Menu	1	1	1
2	File\Revert	Menu	1	1	1
3	File\Close	Menu	1	1	1
4	File\Save	Menu	1	1	1
5	File\Print	Menu	1	1	1
6	File\Exit	Menu	1	1	1
7	Edit\Cut	Menu	1	1	1
8	Edit\Copy	Menu	1	1	1
9	Edit\Paste	Menu	1	1	1
10	View\Navigator window	Menu	1	1	1
11	View\Live video	Menu	1	1	1
12	View\Sample review	Menu	1	1	1
13	View\Toolbar	Menu	1	1	1
14	View\Status bar	Menu	1	1	1
15	View\Load template	Menu	1	1	1
16	View\Save template	Menu	1	1	1
17	View\Add\Spectrum viewer	Menu	1	1	1
18	View\Add\Still image viewer	Menu	1	1	1
19	View\Add\Image data viewer	Menu	1	1	1
20	View\Tools\Curvefit	Menu	1	1	1
21	View\Tools\Peak pick	Menu	1	1	1
22	View\Tools\Information viewer	Menu	1	1	1
23	View\Tools\Data arithmetic	Menu	1	1	1
24	View\Tools\Baseline subtract	Menu	1	1	1
25	View\Tools\Smooth	Menu	1	1	1

26	View\Tools\Zap	Menu	1	1	1
27	View\Remove	Menu	1	1	1
28	View\Remove data	Menu	1	1	1
29	View\Remove all data	Menu	1	1	1
30	View\Save data	Menu	1	1	1
31	View\Next spectrum	Menu	1	1	1
32	View\Previous spectrum	Menu	1	1	1
33	View\Scale\XY full	Menu	1	1	1
34	View\Scale\X full	Menu	1	1	1
35	View\Scale\Y full	Menu	1	1	1
36	View\Scale\Z full	Menu	1	1	1
37	View\Stack\offset\Stack spectra	Menu	1	1	1
38	View\Stack\offset\Offset spectra	Menu	1	1	1
39	View\Stack\offset\Configure offset	Menu	1	1	1
40	View\Pan\zoom\Zoom mode	Menu	1	1	1
41	View\Pan\zoom\Left	Menu	1	1	1
42	View\Pan\zoom\Right	Menu	1	1	1
43	View\Pan\zoom\Up	Menu	1	1	1
44	View\Pan\zoom\Down	Menu	1	1	1
45	View\Properties	Menu	1	1	x
46	View\View map data	Menu	1	1	1
47	Measurement\New\Spectral acquisition	Menu	1	1	1
48	Measurement\New\Image acquisition	Menu	1	1	1
49	Measurement\New\Depth series acquisition	Menu	1	1	1
50	Measurement\New\Map acquisition	Menu	1	1	1
51	Measurement\New measurement	Menu	1	1	1
52	Measurement\Save measurement	Menu	1	1	1
53	Measurement\Setup measurement	Menu	1	1	1
54	Measurement\Run	Menu	1	1	1
55	Measurement\Cycle	Menu	1	1	1
56	Measurement\Abort	Menu	1	1	1

57	Measurement\Measurement queue	Menu	1	1	1
58	Live video\Snap\Single	Menu	1	1	1
59	Live video\Set origin	Menu	1	1	1
60	Live video\Go to origin	Menu	1	1	1
61	Live video\Crosshairs	Menu	1	1	1
62	Live video\Set crosshairs	Menu	1	1	1
63	Live video\Cursor	Menu	1	1	1
64	Live video\Axs	Menu	1	1	1
65	Live video\Scale bars	Menu	1	1	1
66	Live video\Save image	Menu	1	1	1
67	Live video\Focustrack\Start	Menu	1	1	x
68	Live video\Focustrack\Setup	Menu	1	1	1
69	Live video\Properties	Menu	1	1	1
70	Analysis\Mapping review	Menu	1	1	1
71	Analysis\Curvefit	Menu	1	1	1
72	Analysis\Peak pick	Menu	1	1	1
73	Analysis\Information viewer	Menu	1	1	1
74	Analysis\Library search	Menu	1	1	1
75	Processing\Data arithmetic	Menu	1	1	1
76	Processing\Baseline subtract	Menu	1	1	1
77	Processing\Smooth	Menu	1	1	1
78	Processing\Zap	Menu	1	1	1
79	Procedures\Manage	Menu	1	1	x
80	Procedures\SpecificProcedures ?	Menu	1	1	1
81	Tools\AutoAlign\Align	Menu	1	1	x
82	Tools\AutoAlign\Setup	Menu	1	1	x
83	Tools\AutoAlign\VideoUtilities	Menu	1	1	x

84	Tools\Interlock	Menu	1	1	1
85	Tools\XYZ Stage	Menu	1	1	1
86	Tools\Manual beamsteer	Menu	1	1	x
87	Tools\System information	Menu	1	1	1
88	Tools\System configuration	Menu	1	1	x
89	Tools\System health\Health check	Menu	1	1	1
90	Tools\System health\Health check setup	Menu	1	1	x
91	Tools\System health\History	Menu	1	1	1
92	Tools\Calibration\Full calibration	Menu	1	1	x
93	Tools\Calibration\Offset	Menu	1	1	x
94	Tools\Calibration\Quick calibration	Menu	1	1	1
95	Tools\Calibration\Filter calibration	Menu	1	1	x
96	Tools\Calibration\Response calibration	Menu	1	1	x
97	Tools\Reference motors	Menu	1	1	1
98	Tools\Options	Menu	1	1	1
99	Window\New	Menu	1	1	1
100	Window\Close	Menu	1	1	1
101	Window\Close all	Menu	1	1	1
102	Window\Cascade viewers	Menu	1	1	1
103	Window\Tile viewers	Menu	1	1	1
104	Window\Cascade	Menu	1	1	1
105	Window\Tile horizontally	Menu	1	1	1
106	Window\Tile vertically	Menu	1	1	1
107	Window\Arrange icons	Menu	1	1	1
108	SystemConfiguration	Apps	1	1	x
109	Grating Calibration	Apps	1	1	x
110	Filter Calibration	Apps	1	1	x
111	MemFileViewer	Apps	1	1	1
112	BatchConverter	Apps	1	1	1
113	FirmwareVersions	Apps	1	1	1

114	FlashCamera	Apps	1	1	x
115	MapConverter	Apps	1	1	1
116	prjAutoAlignLaserHistory	Apps	1	1	x
117	SlitsReferenceTest	Apps	1	1	x
118	SystemInitialise	Apps	1	1	x
119	WiREDebugFlags	Apps	1	1	x
120	WiREDiagnosticViewer	Apps	1	1	1
121	WiRERegister	Apps	1	1	x
122	WiRESystemLogViewer	Apps	1	1	x
123	Tools\AutoAlign\Run\SiRefFocus	Functions	1	1	x
124	Tools\AutoAlign\Run\LaserAlign	Functions	1	1	x
125	Tools\AutoAlign\Run\CCDAlign	Functions	1	1	x
126	Tools\AutoAlign\Run\SlitSearchAndOptimise	Functions	1	1	x
127	Tools\AutoAlign\Run\SlitOptimise	Functions	1	1	x
128	Tools\Interlock\Test	Functions	1	1	x
129	SpectrumViewer\SaveSettings	Functions	1	1	1
130	WiREAdministrator	CFR	1	x	x
131	Electronic Signature\Sign\Level1	CFR	2	2	2
132	Electronic Signature\Sign\Level2	CFR	2	2	x
133	Electronic Signature\Sign\Level3	CFR	2	2	x
134	Electronic Signature\Sign\Level4	CFR	2	2	x
135	Electronic Signature\Sign\Level5	CFR	2	2	x
136	Electronic Signature\Sign\Level6	CFR	2	2	x
137	Electronic Signature\Post-sign modify\Level1	CFR	2	2	x
138	Electronic Signature\Post-sign modify\Level2	CFR	2	2	x
139	Electronic Signature\Post-sign modify\Level3	CFR	2	2	x
140	Electronic Signature\Post-sign modify\Level4	CFR	2	2	x
141	Electronic Signature\Post-sign modify\Level5	CFR	2	2	x
142	Electronic Signature\Post-sign modify\Level6	CFR	2	2	x
143	Checksum\ReadTamperedFiles	CFR	2	2	2

144 Checksum\ResetChecksum

CFR

2

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