

Baxa Corporation

The Exacta-Mix[®] Audit Trail

Technical Paper

Understanding the operation of the
blackbox feature of the Baxa
automated compounder.


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Introduction

The Windows® Software that drives the Exacta-Mix™ 2400 (EM2400) and Exacta-Mix™ 600 (EM600) compounders' operation includes an audit feature that captures and records all important system events for later analysis and troubleshooting. This feature is referred to as the "blackbox," like the flight data recorder found on airplanes. It is designed to store, for a minimum of 45 days, a full record of the software's view of the compounder's operation.

Structure of the Blackbox

The blackbox is a collection of files on the hard drive of the PC on which the Exacta-Mix Operating Software is installed, archived in the subdirectory *Blackbox*. Events are recorded to one file at a time, until the file reaches a size limit of about 1.33 MB, when it is closed and a new file opened. This file size limitation allows each blackbox file to be copied, uncompressed, to a standard 3.5" floppy diskette if necessary.

The naming convention for the blackbox files is YYYYMMDDhhmmsslll.bbx, where:

- YYYY – current year, e.g., 2003
- MM – current month (numeric), e.g., 09
- DD – current day of month, e.g., 03
- hh – current hour of day (in military style), e.g., 14
- mm – current minute of hour, e.g., 07
- ss – current second of the minute, e.g., 33
- lll – current millisecond, e.g., 960

Times indicated are those of the time when the file is opened for output. The file names assist Administrative and Technical Support personnel in determining which files may be relevant to a specific investigation.

Each blackbox file is itself made up of a series of discrete entries. Each entry contains the following information:

- Date and time the entry was written
- Current user's name
- An audit category – the general area of the program that generated the event. This is a short English description, for example "SECURITY," "PUMPSSENT."
- An audit message – details of the event that is being recorded.
Examples: "LOGIN SUCCEEDED: Username JDOE," "0x0111."

Configuration and Administration

Blackbox files are maintained for a minimum of 45 days, however this period may be lengthened by an Administrative User by editing the "Log Storage" option in the Options editor. Each site, because of the varying number and types of bags that are pumped, will have different storage requirements for the daily blackbox files.

Each time the Exacta-Mix™ Software is started, blackbox files that are older than the configured storage time are deleted from the hard drive.

Security, Data Integrity and Privacy

Each blackbox file is encrypted. Encrypting the files serves three purposes. First, security is maintained, in that users who gain direct access to the files are unable to decipher their content.

Second, data integrity is ensured against malicious attempts to tamper with or alter the blackbox record, since any modifications to a blackbox file must leave the file properly structured and encrypted, or during decryption the file will indicate it has been corrupted.

Third, any data that identifies patients, such as patient names or identification numbers, is protected against inspection by third parties that may intercept them. This reduces the risk that data could be compromised if blackbox files are sent via email to Baxa Technical Support for analysis.

Data Captured in the Blackbox

The blackbox record captures a variety of events. These events include all communications between the software and the compounder as well as user actions.

Low-Level Data Capture

Low-level data is captured and recorded succinctly to minimize the space used by the blackbox file. These entries simply record the data with no interpretation (other entries may provide a comment to highlight particularly important data).

A salient feature of the blackbox is that it captures all communications between the compounder and the software. This data is captured in a human-readable format, but generally represents a binary message that must be further deciphered by Baxa Technical Support. Example:

| Date | Time | User | Audit Category | Audit Message |
|-----------|-------------|------|----------------|-----------------|
| 8/29/2003 | 11:43:45 AM | jdoe | PUMPSNT | 0x0113110000239 |
| 8/29/2003 | 11:43:45 AM | jdoe | PUMPRCVD | 0x011300 |

In this example, the first entry records that the software sent a command to the EM2400 Pump, which can be deciphered as a request to turn the rotor 569 steps at a speed of 51. The second entry records that the pump responded to the command with an acknowledgment (and will begin pumping).

Because the EM2400 and EM600 Compounders use different protocols for communicating commands, their blackbox entries differ significantly.

Other examples of compounder communications captured by the blackbox:

- status requests
- requests to start, pause, stop the pump
- load cell readings
- flow sensor conditions (bubble or occlusion status)
- valve movement requests
- requests to open or close the valve

Another example of a low-level event is data read from the barcode scanner:

| Date | Time | User | Audit Category | Audit Message |
|-----------|-------------|------|----------------|-------------------|
| 8/29/2003 | 11:36:38 AM | jdoe | BARCODE | Received: 017481L |

In this example, the blackbox simply records that the string “017481L” was received from the barcode scanner. This entry does not indicate how that string is interpreted by the software.

High-Level Data Capture

At a higher level, the blackbox describes user actions and provides a description of important low-level events.

Examples of these blackbox entries include:

- Changes to operating parameters
 - formulary, configuration, option changes
- Security
 - startup/shutdown
 - user logins/logouts
- User actions
 - user selection of a formula
 - user pausing the pump
 - user acknowledgment of a warning
 - user running a report
 - user deleting a formula
 - user changing a container
- Setup
 - pump – start, end of calibration as well as resulting calibration factor
 - load cell – empty and reference weights
- Pumping a bag
 - description of formula to be pumped
 - description of sequence of pumping
 - initial bag weight
 - for each ingredient:
 - port from which pumping will take place
 - current remainder in container

- calculation of number of pump steps necessary
- speed, flow factor to be used while pumping
- any bubble or occlusion detection and user's response
- final remainder after pumping
- container swaps, including barcode verification
- final bag weight and percent error

Reading the Blackbox Data

Users with administrative privileges have the ability to run blackbox reports. These reports can be tailored to include only events between two given times, and can be printed or exported to a variety of formats, including Excel spreadsheets. Because the software captures all communications with the compounder, a great deal of data can be generated in a short period of time, and over a full compounding day, thousands of pages of report data may be produced, depending on the number and type of bags being pumped.

Baxa Technical Support can provide user assistance with the interpretation of blackbox data as required. This is best supplied in the form of encrypted blackbox files, as they are in a more compact form than the reports generated through the Exacta-Mix Software.