

ADAMI™

Bench-top fluorescence cell counter

User manual



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ADAMII™ User Manual

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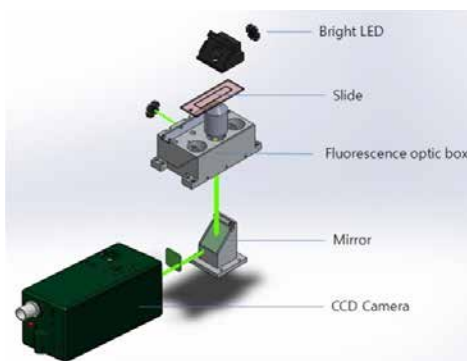
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Introduction

Principle of the assay

The ADAMI[™] Imaged-based fluorescence cell counter is a 4-channels (Bright, FITC, PE and PerCP) bench-top assay platform that uses state-of-the-arts optics and image analysis software for specific immune-fluorescence (IF) counting kits designed for using on ADAMI[™] instrument.

The ADAMI[™] Imaged-based fluorescence cell counter offers an intuitive user interface, and provides the option to save data and generate a report.



Intended purpose/use

The ADAMI[™] is a quantitative in-vitro measurement of hematopoietic stem cells in human blood samples that are made to be used as an aid in the clinical management of patients.



[Features]

- Easy to use and maintain
- Accurate and precise measurement
- 4 channels (one BF + 3 FL)
- Automatic stage to capture 75 images

Cybersecurity guidelines

Introduction

If ADAMII CD34 will be used in a network-connected configuration, following recommendations should be considered.

ADAMII™-CD34 software guidelines

- All users should have their own User ID and PW. ID and PW should not be shared. ADAMII™-CD34 software will restrict a user ID after 5 consecutive failed login attempts.
- Administrative privilege should be given to users whose duties require administrative privilege such as creating new user ID, etc.
- Software and data backups should be performed regularly to allow safe restoring option if needed.
- ADAMII™-CD34 software saves audit trail to monitor all operations on the instrument and the data. The audit trail will be saved in an encrypted manner and can be accessed only through ADAMII™-CD34 software.
- Install antivirus software following company's IT policy and scan hard drives periodically.
- Do not enter sensitive patient information such as patient name or social security number into patient ID to prevent possible exposure of sensitive patient information to unintended uses.

Microsoft® Windows® OS guidelines

- Microsoft Windows operating system should be configured so that log in method and password configuration meet organizational IT standards, including password complexity, password expiration, limits on attempts to guess users' passwords, and passwords reuse rules.
- Administrative access to the Windows operating system should be given only to users that require such access (to perform backups, for example).
- Windows operating systems security updates should only be applied regularly.
- Remote access to ADAMII™-CD34 laptop computer should be enabled following instruction provided by NanoEntek only if it is required.

System requirements

User must have Microsoft Windows administrator account to install ADAMII™-CD34 software.

NanoEntek recommends that ADAMII computer meets the following minimum requirements:

Minimum Specifications

- CPU: Intel® i5 Processor
- OS: Windows 10 (64 bit)
- RAM: 8 GB
- HDD: 512GB
- Monitor: 15.6" Full HD (1920 X 1080)

Product components

ADAMII™ consists of the following components.

If any of the components is missing or damaged, please contact your local sale representative or send an email to ivdst@nanoentek.com.

ADAMII™

1 EA



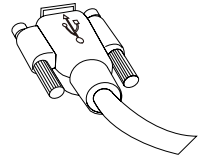
Power cord with 4 adaptor cords (for U.S./Canada/ Taiwan/Japan, Europe or UK)

4 pcs/1 SET



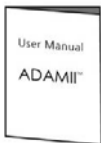
USB connection cable

1 EA



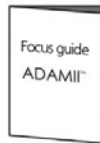
User manual

1 EA



Focus guide

1 EA



Laptop pre-installed with ADAMII-CD34 software

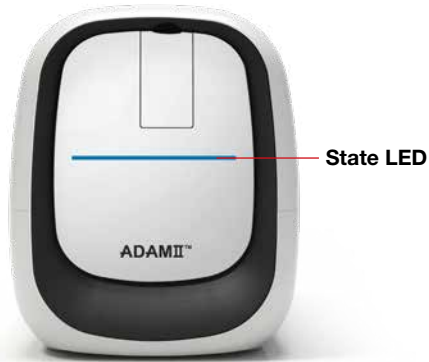
(Please note: Laptop will be packaged separately.)

1 set



Product description

Front view



State LED

Blue LED lights up when the instrument is connected to the laptop and the ADAMII-CD34 software is running.

Slide holder Slide door



Slide holder

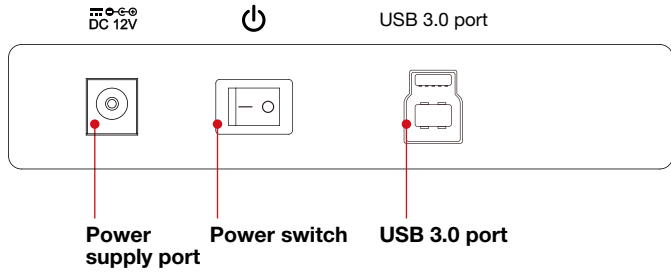
Where ADAMII-CD34 Assay Slide is inserted to.

Slide Door

Where one can access the Slide holder.

Product description

Rear view



Power supply port

To connect the power adapter

Power switch

To turn power On and Off

USB 3.0 port

To connect USB cable to communicate with the laptop

Installation

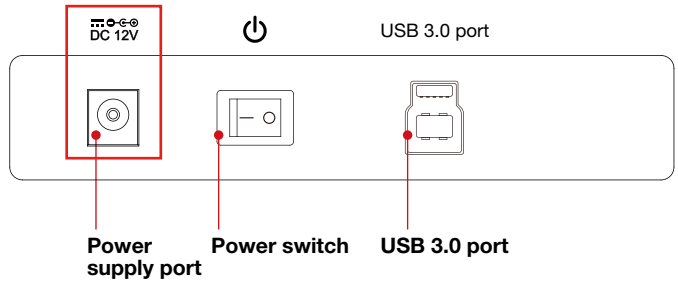
Unpacking

1. Open the box and remove the foam protector.
2. Carefully lift the instrument with two hands.
3. Place the instrument on a flat, stable and level surface.



Connect cables

1. Plug the power cord into an electrical outlet and plug the DC output jack to the power supply port.
2. Connect USB 3.0 cable to the USB ports in the ADAMIII™ and the laptop.



2. Connect the laptop and the ADAMIII™ using the USB cable.




Installation

Run ADAMII CD34 software

1. Turn on the laptop and the ADAMII™.
2. Double-click 'ADAM' icon on the laptop to start the ADAMII-CD34 software.



 *Note: When it is turned on, the ADAMII™ will be ready to use after a quick initialization.*

 *Note: When the ADAMII™ is connected to the laptop and the ADAMII-CD34 software is running, the state LED will light up.*

CAUTION:

- The instrument must be turned ON before starting ADAMII-CD34 software in the laptop.

If the instrument is not on when the software starts, the software will give a warning after searching the instrument for more than 10 seconds.

Home menu

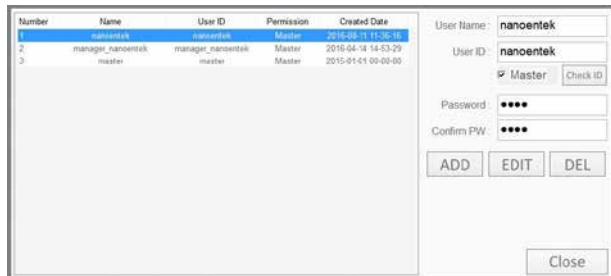
Log in

At the **'Home'** screen, enter the user ID and password to log in. Default ID and password are both **'master'**.



User management

Click **'User management'** when you need to manage accounts (e.g. to add a new user or to change password). To create a new ID, fill out the blanks (user name, user ID, password, confirm PW) and click **'Add'**.



*Note: Only the master user can access the **'User management'**.*

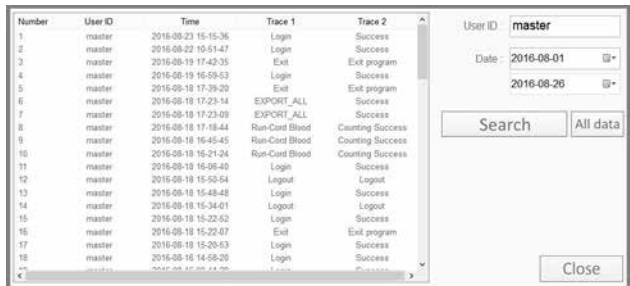
Home menu

Audit trail

Click **“Audit trail”** to search and trace detailed information of each user’s activities.




1. Enter the User ID and set the date that you want to search.
2. Click **‘Search’** button.
3. The record of the selected user is displayed.



The screenshot shows a table of audit trail records for the user 'master'. The table has columns for Number, User ID, Time, Trace 1, and Trace 2. The records show various activities such as Login, Logout, Exit, and Success. The search interface on the right shows the User ID 'master' and the date range '2016-08-01' to '2016-08-26'. The 'Search' button is highlighted.

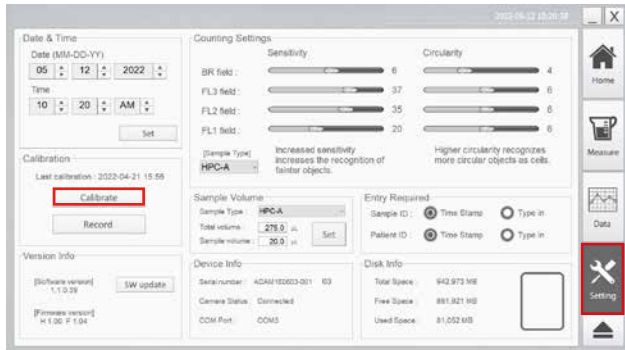
Number	User ID	Time	Trace 1	Trace 2
1	master	2016-08-23 16:15:36	Login	Success
2	master	2016-08-22 10:51:47	Login	Success
3	master	2016-08-19 17:42:35	Exit	Exit program
4	master	2016-08-19 16:59:53	Login	Success
5	master	2016-08-18 17:39:20	Exit	Exit program
6	master	2016-08-18 17:23:14	EXPORT_ALL	Success
7	master	2016-08-18 17:23:09	EXPORT_ALL	Success
8	master	2016-08-18 17:18:44	Run-Card Blood	Counting Success
9	master	2016-08-18 16:45:45	Run-Card Blood	Counting Success
10	master	2016-08-18 16:21:24	Run-Card Blood	Counting Success
11	master	2016-08-18 16:06:40	Login	Success
12	master	2016-08-18 15:53:54	Logout	Logout
13	master	2016-08-18 15:48:48	Login	Success
14	master	2016-08-18 15:34:01	Logout	Logout
15	master	2016-08-18 15:22:52	Login	Success
16	master	2016-08-18 15:22:07	Exit	Exit program
17	master	2016-08-18 15:20:53	Login	Success
18	master	2016-08-16 14:58:20	Login	Success
19	master	2016-08-16 14:57:55	Login	Success

 *Note: Only the master user can access the “Audit trail”.*

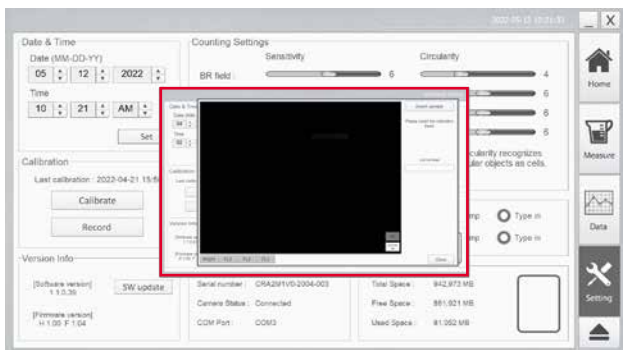
Calibration

Calibration procedure

1. After turning on the ADAMI™ first time, the instrument needs to be calibrated. Subsequently, it is recommended that the calibration is done regularly or at least once a week.



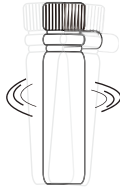
A pop-up window for calibration appears as shown below.



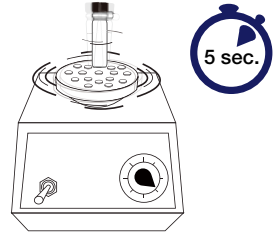
Calibration

Calibration procedure

2. Shake tube labeled with ADAMII Calibration Beads vigorously or vortex briefly for 5 seconds before use.



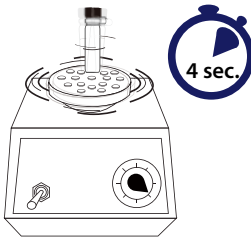
[Shake bottle vigorously]



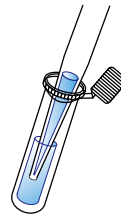
[Vortexing]

- Note:** ADAMII™ Calibration Beads are included in ADAMII™-CD34 kit. Before use, the ADAMII™ Assay Slide should be removed from refrigerator and kept at room temperature for at least 30 minutes. The reagents should be kept at 4°C.

3. Once again, vortex for 4 seconds and pipette 25uL immediately.

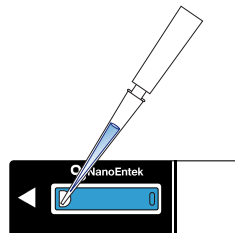


[Vortexing]



[Pipetting Calibration Beads]

4. Load the Calibration Beads into an ADAMII™ Assay Slide.



[Loading volume: 25 uL]

Calibration

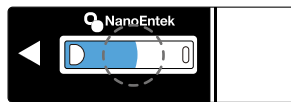
Calibration procedure

⚠ CAUTION:

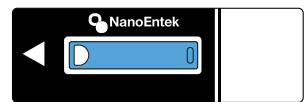
- When loading samples to the slide, please release sample gently and slowly to avoid bubbles because bubbles interfere image analysis.
- Make sure to add fluid slowly. Fast injection may cause spill-over.

⚠ Warning:

- Calibration Beads loading error:
 - Ensure that calibration bead solution is fully loaded into slide.
 - If loading volume is not enough, calibration can be inaccurate.



[Low volume]



[Correct volume]

5. Leave for 20 seconds (Calibration Beads needs time to settle).



6. To insert the Assay Slide, open the slide door and press the black bar in the slide holder. Once the cover of the slide holder pops open, insert the Assay Slide all the way in.

For detailed steps, see page 21.



Calibration

Calibration procedure

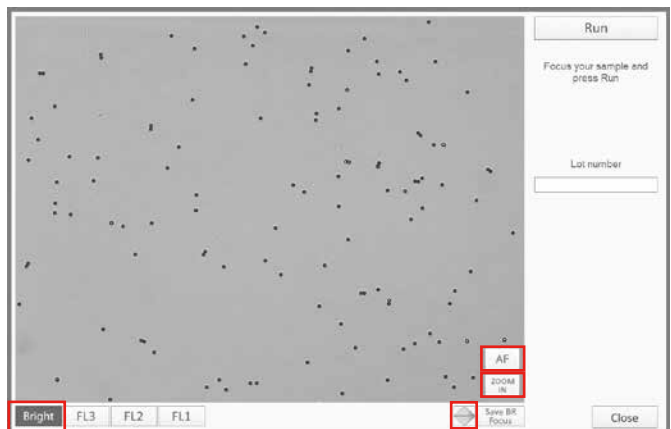
7. Enter lot number of Calibration Beads.

⚠ CAUTION:

- Lot number has to be entered after inserting slide.



8. Select 'Bright' channel and adjust the focus using the focus buttons.
To view beads 2x bigger, press 'Zoom in' button.
If you press the "AF" button, the focusing will be adjusted automatically.



Calibration

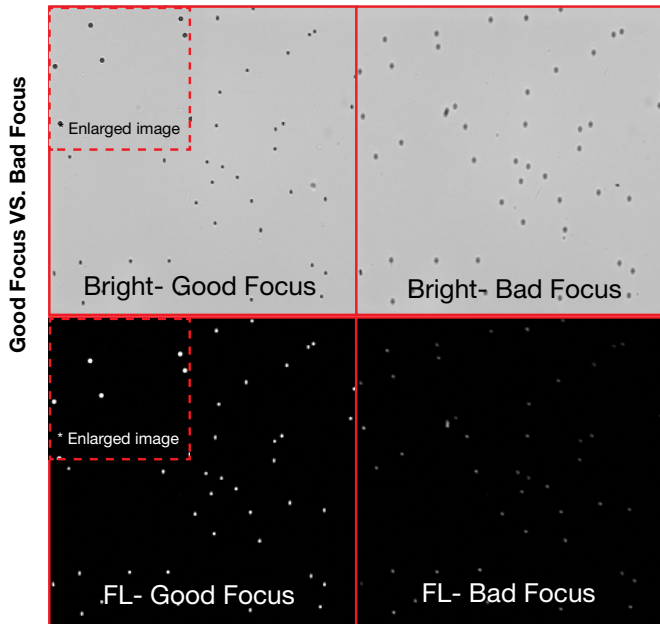
Calibration procedure

9. Press the **'Save BR Focus'** after adjusting focus.



☞ *Note: Please check 'ADAMII™ Focus guide' before setting the focus.*

[Focusing example - representative images]

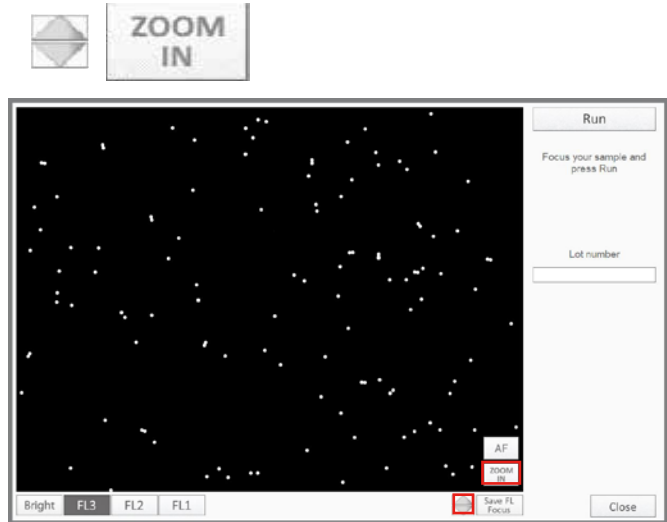


- **Bright - Good Focus:** Compared to gray background, dark inside of beads and bright boundaries around beads.
- **Bright - Bad Focus:** bright inside of beads or blurry boundaries around beads.
- **FL - Good Focus:** Compared to dark background, white inside of beads and crisp boundaries around beads.
- **FL - Bad Focus:** gray inside of beads and fuzzy boundaries.

Calibration

Calibration procedure

10. Select FL3 channel and adjust the focus using the focus button.
To view cells 2x bigger, press the 'ZOOM IN' button.



11. Press the 'Save FL Focus' after adjusting focus.



Note: After saving the focuses of "Bright" and "FL3", the focuses of the other channels (FL2 and FL1) will be automatically adjusted.

12. Press the 'Run' button.



Calibration

Calibration procedure

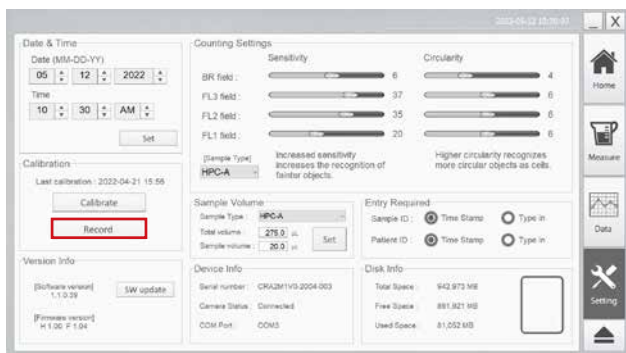
13. When the calibration is completed, the results will be displayed.



☞ *Note: If any of the results are “FAIL”, please contact the manufacturer or distributor.*

☞ *Note: If any of the results are “Low”, please check the focus or expiration date of the Calibration Beads. Or please re-test using another slide.*

14. You can see the previous record of calibration by clicking “Record” button.



Calibration

Calibration procedure

15. The calibration results are displayed. To save the results, click 'Save' button.

Lot number	User	BR Result	FL3 Result	FL2 Result	FL1 Result
11	master	1014.49	PASS(100.19%)	PASS(99.87%)	PASS(97.21%)
test	master	1051.69	PASS(97.32%)	PASS(95.74%)	PASS(97.38%)
test	master	1096.18	PASS(97.42%)	PASS(96.27%)	PASS(97.42%)
1CB15260.3	master	963.11	PASS(98.91%)	PASS(100.48%)	PASS(96.32%)
1CB15260.9	master	991.44	PASS(99.94%)	PASS(100.86%)	PASS(96.00%)
1CB15260.15	master	1010.54	PASS(98.31%)	PASS(100.33%)	PASS(96.76%)
1CB15260.21	master	838.60	PASS(99.84%)	PASS(101.02%)	PASS(96.70%)
1CB15260.27	master	950.59	PASS(98.61%)	PASS(99.93%)	PASS(96.75%)
1CB15260.32	master	1028.33	PASS(98.65%)	PASS(101.15%)	PASS(96.98%)
1CB15260.37	master	955.52	PASS(99.12%)	PASS(100.00%)	PASS(96.12%)
1CB15260.43	master	714.76	PASS(98.80%)	PASS(100.55%)	PASS(96.08%)
1CB15260.49	master	565.93	PASS(98.70%)	PASS(100.91%)	PASS(96.09%)
1CB15260.56	master	961.55	PASS(97.18%)	PASS(99.60%)	PASS(97.65%)

Save Close

16. Press "Close" button to finish calibration.

Lot number	User	BR Result	FL3 Result	FL2 Result	FL1 Result
11	master	1014.49	PASS(100.19%)	PASS(99.87%)	PASS(97.21%)
test	master	1051.69	PASS(97.32%)	PASS(95.74%)	PASS(97.38%)
test	master	1096.18	PASS(97.42%)	PASS(96.27%)	PASS(97.42%)
1CB15260.3	master	963.11	PASS(98.91%)	PASS(100.48%)	PASS(96.32%)
1CB15260.9	master	991.44	PASS(99.94%)	PASS(100.86%)	PASS(96.00%)
1CB15260.15	master	1010.54	PASS(98.31%)	PASS(100.33%)	PASS(96.76%)
1CB15260.21	master	838.60	PASS(99.84%)	PASS(101.02%)	PASS(96.70%)
1CB15260.27	master	950.59	PASS(98.61%)	PASS(99.93%)	PASS(96.75%)
1CB15260.32	master	1028.33	PASS(98.65%)	PASS(101.15%)	PASS(96.98%)
1CB15260.37	master	955.52	PASS(99.12%)	PASS(100.00%)	PASS(96.12%)
1CB15260.43	master	714.76	PASS(98.80%)	PASS(100.55%)	PASS(96.08%)
1CB15260.49	master	565.93	PASS(98.70%)	PASS(100.91%)	PASS(96.09%)
1CB15260.56	master	961.55	PASS(97.18%)	PASS(99.60%)	PASS(97.65%)

Save Close

Measurement

Sample preparation

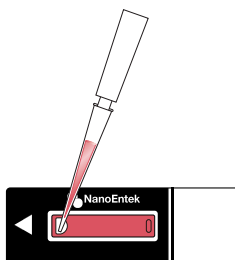
Prepare sample following the instruction enclosed in ADAMIITM-CD34 kit.

Load sample

To measure a sample, click '**Measure**' menu.



Load 25 μ L stained sample into an ADAMIITM Assay Slide.



[Load 25 μ L sample]

- ☞ *Note: Please refer to page 14 to check cautions for loading correct volume.*
- ☞ *Note: Before loading the stained sample or Calibration Beads to the Assay Slide, Please mix the sample thoroughly. (e.g. vortex for a few seconds).*

Measurement

Insert assay slide

1. Open the slide door.



2. Press the black bar to open the slide holder.



3. Insert the Assay Slide into the slide holder.



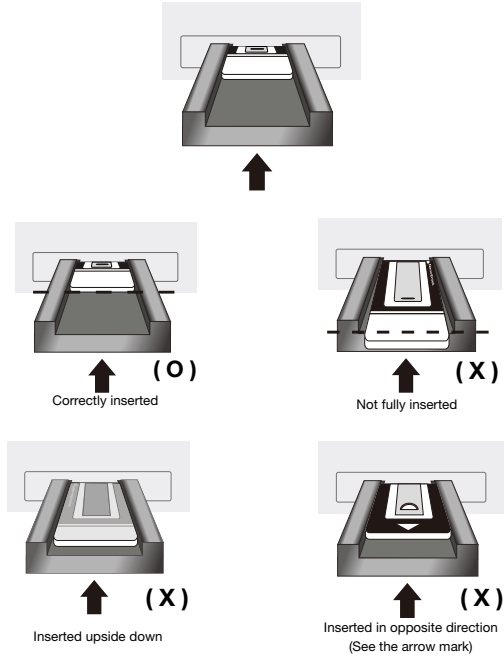
👉 *Note: Assay Slide should be inserted all the way in. Please see the instruction in the next page.*

Measurement

Insert assay slide

⚠ Warning:

- Illustrations of various possible cases of erroneous Assay Slide insertion are presented below.



4. Close the slide holder by pressing down the top portion of the holder tightly until it 'clicks'.



⚠ Warning:

If the slide holder is not properly closed, ADAMITM will give a warning.

Measurement

Insert assay slide

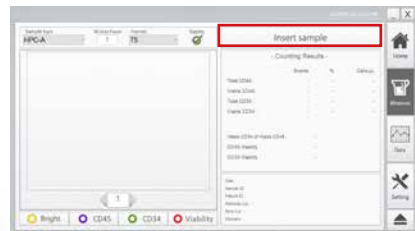
5. Close the slide door.



6. Select sample type, dilution factor and the number of frames.

Sample type	Dilution Factor	Frames	Viability
HPC-A	1	75	<input checked="" type="checkbox"/>

7. Press the **“Insert sample”** button on the ADAMII-CD34 software.
The slide holder containing the Assay Slide will move into the measuring position.



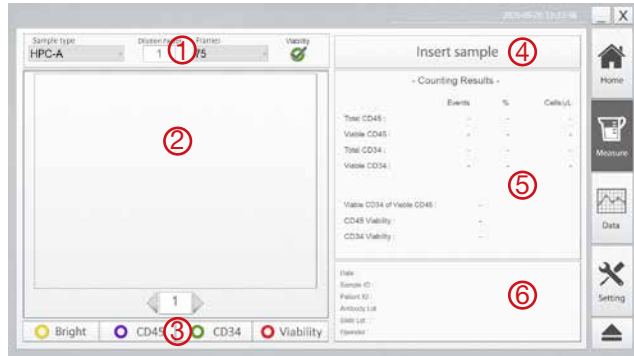
Warning:

- Do not look inside the ADAMII™ instrument when the slide door is open.
Direct exposure to high-energy LED light may be harmful to eyes.

Measurement

Measure menu - Initial mode

The functions of each part in the 'Measure' menu are as follows.



1. Counting mode
2. Display area
3. Detection channel
4. Insert sample
5. Counting results area
6. Test information

Measurement

Measure menu - initial mode

① Counting mode

- **Sample type:** MPB (mobilized peripheral blood), HPC-A (fresh haematopoietic progenitor cell-apheresis collection), fresh cord blood, frozen cord blood, and control (CD34 control materials).
- **Dilution factor:** Enter dilution ratio as a number if the sample has been diluted (the dilution effect during sample preparation has been set in the Setting).
- **Frames:** ADAMI™ can take up to 75 frames of images per sample.
- **Viability:** Check the circle to include viability measurement.

Sample type	Dilution Factor	Frames	Viability
HPC-A	1	75	<input checked="" type="checkbox"/>

② Display area

Live feed of camera will be shown in this window. The window will be activated after inserting slide. (Refer to page 28)



③ Channel

Different channel can be selected. This option will be activated after inserting slide.

<input checked="" type="radio"/> Bright	<input type="radio"/> CD45	<input type="radio"/> CD34	<input type="radio"/> Viability
---	----------------------------	----------------------------	---------------------------------

④ Insert sample

Click **'Insert Sample'** button to insert Assay Slide and move it to the measuring position.

Insert sample

Note: Make sure the slide door and slide holder cap are completely closed.

Measurement

Measure menu - initial mode

⑤ Counting result area

After completing image acquisition and analysis, the results will be displayed here. (Refer to page 33)

- Counting Results -			
	Events	%	Cells/ μ L
Total CD45 :	-	-	-
Viable CD45 :	-	-	-
Total CD34 :	-	-	-
Viable CD34 :	-	-	-
Viable CD34 of Viable CD45 :	-	-	-
CD45 Viability :	-	-	-
CD34 Viability :	-	-	-

⑥ Test information

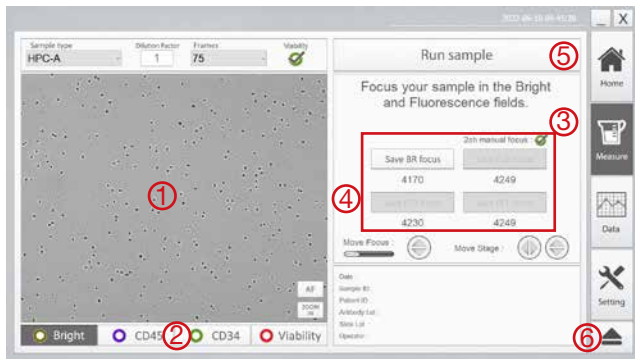
Detailed information of the sample will be displayed here.

Date :
Sample ID :
Patient ID :
Antibody Lot. :
Slide Lot. :
Operator :

Measurement

Measure menu - Focusing mode

Once the Assay Slide is inserted, focusing mode will appear.



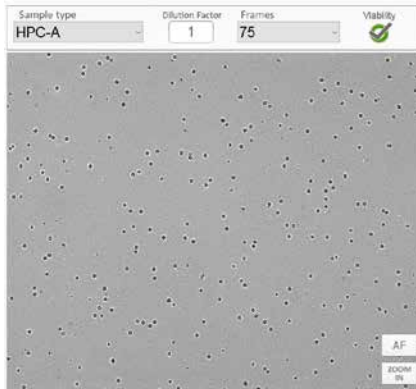
1. Display area
2. Channel
3. Focus option
4. Save focus
5. Run sample
6. Eject

Measurement

Measure menu - Focusing mode

① Display area

Live feed of camera will be shown in this window.



② Channel

Indicate the channel that is being displayed.

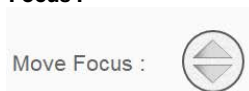
- CD45
- CD34
- Viability for live/dead marker



Note: Viability channel will be measured only when the viability circle is selected.

③ Focus option

1. Focus can be adjusted by clicking up or down arrow in 'Move Focus'.

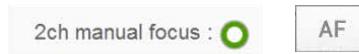


Measurement

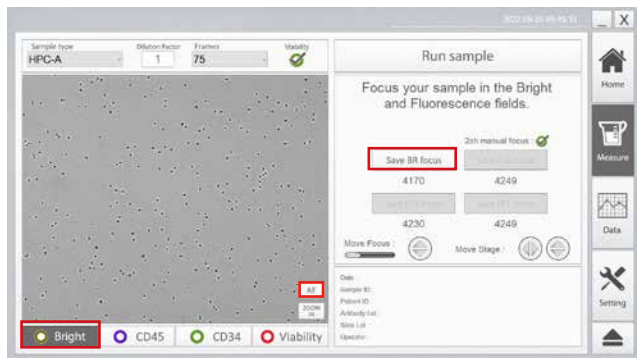
Measure menu - Focusing mode ③ Focus option

2. **2ch manual focus:** If this option is selected, only focuses for Bright and CD45 channels will be manually adjusted and the focuses for the other 2 fluorescence channels will be automatically set based on the CD45 focus position.

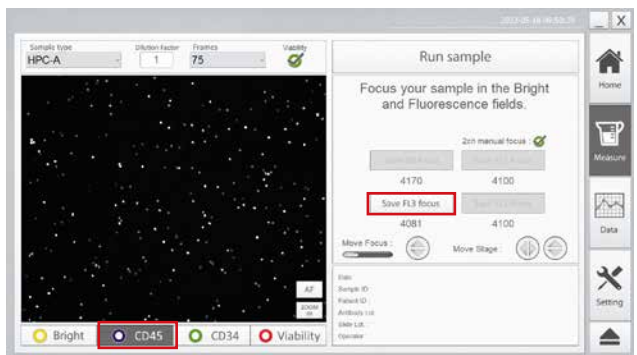
Auto focus : If you press the “Auto focus” button, the focusing will be adjusted automatically.



[Save BR focus]



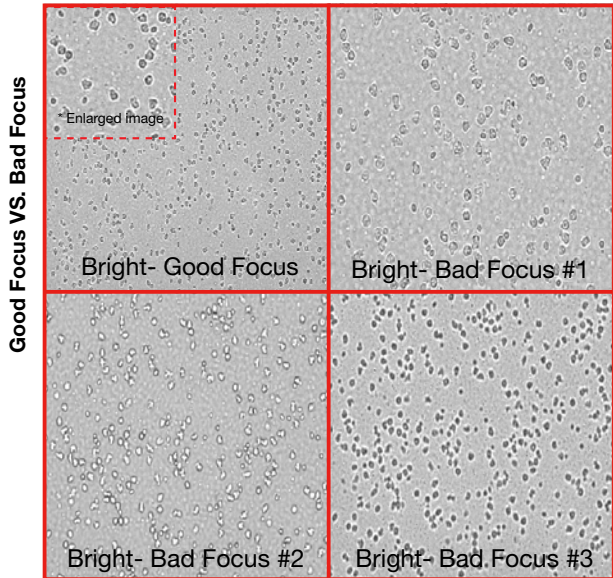
[Save FL3 focus]



Measurement

Measure menu
- Focusing mode
③ Focus option

[Focusing example – bright field]

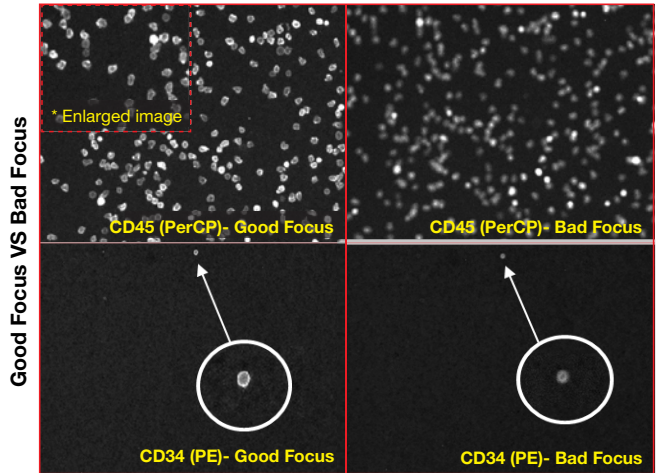


- **Good Focus:** Compared to gray background, dark inside of cells and bright boundaries around cells.
- **Bad focus #1:** Compared to gray background, the inside of cells is not dark and the boundaries are not bright and clear.
- **Bad focus #2:** The inside of cells is white.
- **Bad focus #3:** While the inside of cells is dark and the boundaries are bright, the boundaries are blurry and unclear.

Measurement

- Measure menu
- Focusing mode
- ③ Focus option

[Focusing example – fluorescence channel]



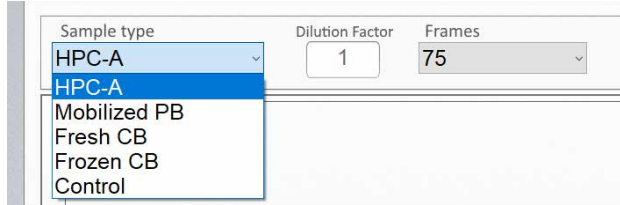
- **Good Focus:** Clear cell image, bright cell body in contrast to the dark background.
- **Bad focus:** Unclear cell image, blurry cell image.

Measurement

Measure menu - Focusing mode

④ Run sample

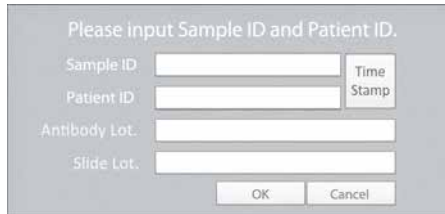
1. Before running samples, make sure that sample type and dilution factor are selected accurately.



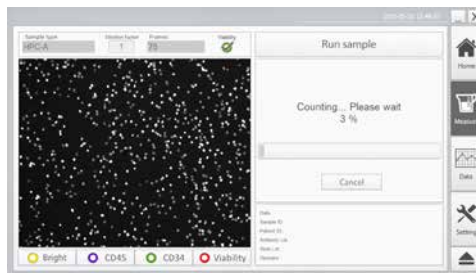
2. Press the “Run sample” button.



3. Enter the Sample ID, Patient ID, Antibody Lot, and Slide Lot.



4. When the counting is done, Assay Slide will be ejected automatically.



Measurement

Measure menu - Focusing mode

④ Run sample

5. The calculated data including total cell count and viability of CD34 and CD45 will be displayed in the counting results area.

	Events	%	Cells/ μ L
Total CD45 :	48998	-	179229.18
Viable CD45 :	47575	-	174024.01
Total CD34 :	178	0.36	651.10
Viable CD34 :	156	0.32	570.63
Viable CD34 of Viable CD45 :		0.33 %	
CD45 Viability :		97.10 %	
CD34 Viability :		87.64 %	

6. To run the next sample, open the slide door, press the button on the slide holder to open the holder, remove the used slide, insert a new slide and repeat the steps.

⑤ Eject

Click **'Eject'** button when you want to manually eject the Assay Slide.

There is no need to use this button after the assay is completed ordinarily. The completed Assay Slide will be automatically ejected at the end of the measurement.



Note: The slide door should be closed at all times except when inserting and removing the slides.

Data

Data menu

Data menu provides the counting results of a measurement, the countings of each channel at each frame, the lists of data, and an option to export data.

The screenshot shows the Data menu interface with the following components and callouts:

- 1. Test information: Measured time, Sample ID, Pathfile ID, Pathfile Lab, Micro L4, Operator.
- 2. Sample information: Sample Name, Measured Frame, Classified Frame, Measured Frame.
- 3. Captured image: A dark image showing particle counts.
- 4. Sample volume information: Total volume, Sample volume, Division Factor.
- 5. Result area: A table with columns for Counts, %, and Count.
- 6. Histogram: A bar chart showing the distribution of counts.
- 7. Raw data table: A table with columns for Frame, MS, FLS, RLS, SLS, and Count.
- 8. Data list: A list of data points with columns for Frame, MS, FLS, RLS, SLS, and Count.
- 9. Export data: Buttons for exporting data to various formats.
- 10. Edit data list: Buttons for selecting all and deleting data.

1. Test information
2. Sample information
3. Captured image
4. Sample volume information
5. Result area
6. Histogram
7. Raw data table
8. Data list
9. Export data
10. Edit data list

Data

Data menu

① Test information

The following information is displayed in the 'Test information'.

- **Measured date:** Displays date and time of measurement
- **Sample ID:** Displays sample ID
- **Patient ID:** Displays patient ID
- **Antibody Lot:** Displays Antibody lot
- **Slide Lot:** Displays slide lot
- **Operator:** Displays operator's ID

```
Measured time : 2020-04-13 03:45
Sample ID : 2020-04-13_03-45-06
Patient ID : 0413HPC-A-3
Antibody Lot :
Slide Lot :
Operator : master
```

② Sample information

In the 'Sample information' section, it displays sample type, number of frames that were measured, deleted and included in the final results.

- **Sample type:** Display the sample type
(HPC-A, Mobilized PB, fresh cord blood & frozen cord blood or Control)
- **Measured frame:** Number of frames that were measured.
- **Deleted frame:** Number of frames that were deleted.
- **Resulted frame:** Final number of frames that were used for the results.
(The number of measured frames subtracted by the number of deleted frames)

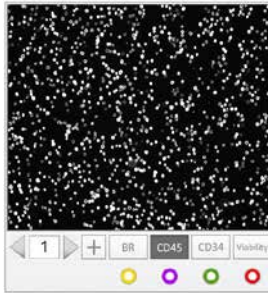
```
Sample type : HPC-A
Measured frame : 75
Deleted frame : 0
Resulted frame : 75
```

Data

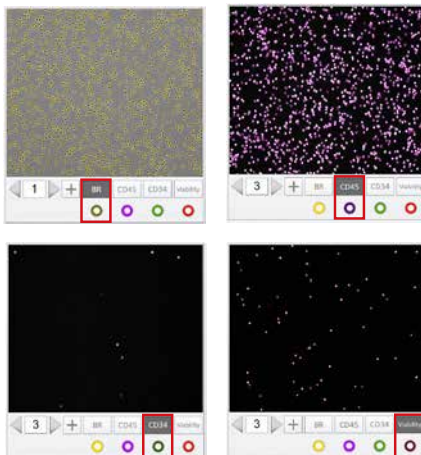
Data menu

③ Captured image

In this window, raw image in each channel at each frame can be reviewed. Click left or right arrow, or enter a number to choose a frame to see images. Click a channel button to see the image in that channel.



Click a circle under a channel name to show circular markers that indicate the cells counted in that channel. Click the circle again to make the markers disappeared. In one particular channel, one can make markers from a different channel appear, for example, one can choose to see an image from bright field and markers from CD45. One can also choose to show more than one markers simultaneously.



- **Yellow:** Cells counted in bright channel
- **Purple:** Cells counted in CD45 channel
- **Green:** Cells counted in CD34 channel
- **Red:** Cells counted in Viability channel

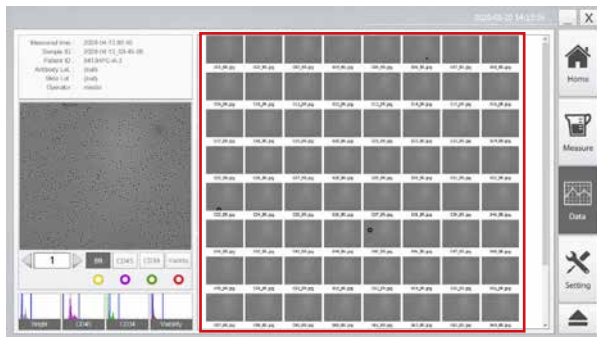
 *Note: This function is available only in the data menu.*

Data

Data menu

③ Captured image

Double click the captured image, then you can check preview images of selected channel on the right side of the screen. To check the preview images of other channels, select that channel and double click the captured image again.



Data

Data menu

④ Sample volume information

In the sample volume section, one can see the total volume of prepared sample and the volume of sample that was used. The dilution factor is the number that a user updated during measurement.

Default values are listed below. Please refer to the package insert included in ADAMII™-CD34 kit.

- **HPC-A:** Total volume = 275 µL, sample volume = 20 µL
- **Mobilized PB:** Total volume = 60 µL, sample volume = 20 µL
- **Control:** Total volume = 60 µL, sample volume = 20 µL
- **Fresh cord blood:** Total volume = 255 µL, sample volume = 50 µL
- **Frozen cord blood:** Total volume 255 µL, sample volume = 50 µL

Total volume : 275.0 µL
Sample volume : 20.0 µL
Dilution Factor : 1

Edit

Click '**Edit**' button to edit the total volume, sample volume and dilution factor.

Edit

Volume/Dilution Factor

Total Volume : µL
Sample Volume : µL
Dilution Factor :

Apply

Close

⑤ Result area

Results area displays the following numbers.

- **Events:** Number of cells identified.
- **%:** Ratio of CD34+ cells in CD45+ cells in a percentage value.
- **Cells/µL:** Absolute numbers in a unit volume (1µL).
- **Viability:** ratio of viable cells in total cells in a percentage value.

	Events	%	Cells/µL
Total CD45 :	48998	-	179229.18
Viable CD45 :	47575	-	174024.01
Total CD34 :	178	0.36	651.10
Viable CD34 :	156	0.32	570.63
Viable CD34 of Viable CD45 :	0.33 %		
CD45 Viability :	97.10 %		
CD34 Viability :	87.64 %		

Data

Data menu

⑥ Histogram

Histogram of cell size in each channel is accessible by double-clicking small inset of histogram. In the pop-up window, one can change the size gating conditions.

1. Click the histogram of each channel, then the cell size graph will be shown. X-axis indicates cell size and Y-axis indicates number of cells.
2. Move blue lines, which indicate the gating condition, to the left or right, or enter number in Min or Max section to change gating condition.
3. Press 'Apply' button to apply new gating condition. Results will be updated.



⑦ Raw data table

The number of event for each frame will be displayed by channels. Frame by frame revision of raw data image and removal of invalid frames can be done on the table. For deleting an invalid frame, click on the right mouse button and select '**Delete**' menu. Then, the "**Result area**" will show the re-calculated data, reflecting the deleted frame(s).

Frame	BR	FL3	FL2	FL1	Deleted
1	30	8	2	6	No
2	43	7	1	5	No
3	40	9	5	5	No
4	32	8	3	4	No
5	43	16	9	6	No
6	27	8	4	4	No
7	30	7	3	3	No
8	34	6	2	4	No
9	38	14	5	9	No
10	33	11	3	8	No

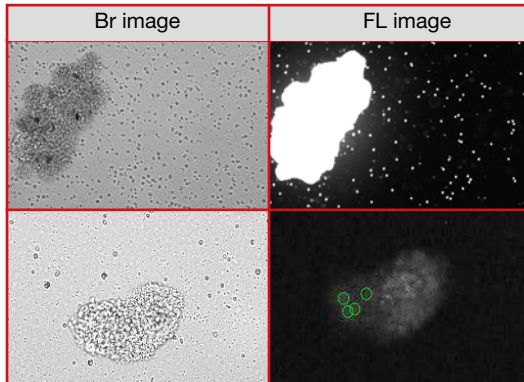
Data

Data menu

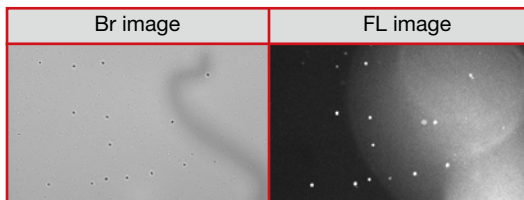
⑦ Raw data table

How to find the invalid frames is described below:

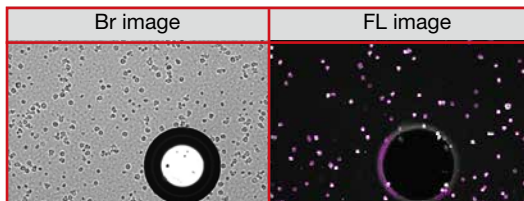
- 1) **Sample aggregation:** When there is aggregation in a specific area of the sample, that frame should be deleted.



- 2) **Dust:** When there is dust inside the slide, that frame should be deleted.



- 3) **Bubble:** After loading the sample, if there is bubble in the slide, that frame should be deleted.

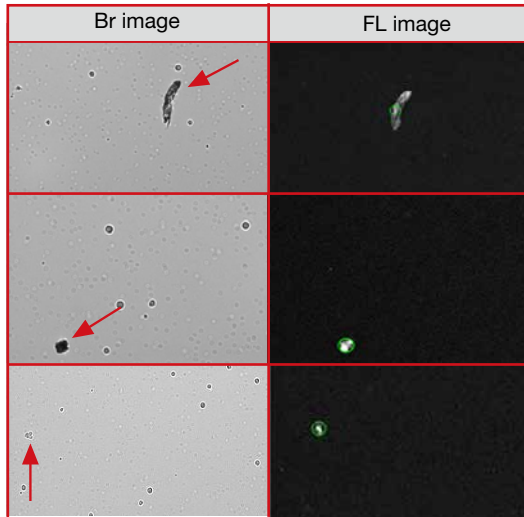


Data

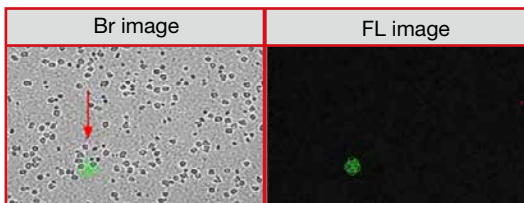
Data menu

⑦ Raw data table

4) **Cell debris:** When there is cell debris, that frame should be deleted.



5) **Overlapped circle:** When there are several circles in one cell, that frame should be deleted.

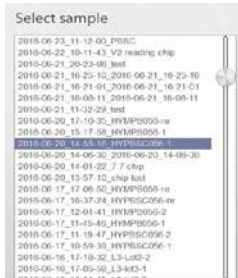


Data

Data menu

⑧ Data list

In the Data list, all previous measurements are shown in a chronological order. Scroll up and down to find the data of interest and select the data to review.



⑨ Edit data list

User can edit the Data list.

- **Rename:** To rename a file, select the data file and click **'Rename'** button to change name of the selected data.
- **Select all:** Click **'Select all'** button to select all of the listed data. You can also select all of the sample data at once by pressing **'Shift'** button.
- **Delete:** To delete a file, select the data file and click **'Delete'** button.



Data

Data menu

10 Export data

ADAMII™ allows you to export the data table(.csv), images(.jpg), and the final report(.pdf). Click 'ALL' button to export the data in 3 types of formats at once.

- **csv file:** Data table containing comprehensive information in a spreadsheet.
- **jpg file:** Raw images of all 4 channels.
- **pdf file:** A report with summaries of measurements including CD34+ cell counts, CD34+/CD45+ ratio, and viability.



[csv file]

	A	B	C	D	E
1	Measured time :	2020-08-06 09:43			
2	Sample ID :	N.B			
3	Patient ID :	2020-08-06_09-43-23			
4	Antibody List :				
5	Slide Lot :				
6	Operator :	master			
7					
8	Sample type :	Mobilized PB			
9	Measured frame volume :	75			
10	Deacted frame volume :	0			
11	Resulted frame volume :	75			
12					
13	Total CD45 :	25709	-	8814.45	
14	Viable CD45 :	25646	-	6792.65	
15	Total CD34 :	143	0.56	48.69	
16	Viable CD34 :	142	0.55	48.69	
17	Viable CD34 of Viable CD45 :			0.55 %	
18	CD45 Viability :			99.75 %	
19	CD34 Viability :			99.30 %	

[jpg file]



[pdf file]

ADAMII™ Count report

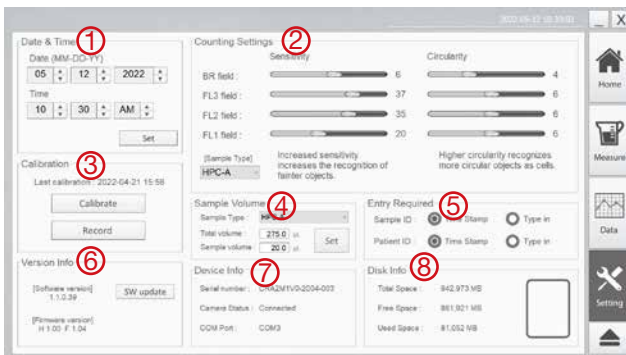
[ADAM-II Counting Results]

Measured time : 2020-08-06 09:43	
Sample ID : N.B	
Patient ID : 2020-08-06_09-43-23	
Operator : master	
Sample type : Mobilized PB	
Measured frame : 75	
Deacted frame : 0	
Resulted frame : 75	
Total volume : 60.0 μ L	
Sample volume : 20.0 μ L	
Dilution factor : 1	
	Events % Cells / μ L
Total CD45 :	25709 - 8814.45
Viable CD45 :	25646 - 6792.65
Total CD34 :	143 0.56 48.69
Viable CD34 :	142 0.55 48.69
Viable CD34 of Viable CD45 : 0.55 %	
CD45 Viability : 99.75 %	
CD34 Viability : 99.30 %	

Setting

Setting menu

Setting menu contains information of ADAMI-CD34 software as well as several user preferences and other Settings. It allows users to change settings including cell counting settings, and update software and firmware.



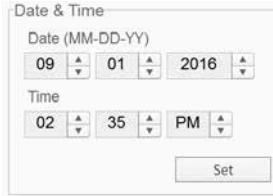
1. Date & Time
2. Counting settings
3. Calibration
4. Sample volume
5. Entry required
6. Update
7. Device info
8. Disk info

Setting

Setting menu

① Date & Time

You can change date and time of ADAMII-CD34 software.

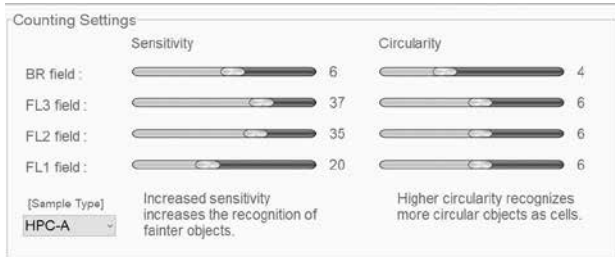


The dialog box is titled "Date & Time". It contains a "Date (MM-DD-YY)" section with three spinners for month (09), day (01), and year (2016). Below that is a "Time" section with three spinners for hour (02), minute (35), and a dropdown for AM/PM (PM). A "Set" button is located at the bottom right.

② Counting settings

It is not recommended to adjust the sensitivity and circularity by the user.

- **Sensitivity** : Refers to the contrast of the objects from the background.
- **Circularity** : Used to determine which objects to include in the measurement based on their roundness.



The dialog box is titled "Counting Settings". It features a "[Sample Type]" dropdown menu set to "HPC-A". Below this are two columns of sliders: "Sensitivity" and "Circularity".

Field	Sensitivity Value	Circularity Value
BR field :	6	4
FL3 field :	37	6
FL2 field :	35	6
FL1 field :	20	6

Below the sliders, there are two explanatory text blocks:

- Sensitivity:** Increased sensitivity increases the recognition of fainter objects.
- Circularity:** Higher circularity recognizes more circular objects as cells.

Setting

Setting menu

③ Calibration

Please refer to page 12~19 for calibration.

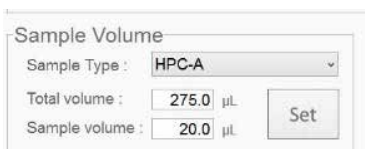


To open the lists of calibration histories, click “Record” button. User can see the records of previous calibrations.



④ Sample volume

While we don't recommend users to change this, user can change the default sample volume and total volume. (Only apply when necessary.)



⑤ Entry required

Set entry option of the Sample ID and Patient ID.



Setting

Setting menu

⑥ Update

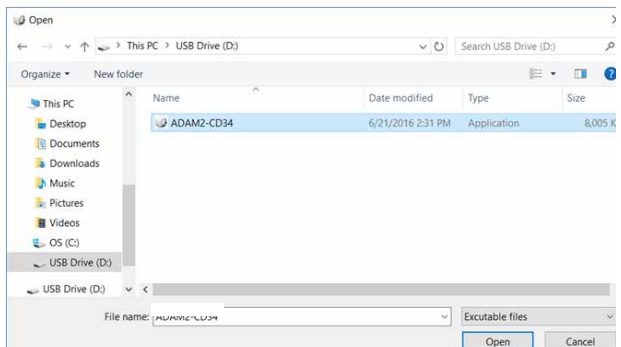
Check the software version to update.

[Software update]

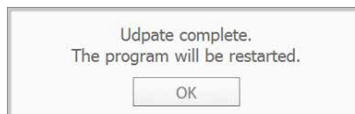
1. We recommend to contact NanoEntek customer service (ivdst@nanoentek.com) if SW or FW needs to be updated.
2. If an update version of SW or FW has been provided, copy the file in a USB drive and plug it into the laptop.



3. After the USB drive appears as an external drive, click 'SW update'.



4. Find the new SW file and double click the file.



5. After completing the update, the following window will appear. Press OK to proceed.
6. The software will restart.

Setting

Setting menu

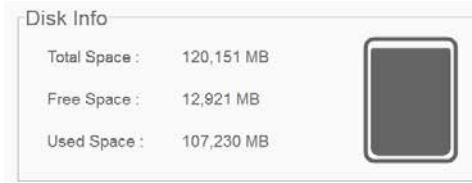
⑦ Device info

Device info indicates serial number of the ADAMI™ and the status of connection between camera in the instrument and the laptop.



⑧ Disk info

Disk info indicates available space in the hard drive installed in the laptop. Please back up or delete your data from the hard drive when the free space is less than 100MB.



Cleaning and Maintenance

Clean the surface of ADAMII™ with a damp cloth. If liquid is spilled on ADAMII™, turn off the power immediately and wipe out liquid.

ADAMII™ does not need regular maintenance. To troubleshoot problems with ADAMII™, contact technical support.

 **IMPORTANT! Never disassemble or service ADAMII™ by yourself.**

Unauthorized repairs may damage ADAMII™ or alter its functionality, which will void your warranty. Contact ivdst@nanoentek.com or your local distributor to arrange for service.

 **IMPORTANT! Always wipe surfaces with ethanol-soaked paper towels.**

Do not directly spray ethanol anywhere on ADAMII™.

 **IMPORTANT! Avoid exposing ADAMII™ to UV light.**

UV light may degrade components, including plastic.

Damage from UV exposure is not covered under the manufacturer's warranty.



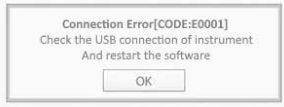





Troubleshooting

Installation	
ADAMII™ does not power on	<ul style="list-style-type: none"> • Check on/off switch on back side of main instrument. • Check power source or contact your distributor.
Operator program does not start	<ul style="list-style-type: none"> • Check on/off switch on back side of main instrument. • Check connection between instrument and PC.
Camera preview	
Camera preview fail	<ul style="list-style-type: none"> • Check connection between instrument and PC. • Reboot the instrument or PC. • Request technical support.
Operation	
Warning message when there are more than 1,000 cells in 1 frame	<ul style="list-style-type: none"> • Dilute the cell concentration less than 1,000 cells/μL • Recommend 500 ~ 900 cells in 1 frame
Total CD45 count is higher than bright count (WBC count)	<ul style="list-style-type: none"> • Delete image that has bubble, fluorescence debris or dust, and then check the result.
Total CD45 count is lower than bright count (WBC count)	<ul style="list-style-type: none"> • Check the focus of image. • If the focus of image was not set properly, load and read the sample again.
Position of Focus is changed (When the focus of first frame and the other frames are different)	<ul style="list-style-type: none"> • Change the slide and read again.
Focusing changes constantly	<ul style="list-style-type: none"> • Request technical support.
Focusing is not adjusted well with autofocus function	<ul style="list-style-type: none"> • Set the focus with 2ch manual focus function.
Background of image is suddenly brighten	<ul style="list-style-type: none"> • First, check the sample type. • Second, if you used the bottom of ADAMII™ CD34 Reagent that almost used, please use the new reagent. • If none of the above 2 steps solve the problem, please request technical support.


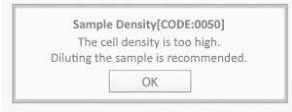

Troubleshooting

Operation	
Calibration fail	<ul style="list-style-type: none">• First, vortex enough for 5 seconds and load sample immediately to read the slide again.• Second, check the focus. When the image is out of focus, the fluorescence of bead is unclear. If the focus is not set continuously in reading step, please request technical support.• If the focus is still not set correctly even you did both the above first and second steps, change the bead.• If none of the above 3 steps solve the problem, please request technical support.
Sensor of slide holder cap is faulty	<ul style="list-style-type: none">• ADAMII™ does not insert and count the slide when the slide holder cap opened.• But if sensor of slide holder cap is faulty and you start counting without closing the cap, then the result will not be accurate. When you eject the slide with the door open, the cap can be broken inside the instrument.
Inaccurate result	
Use of the wrong slide	<ul style="list-style-type: none">• Do not insert the Assay Slide upside down.• Do not reuse the Assay Slide, as leftover dye from the previous reading may affect the next reading.• Do not use any other slides as it results in inaccurate count and may damage the instrument.
Poor image quality	<ul style="list-style-type: none">• While viewing cells in preview state, re-optimize the focus.

Error code

Error code	Reason	Message	Position
E0001	Camera connection fail	 <p>Connection Error[CODE:E0001] Check the USB connection of instrument And restart the software OK</p>	Driver
E0002	Serial connection fail	 <p>Connection Error[CODE:E0002] Check the USB-to-Serial connection And restart the software OK</p>	
E0010	Serial disconnected	 <p>Connection Error[CODE:E0010] Cannot receive the response from instrument. Please check the USB-to-Serial connection. OK</p>	Stage working
E0020	Camera disconnected.	 <p>Camera Error[CODE:E0020] Cannot capture the image from camera. Please check the USB connection. OK</p>	Camera
E0030	Slide holder is opened.	 <p>Slide Holder[CODE:E0030] Slide holder is opened. Please close the holder and try again. OK</p>	Slide inserting
E0031	Slide door is opened.	 <p>Slide door[CODE:E0031] Slide door is opened. Please close the door and try again. OK</p>	Slide ejecting

Error code

Error code	Reason	Message	Position
E0040	Data storage is full	 <p>Data Storage[CODE:E0040] The data storage is full. Backup the data with USB and then delete the data in the storage.</p> <p>OK</p>	Data save
E0050	Sample density is too high	 <p>Sample Density[CODE:0050] The cell density is too high. Diluting the sample is recommended.</p> <p>OK</p>	Measuring
E0060	Update fail	 <p>Update Fail[CODE:E0060] This is not a ADAM-II software. Restart with ADAM-II executable file.</p> <p>OK</p>	SW update

Warranty

NanoEntek provides 1-year warranty service for defects of material and workmanship.

If any defects occur in ADAMI[™], **NanoEntek** provides repair services for the defective parts at its discretion.

The following defects, however, are specifically excluded:

1. Defects caused by improper operation.
2. Repair or modification done by anyone other than NanoEntek or an authorized agent.
3. Damage caused by substituting alternative parts.
4. Use of fittings or spare parts supplied by anyone other than NanoEntek.
5. Damage caused by accident or misuse.
6. Damage caused by disaster.
7. Corrosion caused by improper solvent or sample.

For your protection, ADAMI[™] units being returned must be insured against possible damage or loss. NanoEntek cannot be responsible for damage incurred during shipment of a defective instrument. It is recommend that you save the original packing material in which the instrument was shipped. This warranty is limited to the replacement of defective products.

For any inquiry or request for repair service, please contact ivdst@nanoentek.com or your local distributor.

Safety precautions

Review and follow the safety instructions below:

- If water or other material enters the instrument, adaptor, or power inlet, disconnect the power cord and contact a service person. For operating environment, refer to Product Specifications.
- Do not touch the main plug or power cord with wet hands.
- Always ensure that the power supply input voltage matches the voltage available at your location.
- This instrument is air-cooled and its surfaces may become hot during operation. During installing, leave a space of more than 10 cm (4 inches) around the instrument and do not place any objects between the instrument and the walls.
- Do not install the instrument on a slant or a place prone to vibrations, which induces the risk of instrument malfunction or damage of the instrument.
- Never insert any objects into the air vents of the instrument as this could result in electrical shock, personal injury, and equipment damage.
- Plug the power cord firmly into the wall outlet and AC adaptor.
- To avoid potential shock hazard, make sure that the power cord is properly grounded.
- Be sure to position the instrument where it is easy to disconnect.
- Turn off the instrument before unplugging the power cord and/or moving the instrument.
- If the instrument is dropped or broken, disconnect the power cord and contact a service person. Disassembly of case will void warranty.
- Use only authorized accessories (adaptor, power cord, and USB drive).



Warning

Class A equipment is intended for use in an industrial environment.

In the documentation for the user, a statement shall be included drawing attention to the fact that there may be potential difficulties in ensuring electromagnetic compatibility in other environments, due to conducted as well as radiated disturbances.

Consignes de securite

Examinez et suivez les consignes de securite ci-dessous :

- N'installez pas l'instrument dans un endroit humide comme une serre ou un incubateur pour eviter un risque de choc electrique. Si de l'eau ou tout autre materiau penetre dans l'instrument, l'adaptateur, ou l'entrees d'alimentation, debranchez le cordon d'alimentation et contactez un technicien de service. Pour l'environnement d'exploitation, reportez-vous aux specifications du produit.
- Ne touchez pas la fiche ou le cordon d'alimentation principale avec les mains mouillees.
- Assurez-vous toujours que la tension d'entree d'alimentation correspond a la tension disponible dans votre endroit.
- Cet instrument est refroidi a l'air de sorte que ses surfaces peuvent devenir chaudes pendant le fonctionnement.
- Lors de l'installation de l'instrument, laissez un espace de plus de 10 cm (4 pouces) autour de cet instrument et ne placez aucun objet entre l'appareil et le mur.
- N'installez pas l'instrument sur une pente ou un endroit soumis a des vibrations, ce qui induit le risque de dysfonctionnement ou d'endommagement de l'instrument.
- N'inserez jamais aucun objet dans les orifices d'aeration de l'instrument, car cela pourrait entrainer un choc electrique, des blessures chez les utilisateurs et des dommages d'equipement.
- Branchez le cordon d'alimentation fermement dans la prise murale et l'adaptateur secteur aussi.
- Pour eviter un risque potentiel de commotion electrique, assurez-vous que le cordon d'alimentation est correctement mis a la terre.
- Assurez-vous de positionner l'instrument de telle sorte qu'il soit facile de debrancher l'instrument.
- Eteignez l'instrument avant de debrancher le cordon d'alimentation et / ou de deplacer l'instrument.
- Si l'instrument est casse ou qu'il soit tombe, debranchez le cordon d'alimentation et contactez un technicien de service. Ne demontez pas l'instrument et la garantie sera annulee en cas de demontage.
- Utilisez uniquement les accessoires autorises (l'adaptateur, le cordon d'alimentation, et le lecteur USB).

















Prudence

Le produit de classe A est conu pour l'utilisation dans un environnement industriel.

Dans la documentation de l'utilisateur, la declaration doit etre incluse pour attirer l'attention sur le fait qu'il peut y avoir des difficultes potentielles pour assurer la compatibilite electromagnetique dans d'autres environnements, en raison des perturbations rayonnees et.













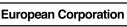

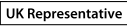


Safety Symbols

The following symbols are found on the medical device and this document. Always use the instrument safely.

Symbol	Meaning
	Caution or Warning, Consult accompanying documents
	Protective earth (Ground)
	Power On/Off
	The moving parts symbol indicates areas of the medical device in which moving parts can cause injuries. Do not operate the medical device with the door open.
	This instrument has been tested and found to comply with the limits for a Class A digital medical device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the instrument is operated in a commercial environment. This instrument generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this instrument in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.
	This medical device and consumables conforms to the EC Declaration of Conformity.
	UK Conformity Assessment
	USB Connection
	The LAN Port symbol identifies the communication between the medical device and the only external computer.
	In vitro diagnostic medical device
	This product conforms to UL 61010-1, CAN/CSA C22.2 No.61010-1 “Safety Requirements for Electrical Instrument for Measurement, Control, and Laboratory Use, Part I: General Requirements.” This instrument bearing the TÜV symbol are certified by TÜV Product Services to be in conformance with the applicable safety standard for the US and Canada.
	Catalogue number/Reference number
	Serial number
	Manufacturer

Safety Symbols

The following symbols are found on the medical device and this document. Always use the instrument safely.

Symbol	Meaning
	Date of Manufacturer
	Electrical rating
 <small>www.nanoentek.com/eifu.php</small>	Consult Instructions for Use An electronic instructions for use (eIFU) indicator (website address) may accompany the symbol when used to indicate an instruction to consult an eIFU.
	Disposal of your old appliance 1. When this crossed-out wheeled bin symbol is attached to a product it means the product is covered by the European Directive 2012/19/EU. 2. All electrical and electronic products should be disposed of separately from the municipal waste stream via designated collection facilities appointed by the government or the local authorities. 3. The correct disposal of your old appliance will help prevent potential negative consequences for the environment and human health. 4. For more detailed information about disposal of your old appliance, please contact local distributor, waste disposal service or call the number listed in the manual.
	LED
	For prescription use only CAUTION: Federal (The U.S.) law restricts this device to sale by or on order of a physician.
	Keep dry Keep away from rain
	Fragile, handle with care
	This way up
	General symbol for recover/recyclable
	Team lift
	US Corporation
	European Corporation
	Authorized representative in the European Community
	Authorized representative in United Kingdom
	Authorized representative in Switzerland
	Authorized representative in Brazil

Product specifications



ADAMII™	
Light source	Bright, Green (PE), Green (PerCP) and Blue (FITC)
Camera	High-sensitivity monochrome CCD
Stage	Automated X-Y-Z stage
Exported formats: Image	CSV, PDF, JPEG
Electronic input	12VDC, 5.0A
Operating power	100 – 240 V, 1.5 A, 50/60 Hz
Operating environment	5 - 40 °C, 20 – 95 %
Weight	19.3 kg
Dimensions	300 x 420 x 370 mm (L x W x H)

Ordering information

Cat. No.	Description	Components
ADAM2	ADAMII™, Bench-top Fluorescence Cell Counter	<ul style="list-style-type: none"> · Main instrument · Power cord · USB connection cable
CD34K-025	ADAMII™-CD34 Kit	<ul style="list-style-type: none"> · ADAMII™-CD34 Reagent · 10X RBC Lysis Buffer · ADAMII™ Calibration Beads · ADAMII™ Assay Slide

Technical support

Visit the our Website at www.nanoentek.com for :



- Technical resources, including manuals, FAQs, etc.
- Technical support contact information
- Additional product information and special offers

For more information or technical assistance, please call or email.

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Website

www.nanoentek.com



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ADAMII™

For ADAMII™-CD34

NESMU-ACD34-002EN(V.0.2)



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