

1 What is Kaluza?

Kaluza is a stand-alone software package for the analysis of flow cytometry listmode data stored as .FCS or .LMD files. It is intended for Research Use Only.

2 What operating systems does Kaluza run on? Does it run on the Mac?

Kaluza v1.0 is compatible with:

1. Microsoft Windows XP (32-bit)
2. Microsoft Windows Vista (32-bit)

Kaluza v1.1 is compatible with:

1. Microsoft Windows XP (32-bit)
2. Microsoft Windows Vista (32-bit)
3. Microsoft Windows 7 (32-bit)
4. Microsoft Windows 7 (64-bit)

Kaluza has been independently shown to operate on Intel-based Apple Mac hardware while running the above operating system configurations in a virtual environment. However, these configurations have not been validated and are chosen at the user's risk.

3 What software libraries does Kaluza need?

The following libraries are required to install Kaluza and are included as part of the Kaluza installation program:

1. Windows Installer Technology 3.1
2. Microsoft .NET Framework 3.5 SP1
3. Microsoft Visual C++ 2008 SP1 Redistributable version 9.0
4. A PDF reader is required to open the Kaluza Instructions for Use. One is included on the Kaluza installation CD as an optional install.

4 What kind of computer hardware does Kaluza need?

The minimum requirement for a computer to run Kaluza is one which meets the requirements for operating systems and libraries above. For optimal performance please take the following into consideration:

1. For optimal performance, greater system capabilities may be required in some situations. These include:
 - a. Larger files (greater number of events)
 - b. Higher number of parameters (more colors)
 - c. More complicated protocols (many levels of gating, larger numbers of plots, etc)

Also see the "Hardware Options" section below for information.

2. Kaluza's performance benefits from larger amounts of RAM. For 32-bit operating systems up to 3GB is recommended. For 64-bit operating systems, more than 4GB is recommended.
3. Kaluza's performance benefits from multi-core and multi-CPU systems.
4. Kaluza works at screen resolutions as low as 1024x768, but larger resolutions and a wide-screen aspect ratio are recommended.
5. Kaluza may require up to 200MB of disk space to install, depending on what libraries are installed. Beyond that, the only requirement is for space to store listmode data. Listmode files can be quite large and faster disk subsystems are recommended in that case.

5 Does Kaluza use any optional hardware?

Kaluza supports the NVidia Tesla C1060 supercomputer board. If this board is installed, Kaluza automatically will use it if the correct drivers are installed. (The correct level of drivers from NVidia are required and are included on the Kaluza install CD, but must be installed by the user.) This board has 240 CPUs and 4GB of RAM and greatly accelerates Kaluza analyses.

6 Does Kaluza use any optional software?

The Kaluza installation CD contains a PDF printer driver which the user may install if they wish. This driver can be installed to allow Kaluza to create PDF representations of user's analyses. Other PDF printer drivers, such as the one from Adobe Systems, also work.

Language packs for Kaluza may be found at <http://www.coulterflow.com/bciflow/kaluza/index.php>. Users may install these to view Kaluza in their local language (if available). Each user's language preference is stored separately.

7 Does Kaluza affect my existing files in any way?

No. However, the Kaluza software installer can optionally associate .FCS and/or .LMD files with Kaluza. If this is done, then any associated file will be displayed with the Kaluza icon and opening it from the operating system will cause it to be loaded into Kaluza, automatically starting Kaluza if necessary. These file associations can be changed by accessing the Kaluza installer via the control panel (Add/Remove Programs, Change).

Please note that associating listmode files with Kaluza utilizes a feature of Microsoft Windows to change the icon that they are displayed with. The listmode files are not modified in any way by Microsoft Windows or by Kaluza. The listmode files will continue to function as before with other flow cytometry analysis software, although the Kaluza icon may be used if these files are sent as an attachment via email. Files sent this way are still standard listmodes, despite the icon, and are not "Kaluza files". Kaluza will not be required by the recipient to open them.

8 Does Kaluza have any network requirements?

The Kaluza software does not interact with any network, with the following exceptions:

1. If a network license is used, it interacts with the network (see "Licensing Technology" below)
2. The About Box within the software contains hyperlinks to the Kaluza page on coulterflow.com and to the Tesla page on nvidia.com. Clicking on these links opens the appropriate page in the default web browser. No information is sent when this is done.

9 What kind of Licensing Technology does Kaluza use?

The Kaluza software is licensed. This license is enforced by technology called “HASP” by SafeNet, Inc (formerly Aladdin Systems). This technology is automatically installed by the Kaluza installation program and is required for use of the software. SafeNet’s website is <http://www.safenet-inc.com/>. Several configurations are available:

1. Trial License: The trial license is a software-based license. It is installed automatically when Kaluza is installed. It expires 30 days from the first time it is used. (Please note that this expiration date starts when the license is first used, not when Kaluza is first installed.) The trial license is intended to make it easy to evaluate the software. Please note that trial licenses will not function if Kaluza is used within a virtual machine environment.
2. Single User License: The single user license is provided on a USB device commonly referred to as a “key” or a “dongle”. This key must be plugged into a free USB port on the computer that Kaluza is being used on to enable Kaluza to function. Please note that this device is **not** a USB flash drive:
 - a. It does not appear in the operating system’s file system.
 - b. The user cannot store data on it.
 - c. Kaluza can read from, but not write to, it using special software provided by the vendor.

Please note that the single user license will not work via Microsoft Window’s remote desktop. A network license is recommended for this scenario.

3. Timed Single User License: As single user license above, but limited to use for one year from the time the license is first accessed.
4. Network License: The network license allows multiple Kaluza licenses to be stored on a single computer which can then be accessed by other computers across an Ethernet network. The network license is provided by a USB device similar to the single user license. The computer which hosts the network license must be capable of installing Kaluza and have a free USB port. There are no other requirements for this computer, other than optionally: high uptime and physical security. Unique characteristics of the network license:
 - a. Network licenses follow a “concurrent use” model. The Kaluza software can be installed on an unlimited number of computers, but the number of users operating the software on these computers at once is limited to the number of available network licenses.
 - b. Each computer accessing a network license must be configured to do so. This done by accessing <http://localhost:1947> in a web browser at each computer. Instructions for this procedure are contained in the Kaluza Instructions for Use.

10 How does Kaluza interact with the file system?

Kaluza reads user-provided listmode data from .FCS and .LMD files stored in the file system. These files must be in FCS1.0, FCS2.0, FCS3.0 or FCS3.1 format. Kaluza will never overwrite, change, or delete these files.

Kaluza may read images in most standard formats as instructed to by the user.

Kaluza may read CSV files as instructed to by the user.

Kaluza may store user’s work in one of several formats if instructed to do so:

1. A .analysis file containing copies of one or more listmode files and the user's protocol(s).
2. A .protocol file containing the user's protocol.
3. A .compensation file containing the spillover matrix for a protocol.
4. A CSV representation of the spillover matrix.
5. A PDF representation of their analysis, using the provided optional printer driver.
6. A CSV with selected statistics from their analysis.

If the Kaluza software exits unexpectedly, it will write a log file to one of the following locations:

1. On Microsoft Windows XP:
C:\Documents and Settings\\Local Settings\Application Data\Beckman_Coulter,_Inc\Kaluza\- 2. On Vista and Win7:
C:\Users\\AppData\Local\Beckman_Coulter,_Inc\Kaluza\

Kaluza uses temporary files in the location specified by the operating system configuration.

Kaluza stores user options in a user configuration file which can be found at:

C:\Users\\AppData\Local\Beckman_Coulter,_Inc\Kaluza.exe_Url_<random>\<version>\user.config

11 What are Kaluza's database requirements?

None; Kaluza does not use any database technology.

12 What kind of security requirements does Kaluza have?

Kaluza has the following security requirements for the account of the user operating it:

1. Elevated privileges (typically administrator) are required to install the software.
2. For operation Kaluza requires privileges no greater than "restricted user".
3. Kaluza must have read access to file system data that it is told to read.
4. Kaluza must have write access to file system folders where it is told to write.

Other than the above, Kaluza does not interact with the operating system's security features.

13 What security features does Kaluza have? Does it support 21 CFR Part 11?

Kaluza has no features specifically designed to support security or control procedures:

1. It does not implement its own user accounts
2. It does not encrypt outputs
3. It does not password protect access
4. It does not password protect outputs
5. It does not offer electronic signature capabilities