



# SCITECX LAB AB



Application Note **EN**  
code e005



## HYCLAS AIR SAMPLER - 21CFR PART 11 AUDIT TRAIL

Rel. 00 - 10/2023



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Application Note - code **e005**  
**21CFR Part 11 - Audit Trail**

## INTRODUCTION

The 21 CFR Part 11 rule states that the FDA view is that the risk of falsification, misinterpretation, and change (without leaving evidence) within the GMP environment are higher with electronic records than paper records, and therefore specific controls are required.

In the application note e004 it is explained the general compliance of HYCLAS sampler to the requirements of the 21CFR part11. In this application note we will see in details one of the typical features: the Audi Trail.

## 21 CFR part 11 Requirements

The 21 CFR 11 is composed of few pages and includes some clause that must be met to declare the air sampler as "compliant".

The clauses that specifically requires the presence of the audit trail is the clause (e), Section 11.10 Subpart B, that state:

*"Use of secure, computer-generated, timestamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and shall be available for agency review and copying."*

## HYCLAS sampler Audit Trail

In the HYCLAS air sampler the Audit Trail is available; every time a parameter is modified; the audit trail records the modification.

Every record of the Audit Trail is composed of two rows as follows.

Record:	Explanation:						
12349 01JUN2022 12:12 user01: Change volume1 1000 to 1005	<table border="1"><tr><td>12349</td><td>01JUN2022 12:12</td><td>user01:</td></tr><tr><td>Change volume1</td><td>1000</td><td>to 1005</td></tr></table>	12349	01JUN2022 12:12	user01:	Change volume1	1000	to 1005
12349	01JUN2022 12:12	user01:					
Change volume1	1000	to 1005					

The complete Audit Trail is composed by a list of every modification made that can impact the sampling data record.



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With the HYCLAS air sampler it is possible to View, print or export the Audit Trail

```
AUDIT TRAIL del 24 Sep 2023
* HyCLAS 100 * SN: 0000001
ALL RECORDS
-----
00417 23Sep2023 16:16:54 adm01
Erase audit trail
00418 23Sep2023 16:17:24 adm01
admin02 created
00419 23Sep2023 16:17:24 adm01
admin03 created
00420 23Sep2023 16:17:24 adm01
admin04 created
00421 23Sep2023 16:17:24 adm01
admin05 created
00422 23Sep2023 16:17:54 adm01
user01 created
00423 23Sep2023 16:17:54 adm01
user02 created
00424 23Sep2023 16:17:54 adm01
user03 created
00425 23Sep2023 16:17:54 adm01
user04 created
```

Audit Trail on PDF File

```
23 Feb 2023 14:02
AUDIT TRAIL 00001/00002
00001 22Feb2023 13:11:06 adm01
admin01 created
00002 22Feb2023 13:15:16 adm01
Change admin01 password
00003 22Feb2023 13:22:54 -----
Wrong passord user01 1/3
00004 22Feb2023 13:36:47 adm01
admin01 created
00005 22Feb2023 13:50:31 adm01
Set Volume1
00006 22Feb2023 13:58:14 adm01
user01 created
```

Audit Trail on Air Sampler Display

## Filtering Audit Trail Data

Since the Audit Trail records a lot of information, it can contain hundreds of records. In order to help the operator to quickly look for the required information, with the HYCLAS air sampler it is possible to filter the AUDIT TRIAL.

It is possible to filter information based on:

- **Period of Time**  
Select the Start Date and End Date.

23 Feb 2023 14:02

START DATE

02/23

mm/yy

23 Feb 2023 14:02

END DATE

02/23

mm/yy





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- **Operator**  
Select the desired operator.

23 Feb 2023 14:02

START DATE

**02/23**

mm/yy

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- **Full Audit Trail**  
To export full Audit Trail.

The Audit Trail will be generated according the desired filter.

In the PDF file the filter information will be reported in the header.

AUDIT TRAIL of 28 Oct 2022	AUDIT TRAIL of 28 Oct 2022
<pre>nyCLAS 100 * SN: 0000001 OPERATOR: user01 ----- 00015 25Oct2022 13:01:03 usr01 Change user01 password 00016 25Oct2022 13:01:03 usr01 Login 00017 25Oct2022 13:02:03 usr01</pre>	<pre>nyCLAS 100 * SN: 0000001 FROM 01Jan2022 TO 31Oct2022 ----- 00001 25Oct2022 12:54:19 adm01 admin01 created 00002 25Oct2022 12:54:19 adm01 Change admin01 password 00003 25Oct2022 12:54:19 adm01</pre>



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## Audit Trail Data Integrity

In order to provide Data Integrity, in the HYCLAS air sampler the saved Audit Trail function have these features:

- **Progressive number**  
Every operation is recorded using a unique counter.  
This counter cannot be reset even if the Audit trail is deleted.
- **Protection against deletion**  
Only exported Audit Trail can be deleted by administrators.  
If a single data has not been previously exported, it is not possible to delete the Audit Trail.
- **Deletion traceability**  
The deletion of the Audit Trail creates an event.  
It is always possible to know who and when deleted the Audit Trail.
- **Capacity Alarm**  
When the Audit trail database reaches the 80% of memory space, a warning message is generated.
- **VIEW (Data not modifiable)**  
The Audit Trail as shown on HYCLAS display is not modifiable.
- **EXPORT (Data not modifiable)**  
It is possible to export the Audit Trail on USB stick.  
The data are saved in a secured PDF file.
- **PRINT (Data not modifiable)**  
It is possible to send the Audit Trail on a PC or an external printer.  
This communication is unidirectional, data can only be printed, the PC software cannot make any modification to the HYCLAS database.