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1 Introduction

FiberStudio® FSHD CE-IVD is the Genomic Vision detection, analysis and review software for the FSHD Combing Assay. This document provides a comprehensive general functional description of FiberStudio® FSHD CE-IVD.

Specific Instructions for Use regarding the review and the interpretation of the results provided by FiberStudio® FSHD CE-IVD software must be applied. Those instructions, under the reference IFU-M&S-08, can be accessible into the software (on the first screen click the button “?”), as this User Manual (IFU-M&S-09).

2 Intended use

The “FiberStudio® FSHD CE-IVD software” is specifically developed by Genomic Vision for the analysis of Molecular Combing results. It is designed to perform the detection, measurement and interpretation of hybridization signals (ROIs) on combed DNA, thanks to the Genomic Morse Code (GMC) detection strategy. For the FSHD assay the software will identify ROI’s with variable green segments and red or blue segments nearby corresponding to the hybridization of the FiberProbes® FSHD on combed DNA extracted from blood samples and prepared according to the Molecular Combing procedures. Doing so, it will enable the characterization of the 3.3kb-D4Z4 repeat-containing loci on chromosomes 4 and 10.

Important note: In addition to the “FiberStudio® CE-IVD FSHD Software”, the FSHD combing test requires the mandatory use of the FiberProbes® FSHD CE-IVD and of the FiberVision® automated scanner.

3 Accessing the application

FiberStudio® FSHD CE-IVD is a web application. Access should be performed with Google Chrome web browser.

To access FiberStudio® FSHD CE-IVD software, enter the following URL:

https://fshd.fiberstudio.online

The login page is displayed.
4 "Login" page

This page enables you to connect to the application and shows the application version number at the foot of the page (this version number is also displayed in the browser tab).

All users have their own user names and passwords. Once the user name and password have been entered, press "Log in": the "slide manager" page is then displayed.

When users are connecting for the first time, they will initially be redirected to a page inviting them to personalize their passwords:

![Login page image](image_url)
Enter your new password and confirm it as indicated in the window above. To be valid, the new password must contain at least 6 characters, a number, a lower case letter, and an upper case letter.

5  "Slide Manager" page

The page lists the slides registered on the FiberStudio® FSHD CE-IVD database:

5.1 Disconnecting

The upper left button enables you to disconnect from the application and return to the login page. The user’s name is displayed next to the button.

If there is no user activity for at least 30 minutes, the user is automatically disconnected.

**Important note**: make sure you click this button before closing the navigator. If you forget to disconnect from the application, your session will remain open on the server and you will have to wait 30 minutes to make it close automatically before you can connect again.
5.2 Change password

This button enables you to access the change password page:

![Change password interface](image)

Enter the current password in the first box and then the new password in the next two boxes. To be valid, the new password must contain at least 6 characters, a number, a lower case letter, and an upper case letter.

5.3 Register coverslip

This button enables you to display the Register coverslip page.

5.4 User manual

This button enables you to download the user guide and Instructions for Use.

5.5 Server disk usage

The upper right part displays information about the server disk usage.

The first value is the space in bytes taken by all slides. In the previous example, 60 TB are used (1 TB = $10^{12}$ bytes). This value turns red when it is above 80% of the total server capacity.
The second value is the total number of slides registered in the database.

Extra information may also be displayed if one hovers over that information:

![Image of disk space information]

**Total**: total capacity of the server.

**Used**: total used space and number of registered slides.

**Remaining**: remaining space on the server.

### 5.6 Low disk space

⚠️ When this icon is displayed and blinking it indicates that the disk space on the server is low. One can hover over this icon to display a message showing exactly how much space is remaining. A slide with 3 fluorophores requires about 55 GB to be scanned properly. To free up disk space, a user with project manager or administrator privileges will have to connect to FiberStudio® FSHD CE-IVD to delete or archive slides.

### 5.7 Filters

![Image of filter box]

This box enables you to filter the list of slides by identifying the patient ID or slide name.

- Press Enter or the button shaped like a funnel in order to start the filtering process.
- This button enables you to redisplay the full list of slides while preserving the data already entered.

The wildcard character (*) may be used to match any sequence of characters. For example if you want all slides with a patient name starting with “XA”, enter “XA*” in the Patient box.
5.8 Sorting

By default, the slides are sorted by decreasing date: the most recent appears first.

Click on the column ‘name’ to sort the list in that column. A second click on the same column reverses the sorting order (descending/ascending).

A small triangle is displayed next to the column in which the sort has been carried out.

An upward triangle indicates a sort in ascending order, and a downward one a sort in descending order.

5.9 Choice of results page

The displayed number indicates the number of slides sorted by the most recent filtering process. If all filter boxes are empty, no slides have been filtered and this number is equal to the total number of slides held on the database.

The number of slides displayed is limited to 100 per page. The remaining pages may be displayed by clicking on the buttons "Page 1", "Previous page", "Next page", "Last page". The dropdown list enables you to access a particular page directly.

5.10 Slide list
5.10.1 **Patient ID**

This field displays the Patient ID associated with the slide.

Users with project manager or administrator privileges may modify the Patient ID of a slide. Simply click on the **Patient ID** value to display the following dialog box:

![Patient ID dialog box](image)

Click on OK to validate the change or Cancel.

If a report exists for that patient, you cannot change the patient ID anymore. The following message is displayed if you try to do so:

![Patient ID error message](image)

5.10.2 **Dates**

The date field corresponds to the scan date. It is displayed in the language of the operating system of the Web browser being used.

5.10.3 **Slide name and coverslip number**

The slide name contains the assay type and coverslip number.

Users with project manager or administrator privileges may modify the coverslip number of a slide. Simply click on the **Name** value to display the following dialog box:
Click on OK to validate the change or Cancel.

If a report exists for that slide, you cannot change its coverslip number anymore. The following message is displayed if you try to do so:

```
This slide cannot be modified because a report exists for it. You must delete the existing report first.
```

5.10.4 **Number of ROIs (Region Of Interest)**

For each slide, the number of ROIs is displayed. This number includes all kinds of ROIs: automatically detected, manually added, reviewed or not.

5.10.5 **Status**

The status of the slide may be one of the followings:

<table>
<thead>
<tr>
<th>Status</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scanning</td>
<td>The slide is currently being scanned and is no displayable yet.</td>
</tr>
<tr>
<td>Scan error</td>
<td>An error occurred while scanning the slide.</td>
</tr>
<tr>
<td></td>
<td>Hovering the error icon 🔄 will display a short description of the error.</td>
</tr>
<tr>
<td></td>
<td>For most of errors, it is also possible to download a file containing</td>
</tr>
<tr>
<td></td>
<td>detailed information concerning the error. Simply click on the error</td>
</tr>
<tr>
<td></td>
<td>icon to do so.</td>
</tr>
</tbody>
</table>
### Status and Meaning

<table>
<thead>
<tr>
<th>Status</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scan aborted</td>
<td>The scan process was cancelled from the scanner software.</td>
</tr>
<tr>
<td>Scan complete</td>
<td>The scan process is complete for the slide but no algorithm has run yet, thus the slide is not displayable yet.</td>
</tr>
<tr>
<td>Ready for viewing</td>
<td>The tiling algorithm has run on the slide, meaning the slide is displayable into the viewer, but no ROI detection algorithm has run yet.</td>
</tr>
<tr>
<td>Ready for review</td>
<td>Both tiling and ROI detection algorithms have run on the slide. The slide is displayable in the viewer, and the users may start reviewing detected signals.</td>
</tr>
<tr>
<td>Under review</td>
<td>A user has started reviewing the slide. This status is accompanied with a progress value: the percentage of reviewed ROIs.</td>
</tr>
<tr>
<td>Reviewed</td>
<td>A user has validated the review of a slide. Caution: this does not necessarily means all ROIs have been reviewed.</td>
</tr>
<tr>
<td>Archived</td>
<td>The slide is archived and can no longer be displayed nor its report be downloaded.</td>
</tr>
</tbody>
</table>

In addition, one or more of the following status may be displayed:

<table>
<thead>
<tr>
<th>Status</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>XXX error</td>
<td>An error occurred during the given algorithm.</td>
</tr>
<tr>
<td>Queued for XXX</td>
<td>The slide has been queued for the given algorithm and will be processed as soon as possible.</td>
</tr>
<tr>
<td>XXX running</td>
<td>The given algorithm is running on the slide. A progress value and an estimation of the remaining time are displayed.</td>
</tr>
</tbody>
</table>
5.11 Display a slide

This button allows a slide to be displayed and reviewed. It is only available if the tiles for the slide in question have been generated. However, signal detection is not necessary in order for a slide to be viewed.

Several users may view the same slide. It is also possible for the same user to view several slides at the same time. However, a slide can only be reviewed by a single user at a time, and a user cannot review several slides at the same time.

The name of the user (here “manager”) who has locked the slide appears as follows:

<table>
<thead>
<tr>
<th>Patient ID</th>
<th>Date</th>
<th>Name</th>
<th>Status</th>
<th>ROIs</th>
</tr>
</thead>
<tbody>
<tr>
<td>TEST1</td>
<td>5 sept. 2016 19:09:51</td>
<td>FSHD_CE-IVD-46421-test1</td>
<td>Locked by manager</td>
<td>1270</td>
</tr>
</tbody>
</table>

5.12 Analyze a reviewed slide

This button performs an analysis on one or more reviewed slides associated with the same patient. For more information please refer to section Report generation page.

Note: if this button is grayed out, it is because the slide has not status “Reviewed”. If this button is not present, it means a report already exists for this slide (see next section to download the report).

5.13 Download

This button enables you to download the report if one exists and the ROIs (Regions Of Interest) images if there are any. If no ROIs are available for the slide, then this button is disabled.

Upon clicking that button the following dialog box is displayed:
5.13.1.1 “Download report” section

**Download report**

- PDF report
- ODS report

To delete the report, click on button .

Note that if the slide has no report, these buttons are not available:

**Download report**

No report available.
5.13.1.2 “Download ROIs” section

Download ROIs

Select the status of the ROIs you want to download:

- Validated
- Discarded
- Dismissed
- Waiting for review

**ROIs without measures**  **ROIs with measures**

To download ROI images, including non-validated ROIs, tick the boxes of the categories you want to download. Then click on the type of images you want to start the download:

- Choose **ROIs as images without measures** to download a zip file containing all ROIs as jpeg files. Those images will not contain the measured labels.
- Choose **ROIs as images with measures** to download a zip file containing all ROIs as jpeg files. Those images will contain the measured labels.

6 "Register coverslip" page

This page lists the coverslips registered into the scanner database and all scan processes. To access the **Register coverslips** page, click on button 📝.

![Coverslips](image1)

![Scans](image2)
6.1 Filters

This box enables you to filter the list of coverslips and scan processes by:

- Patient ID,
- Coverslip number,
- Barcode number,
- Scan process status

The lists are automatically updated as the text is entered in the boxes.

6.2 Register a new coverslip

To register a new coverslip in the database, click on the button. The following box is displayed:

Enter the Patient ID associated with the new coverslip, then the coverslip number, then the barcode number (you may use the provided barcode reader device).

Click on the button if you want to register another coverslip.

Note: if you register more than one coverslip using the barcode reader, a new row will automatically be added after each reading.

Click on OK to register all entries or Cancel to cancel the registration.

Note:
- If there are incomplete rows, the OK button is disabled.
- The same coverslip number cannot be entered more than once in the database.
• The same barcode number cannot be entered more than once in the database.

6.3 Editing or deleting an existing coverslip

It is possible to edit a coverslip if there is no scan process associated with it.

This button enables you to edit the coverslip. Clicking on this button displays the following box:

![Edit coverslip](image)

Simply modify the incorrect fields and click OK to validate the changes.

This button enables you to delete the coverslip from the database.

6.4 Scans

This table shows the scans ongoing or performed on FiberVision® scanner. Only slides associated with FSHD combing assay are shown in this table although the scanner database may contain other combing assay types.

6.4.1 Patient ID, Coverslip, and Barcode

These fields display the value entered by the user at the time of the coverslip registration.
6.4.2 Assay & Configuration

This field displays the assay type associated with the sample on the first line, and the scanning configuration used to scan it on the second line.

When a slide is registered into the scanner database, it is assigned the default scanning configuration “FSHD CE-IVD”. But when using FiberVision® scanner, one may select another scanning configuration to scan the sample.

In the previous example, the first row shows a slide scanned using “FSHD standard” configuration whereas the second row shows the same coverslip scanned using “FSHD CE-IVD”.

**Important note:** only samples scanned using “FSHD CE-IVD” scanning configuration will be processed by FiberStudio® FSHD CE-IVD software.

6.4.3 Start date

This field displays the starting date and time of a given scanning process.

6.4.4 Status

This field displays the status of a given scanning process. It may have one of the following values:

<table>
<thead>
<tr>
<th>Status</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>RUNNING</td>
<td>The sample is being scanned.</td>
</tr>
<tr>
<td>COMPLETE</td>
<td>The sample has been scanned.</td>
</tr>
<tr>
<td>CANCELED</td>
<td>A user has canceled the scanning process.</td>
</tr>
<tr>
<td>ERRORED</td>
<td>An error occurred while scanning the sample. More information about the error may be given in the “Slide manager” page.</td>
</tr>
</tbody>
</table>
7 "Viewer" page

This page enables a slide to be viewed and also its associated ROIs if there are any.

7.1 Navigation

You can navigate in the image as follows:

- The mouse wheel can be used to zoom into the pointed area, the scanned pixel remaining fixed.
- You can move around the image by clicking and holding down the left-hand button of the mouse or by using the keyboard’s arrows.
- A double click provides maximum zoom in.

It is also possible to use the upper left thumbnail:
This thumbnail contains a map of the whole slide image. The red rectangle corresponds to the part displayed in the viewer.

- A single click on the thumbnail centers the red rectangle on the targeted pixel and consequently updates the viewer.
- The red rectangle may be moved around by moving the mouse while clicking and holding the left-hand button.
- The +/- buttons enable the zoom factor to be increased or decreased.
- The "home" button resets the zoom.

The level of zoom displayed:

- is 0 when images are displayed at their normal size (1 viewer pixel = 1 scanner pixel)
- is positive when the pixels are enlarged
- is negative when the pixels are reduced

Between each zoom level, the pixel size is divided (or multiplied) by 2.

7.2 Buttons

7.2.1 Return to the slide list

This button enables you to return to the ‘Slide manager’ page. If you click on this button and you were in "review mode", the slide is unlocked.

7.2.2 Slide information

This icon displays slide information by hovering over it (name, date of acquisition, etc.).
7.2.3 Adjust image rendering

This icon displays a window when the mouse hovers over it (clicking on it has no effect).

The window enables the image contrast and brilliance to be adjusted, as well as red/green/blue color composition to be changed:

The various cursors may be adjusted between 0 and 200%.

- Clicking on the percentage value icons resets the cursor to the mid-point (value = 100%)
- Clicking on a color icon deactivates/activates the color:
  - If the cursor is not set at 0%, it is set to 0% (the color is deactivated).
  - If the cursor is set at 0%, it is reset to 100%.
  - F2 key is a shortcut for switching red color on/off.
  - F3 key is a shortcut for switching green color on/off.
  - F4 key is a shortcut for switching blue color on/off.
- Display tiles grid box enables the separations between the various scanned fields of view to be viewed.
- Black & White display mode enables you to display a single color channel (red, green, or blue) in black and white for a better contrast.
- ROI popup opacity enables you to display the ROI popup as semi-transparent.
7.2.4 Black & White display mode

Black & White display mode enables you to display a single color channel (red, green, or blue) in black and white for a better contrast. In this mode, the selected channel is highlighted as shown below:

Simply click on another color to display that color. Additionally, you may use the following keyboard shortcuts:

- F1: toggles Black & White display mode on/off.
- F2: selects red channel.
- F3: selects green channel.
- F4: selects blue channel.

7.2.5 GMC assistance

This button enables to display at the top of the page the different categories of the GMC and the patterns associated to each one.

In addition to these 4 categories, the following are also used during a review: 4q, 10q, qA, qB, Unusual, None, and Extra. For more information about these categories, refer to the Instruction For Use.

7.2.6 Review mode

This button enables a mode review to be carried out. When you click on it, it turns red (the slide is then locked) and the first non-reviewed ROI on the slide is then displayed. If the slide contains no ROIs, the viewer moves to the upper left-hand corner of the image.
If the slide has been locked by another user (or by the signal detection algorithm), the icon is greyed out with a lock superimposed over it. Hovering the mouse over the lock will display the name of the user who locked the slide:

![Locked by Olivier]

This icon is not automatically updated: once the slide is unlocked, the page must be updated manually in order for the normal icon to reappear.

For more information about this mode, refer to section Review.

7.2.7 Mode manual cropping

This button enables a mode manual cropping to be carried out. When you click on it, it turns red (the slide is then locked) and the viewer moves to the upper left-hand corner of the image.

For more information about this mode, refer to section Manual cropping.

7.2.8 Filter ROIs

This button enables you to filter the displayed ROI. When the mouse hovers over this button, a box similar to the one below is displayed:

![Filter ROIs interface]

### Filter ROIs by status
- Validated
- Discarded
- Dismissed
- Waiting for review

### Filter ROIs by score
Score: 5
300 ROIs

### Filter ROIs by category
- Select all
- Unselect all
- 4qA
- 4qB
- 10qA
- 10qB
- 4q
- 10q
- qA
- qB
- Unusual
- None
- Extra

Matched ROI(s): 300
ROIs may be filtered by:

- **Status**: untick one or more of these check boxes to hide the corresponding ROIs.
- **Score**: a confidence score is calculated for each ROIs. By default, the 300 “best ROIs” are shown, the others are hidden. Moving this slider enables you to show more ROIs.
- **Category**: if a category is associated with the ROIs, you may choose to display or hide them by ticking/unticking the corresponding boxes.
- **Intact status**: ROIs may be marked “intact” or not. You may choose to display or hide them by ticking/unticking the corresponding boxes.

As soon as a filter option changes, the first matching ROI is displayed unless the current ROI already matches the selected criteria. The total number of ROIs matching all of the criteria is displayed in **Matched ROI(s)** field.

Once a filter is set, the filter icon turns red: 🟢. Simply click the button to switch off all filters are display back all ROIs.

After an analysis has been performed on a slide, extra filtering options are available:

For more details, see part [Selective review](#).
7.2.9 Center the active ROI

This button enables you to refocus the view on the active ROI.

7.2.10 Find an ROI

This button enables an ROI to be found from its number:
- Enter the number in the box.
- Press Enter or click on the icon for centering the view of the requested ROI.

7.2.11 ROI display options

This series of buttons controls the way active or non-active ROIs are displayed. The selected option is shown in red.

- This button displays all ROIs thus making them selectable with the mouse.
- This button displays unselected ROIs as semi-transparent. Semi-transparent ROIs are not selectable. This option is selected by default.
- This button completely hides unselected ROIs.
- This button completely hides all ROIs.

7.2.12 Validate the review

When “Review mode” is active, this button enables you to validate the review. You may validate the review even though all ROIs have not been reviewed. Upon clicking that button, the status of the slide switches to Reviewed allowing a report to be edited.

If you click this button again, then the Reviewed status of the slide will be removed (after confirmation), allowing the review to be reset or continued.

7.2.13 Reset the review

When “Review mode” is active, this button enables you to reset the review. Reseting the review means the status of all validated and discarded ROIs will be set back to waiting, allowing a fresh new review to be performed. Upon clicking that button, the following box is displayed:
Select the option you want and validate by clicking OK.

### 7.3 Extra information on ROIs

When hovering over this icon at the bottom of the panel, a popup similar to the following one is displayed:

![Popup showing quantities of validated and intact ROIs](image)

This window shows the quantities of validated and intact ROIs of each category.
7.4 Manual cropping

7.4.1 Navigation during the manual cropping

In “manual cropping” mode, the user explores the slide line by line from the left to the right and manually adds ROIs. Navigation using the mouse is disabled and the zoom can be changed within a limited range. The user can use the left and right arrow keys or the mouse wheel to sweep the lines. When reaching the right edge of the slide, pressing the right arrow key again will make the viewer automatically reset to the start of the next line.

When entering the manual cropping mode for the first time, the viewer displays the upper left-hand corner of the image. During the manual cropping, the navigation thumbnail displays the explored areas in yellow:

The explored areas are saved regularly. When entering the manual cropping mode, the viewer will load them and display the last one.

Note: if the zoom level is too low, the explored areas will no longer turn yellow. In fact, the review can only be considered to have been correctly completed if the zoom level is sufficiently high.

Once manual cropping mode is exited, the yellow area is no longer displayed.

7.4.2 Adjusting the movement settings

In manual cropping mode, the display settings box shows extra sliders allowing the user to adjust the movement settings:
The “FOV” (Field of View) parameter controls how far the view will go upon pressing the arrow key (or upon using the mouse wheel). The value is expressed as a percentage of the current FOV.

The “Keyboard speed” parameter controls the repeat rate while the arrow key is being held down.

If changed, these parameters are saved in the navigator and will be reused for all other slides.

7.5 Review

To enter “Review mode”, click button . The first available ROI is then displayed, as well as its popup (bubble):

7.5.1 The popup

The classification is displayed in the upper left corner. It corresponds to the pattern recognized by the software (here \texttt{4q}).

The left/right buttons allow movement to the previous/next ROI. The keyboard shortcuts “Ctrl + left arrow”/“Ctrl + right arrow” may also be used.

The number of the current ROI is displayed between these two buttons.

The validate button is only available if all colors have been entered properly. Once it is clicked on, it will automatically move to the next ROI on the slide. The ‘Enter’ key also validates the ROI.
The **Discard button** allows the user to discard the current ROI. Once it is clicked on, it will automatically move to the next ROI on the slide. The Space bar also discards the ROI.

The **Dismiss button** allows the user to dismiss the current ROI. Once it is clicked on, it will automatically move to the next ROI on the slide.

If a change has been made (movement of a tab stop, deletion of a signal, etc.) 2 additional buttons appear: undo/redo:

- The **undo button** enables a return to the ROI detected by the algorithm (all user changes will be cancelled). Its keyboard shortcut is Ctrl+Z. If the ROI was manually added by the user, this button is not visible.

- The **redo button** allows cancelled user changes to be restored. Its keyboard shortcut is Ctrl+Y. If the ROI was manually added by the user, this button is not visible.

The **delete button** allows the user to delete the ROI. This button is visible only for manually added ROIs.

When an ROI is validated, discarded, or dismissed:

- It is immediately saved in the database.

- The next ROI is displayed.

- Once the ROI is validated or discarded, it cannot be modified anymore (all buttons turn grey for that ROI).

- It is possible to return to a validated/discarded/dismissed ROI and to restore its "pending review" status: simply click on the validate/discard/dismiss button again.
7.5.2 Editing an ROI

To do any modification, the review mode has to be switched.

7.5.2.1 Change the position of the signal

- Press and hold down the Ctrl key to bring up the signal trace and its handles (white squares):

  - Click on a handle and move the mouse while holding down the mouse button in order to move the handle.

When a handle is moved, the distance between the tab stops and the opposite handle is preserved. For example, in the following image the right handle has been moved but the tab stops stayed in place.
7.5.2.2 Manually add an ROI

- Hold the Ctrl key down.
- Click and hold the left click button of the mouse on the start of the signal and drag the mouse along the fiber.
- Release the mouse button and the Ctrl key.

7.5.2.3 Changing a color

- Click on the letter corresponding to a color (it turns orange) and press the appropriate letter. The next letter/color is automatically selected.
- The following letters are allowed: R (red), G (green), B (blue), M (magenta), C (cyan), Y (yellow), W (white) and minus key - (gap).
- "Delete" or "Backspace" deletes the track:
  - If it is the last track, the final tab stop is deleted.
  - Otherwise, the tab stop immediately preceding the color is deleted.
  - If it is the ROI's only color, both tab stops are deleted.
- The left/right arrows on the keyboard enable selection of the previous/next track.
- "Page down" selects the tab stop immediately before the selected color.
7.5.2.4 Changing a tab stop

- Click on the tab stop (it turns orange).

- Use the mouse wheel for broad movements of the tab stop (10-pixel pitch).

- Use the mouse wheel while holding the Shift key for fine movements, or use the up/down arrows on the keyboard.

- "Delete" or "Backspace" deletes the tab stop, if it is the first or last tab stop, the first or last track is deleted.

- The left/right arrows allow the selection of the previous/next tab stop.

- "Page up" selects the track immediately after the selected tab stop or the last track if the last tab stop has been selected.

7.5.2.5 Adding a tab stop

- Hold the Shift key down.

- Click on the desired location in the signal.

- Any changes will only be saved when the ROI is validated, discarded or dismissed.

7.5.2.6 Other actions

- Shift+Delete deletes all tab stops and all tracks. A confirmation box is displayed.

- To remove the current selection (track or tab stop), click on an empty area in the image.
7.5.3 Completion of the review

After 70 intact ROIs have been validated, the following message will be displayed:

![Message: There are enough intact signals for the analysis process. Do you want to validate the review now?](image)

Click OK to validate the review or Cancel to review more ROIs.

After all ROIs have been reviewed, FiberStudio® FSHD CE-IVD will ask the user to change the status of the current slide to “Reviewed”:

![Message: All ROIs have been reviewed. Do you want to validate the review?](image)

To manually validate or invalidate a slide, click on the button on the left toolbar.

Note that this button is only available if the “Review” mode is activated.

7.6 Selective review

After a slide has been reviewed and processed by the analysis algorithm, the user may go back to the viewer and see the different classes found by the analysis algorithm.

These extra information are available in the ROI filter box:
By default, only **validated** and **intact** ROIs are shown.

Check boxes are displayed in front of each detected allele. Simply untick a box to hide all ROIs associated with the given allele in the viewer. An ROI might be associated with more than 1 allele, in that case all these alleles must be unticked in order to hide the corresponding ROIs.

In selective review mode, ROI’s popup box will also display the allele associated for each ROI as shown below:

### 7.7 Keyboard shortcuts

List of keyboard shortcuts:

<table>
<thead>
<tr>
<th>Keyboard action</th>
<th>Action or result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shift</td>
<td>During the edition of an ROI, displays the position of any new tab stop.</td>
</tr>
<tr>
<td>Shift + mouse wheel</td>
<td>When a tab stop is selected, provides fine movements</td>
</tr>
<tr>
<td>Ctrl</td>
<td>Moves to &quot;add manual ROI&quot; or &quot;handle movement&quot; mode (the handles of the selected ROI or fiber appear).</td>
</tr>
<tr>
<td>Keyboard action</td>
<td>Action or result</td>
</tr>
<tr>
<td>--------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Left/right arrows</td>
<td>When a tab stop is selected, moves to the previous/next.</td>
</tr>
<tr>
<td></td>
<td>When a track is selected, moves to the previous/next.</td>
</tr>
<tr>
<td>Shift + left/right arrows</td>
<td>When a tab stop is selected, adds a tab stop at the left or the right of it and selects the newly added tab stop.</td>
</tr>
<tr>
<td>Up/down arrows</td>
<td>Moves the selected tab stop.</td>
</tr>
<tr>
<td>Home</td>
<td>Selects the first tab stop or first track.</td>
</tr>
<tr>
<td>End</td>
<td>Selects the last tab stop or last track.</td>
</tr>
<tr>
<td>Page down</td>
<td>When a track is selected, selects the tab stop immediately previous the track.</td>
</tr>
<tr>
<td>Page up</td>
<td>When a tab stop is selected, selects the track immediately after the tab stop.</td>
</tr>
<tr>
<td>Ctrl + left/right arrows</td>
<td>Selects the previous/next ROI.</td>
</tr>
<tr>
<td>Backspace or Delete</td>
<td>When a tab stop is selected, deletes it and merges the two tracks surrounding the tab stop based on the rules described in the section Changing a tab stop. If a track is selected, deletes it as well as the tab stop to its left (or right if it is the last track).</td>
</tr>
<tr>
<td>Shift + Backspace or Delete</td>
<td>Upon confirmation, deletes all tab stops and all tracks of the selected ROI.</td>
</tr>
<tr>
<td>Enter</td>
<td>Validates the selected ROI.</td>
</tr>
<tr>
<td>Space</td>
<td>Rejects the selected ROI.</td>
</tr>
<tr>
<td>Ctrl+Z</td>
<td>Restores the initial status of the selected ROI.</td>
</tr>
<tr>
<td></td>
<td>Available if:</td>
</tr>
<tr>
<td></td>
<td>• An ROI is selected.</td>
</tr>
<tr>
<td></td>
<td>• It is produced by a detection algorithm.</td>
</tr>
<tr>
<td></td>
<td>• It has been changed by the user.</td>
</tr>
<tr>
<td>Ctrl+Y</td>
<td>Restores changes canceled after a Ctrl+Z.</td>
</tr>
<tr>
<td>F1</td>
<td>Enables or disables Black &amp; White display mode.</td>
</tr>
<tr>
<td>F2</td>
<td>In Black &amp; White display mode, selects the red channel. In normal mode, switch red channel on/off.</td>
</tr>
<tr>
<td>F3</td>
<td>In Black &amp; White display mode, selects the green channel. In normal mode, switch green channel on/off.</td>
</tr>
<tr>
<td>F4</td>
<td>In Black &amp; White display mode, selects the blue channel. In normal mode, switch blue channel on/off.</td>
</tr>
</tbody>
</table>
8 Report generation page

8.1 Analyzing the ROIs

After clicking on the Report icon on the Slide manager page and selecting the slide(s) to include in the report, the statistical analysis algorithm is launched:

![Analyzeing validated ROIs. Please wait...](image)

Once the analysis is complete the report generation page is displayed.

**Note**: the report button is available only if the slide has status “Reviewed” and if there is no report for the slide yet.

8.2 General information

At the top of the page, general information are displayed:

![Report](image)

8.3 ROI selection

The analysis algorithm groups ROIs by categories (usually an allele) and these categories are shown in the report generation page. For each category, ROIs associated with this category are listed. Just click on one ROI to include it into the final report:
Normal categories are displayed in blue, Unusual and excluded ROIs in red.

### 8.4 Extra allele

It is possible to create an extra category from one or more ROIs classified **Unusual**:
To do so:

- Tick the box “Show as extra allele”.
- Select the ROIs you want to be associated with the “Extra” allele.
- At the bottom of the page, click on “Return to review” or “Save”.

For more details about the extra allele, please refer to the Instruction For Use.

8.5 Generate the final report

Once all ROIs to be included into the report have been selected, you may enter additional comments in the provided field:

```
Comments:
```

Text entered in the Comments field will be included in the final generated report.

Finally, click on "Save" at the bottom of the page to generate the final report in PDF format.

For more details about report content, please refer to the Instruction For Use.

8.6 Return to review button

It is also possible to return to the viewer page in order to perform an extra review based on the analysis output. This extra review is called “selective review” and allows the user to review the ROIs associated with a given category. The “Return to review” button is located at the bottom of the report page:
9  Frequently asked questions

9.1  My slide has status “Scan error”, what can I do?

Slide marked “Scan error” cannot be processed using FiberStudio® FSHD CE-IVD. The coverslip needs to be scanned again on the FiberVision® automated scanner.

It is recommended to delete the corresponding slide, in order to save disk space.

9.2  The viewer icon is grayed out, how can I visualize my slide?

The viewer is enabled only after the “tiles builder” algorithm is finished. If this icon is grayed out, it means the “tiles builder” algorithm has not been started or completed yet. Check the status of the slide:

- “Queued for tile builder” means the slide is waiting to be processed because another slide is currently being processed.
- “Building tiles” means the slide is being processed but the algorithm has not completed yet.

9.3  The report button is grayed out, how can I edit a report?

The report button is enabled only for slides which has the “Reviewed” status and if a statistical analysis algorithm is available for the associated assay type. To change the status of a slide “Reviewed”, one must:

- Go to the viewer page.
- Switch to review mode using the button.
- Validate the review using the button.

9.4  The report button is not visible, how can I download my report?

The report button is used to perform an analysis of the reviewed slide(s) and access the report generation page. Once the report is created, this button is no longer displayed. The report can be downloaded using the download button.
9.5 I want to reset my review but the reset button is grayed out. How can I do?

The Reset Review Button is available only in review mode. To switch to review mode, follow these steps:

- If button is grayed out, click on button to invalidate the review.
- Click on button to switch to review mode.

9.6 How can I review two overlapping ROIs?

Sometimes, detected signals may be very close to each other and difficult to review, like in the following example:

In such a situation, you may hide unselected ROIs by clicking on the third button of the ROI display options buttons as shown below:

Upon clicking on that button, only the active ROI will be displayed:
Our experts are available to answer your questions

http://www.genomicvision.com

support@genomicvision.com