Description

Currently, many institutions related to the healthcare sector use their own traceability software, external to ours. However, this software cannot be directly connected to the different incubators, so the sterilization process within such software remains incomplete.
In order to meet such requirement, Traceability software incorporates (as of version 4.4) a new module named "Traceability Exchange". Such module acts as interface between the compatible incubators and the third parties software, using a system of XML files to implement the data exchange between both systems.

This module is the only component that requires a license in order to operate. It has a one-year trial period, and once finished, the client must pay for a new license.

The results are exported at the same time they are being saved within Traceability software, that is to say, the incubator should be connected to the equipment, take the incubation result, complete the mandatory data, and file it in order to create the exchange file.

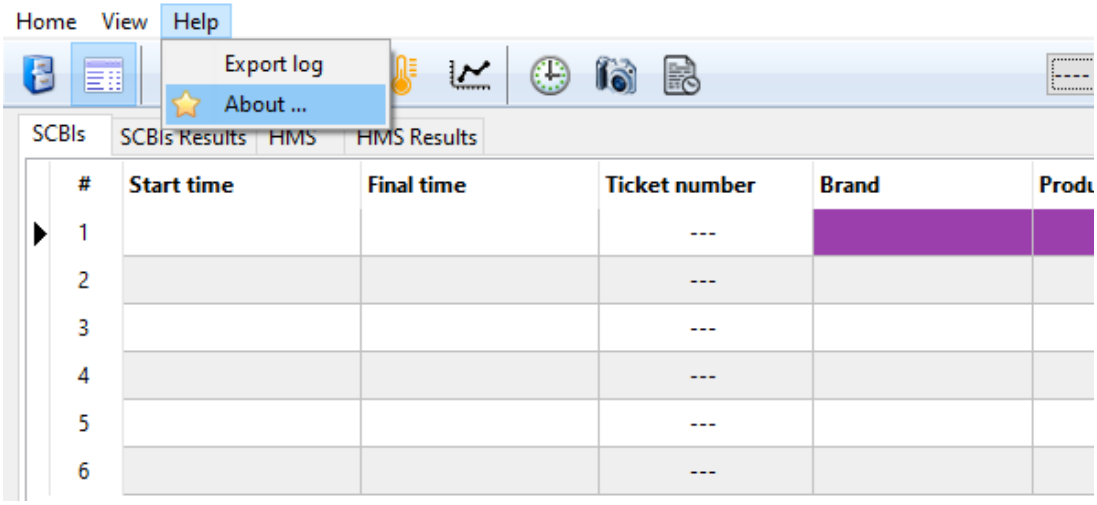
PLUS edition

The Traceability Software incorporates another type of License, since version 4.3, it is called "Traceability Exchange+" and it has a trial period of 3 months.

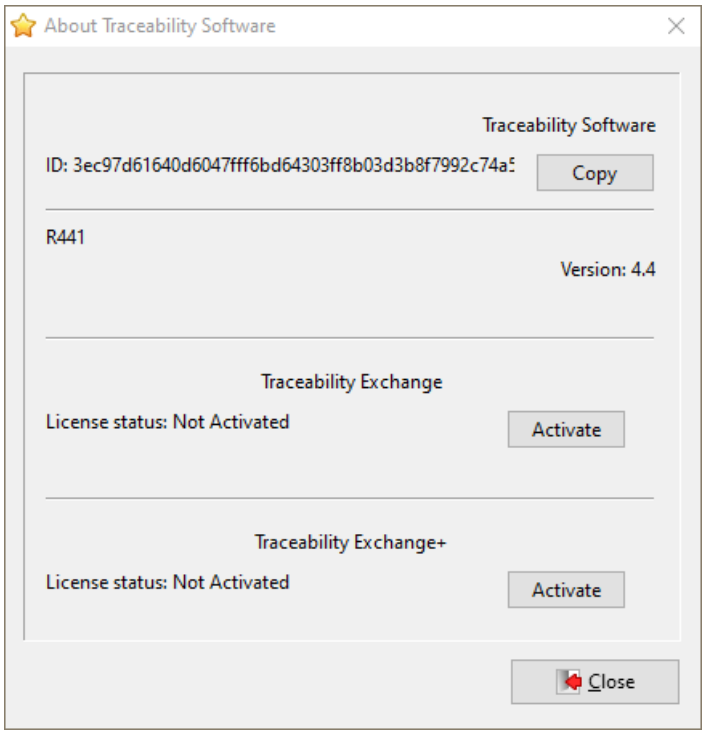
If the user has this License active, all the Biological Indicators and Protein Tests will be saved automatically, regardless of the fields completed, as long as the software remains open. This is true for all the incubators connected to the licensed software, not just the one selected.

Activation process

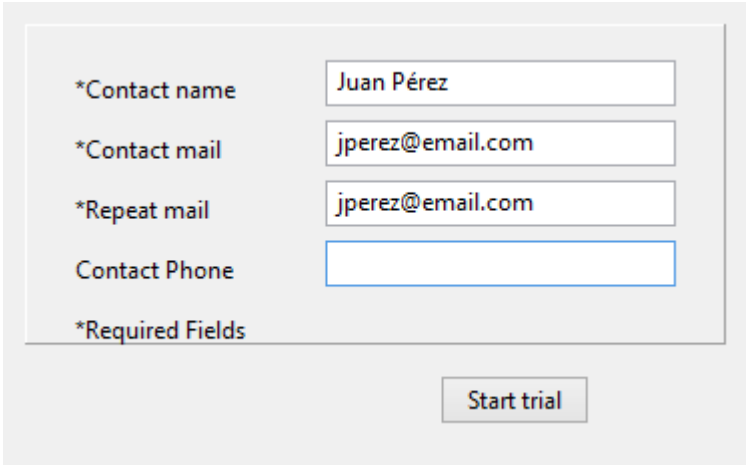
When installing version 4.4 of Traceability software, the functionality "Exchange" is deactivated by default. In order to activate it and start the trial period, you should access the menu "About…"



In the pop-up window, the license status will appear as "Not activated" and button to start this functionality will also show up.

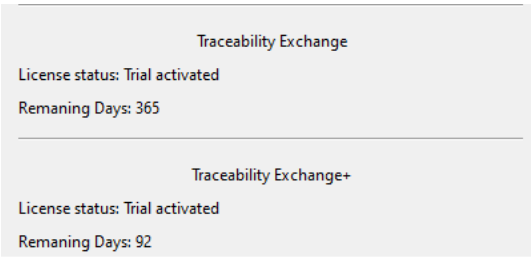


It is necessary to have access to Internet and to complete some contact information in order to start the trial period.



Functioning

Once this functionality is activated, whether in the trial period or in the paid license, the user can check its status in the "About…" window.



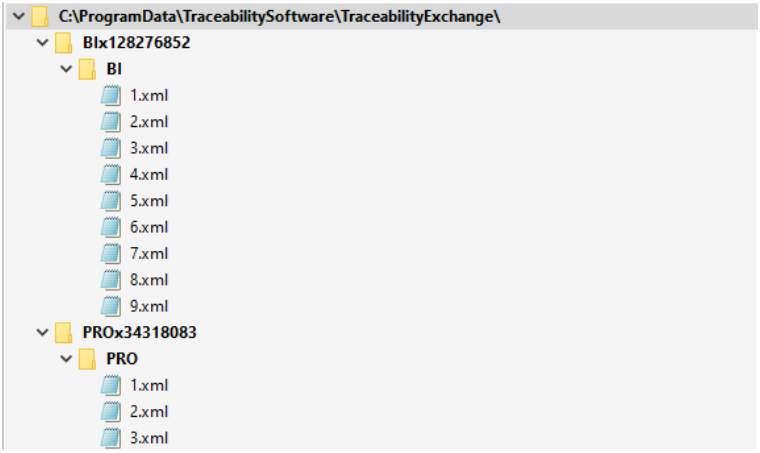
If both licenses are activated at the same time, only the PLUS version will take effect.

Every time an incubation result is filed, regardless of the incubator connected and the type of process, a XML file will be created in the following files' structure:

The root folder will ALWAYS be C:\ProgramData\TraceabilitySoftware\TraceabilityExchange

Inside this folder, a new folder is created for each incubator, with the format [LOT] [SERIES], being for this example the model Bix3 the lot 4218 and the series number 999. Biological indicators' incubations are located in the "BI" folder, whereas the ones corresponding to hygiene Indicators are in the folder "PRO".

The filenames are sequential numbers.



Each file represents a filed incubation. Some examples are available in the Appendix

Biological Indicator Result Schema:

```
<?xml version="1.0" encoding="utf-8" ?>

<xs:schema attributeFormDefault="unqualified" elementFormDefault="qualified"
xmlns:xs="http://www.w3.org/2001/XMLSchema">

  <xs:element name="BI">

    <xs:complexType>

      <xs:sequence>

        <xs:element name="Slot" type="xs:integer" minOccurs="0" />

        <xs:element name="Serial" type="xs:integer" minOccurs="0" />

        <xs:element name="Lot" type="xs:string" minOccurs="0" />

        <xs:element name="Operator" type="xs:string" minOccurs="0" />

        <xs:element name="Start_time" type="xs:dateTime" minOccurs="0" />

        <xs:element name="Finish_time" type="xs:dateTime" minOccurs="0" />

        <xs:element name="Brand" type="xs:string" minOccurs="0" />

        <xs:element name="Product_code" type="xs:string" minOccurs="0" />

        <xs:element name="Batch" type="xs:string" minOccurs="0" />

        <xs:element name="Mode" type="xs:integer" minOccurs="0" />

        <xs:element name="Process" type="xs:integer" minOccurs="0" />

        <xs:element name="DValue" type="xs:decimal" minOccurs="0" />

        <xs:element name="SCBI_status" type="xs:integer" minOccurs="0" />

        <xs:element name="Result" type="xs:unsignedByte" minOccurs="0" />

        <xs:element name="Avg_temp" type="xs:decimal" minOccurs="0" />

        <xs:element name="Book" type="xs:string" minOccurs="0" />

        <xs:element name="Sheet" type="xs:string" minOccurs="0" />

        <xs:element name="Cycle" type="xs:integer" minOccurs="0" />
```

```
            <xs:element name="Steril_ID" type="xs:string" minOccurs="0" />
            <xs:element name="Sterilizer" type="xs:string" minOccurs="0" />
            <xs:element name="Steril_serial" type="xs:string" minOccurs="0" />
            <xs:element name="Load_number" type="xs:string" minOccurs="0" />
            <xs:element name="Prog_number" type="xs:string" minOccurs="0" />
            <xs:element name="Conditions" type="xs:string" minOccurs="0" />
            <xs:element name="Observations" minOccurs="0" />
            <xs:element name="Archive_time" type="xs:dateTime" minOccurs="0" />
            <xs:element name=" TicketId" type="xs:integer" minOccurs="0" />
          </xs:sequence>
        </xs:complexType>
      </xs:element>
    </xs:schema>
```

Biological Indicator Result Data Detail

NodeName	DataType	VALUES	Description
Slot	INTEGER	MIN=1 MAX= 12	Position of the incubator where the BI is being incubated and read.
Serial	INTEGER	MIN=0 MAX= 999	Serial number of the incubator
Lot	STRING (32)		Lot number of the incubator
Operator	STRING (16)		Name of user that was logged in during incubation of this BI
Start_time	DATETIME	YYYY-MM-DDThh:mm:ssTZD	Gives the exact date and time of beginning of the incubation
Finish_time	DATETIME	YYYY-MM-DDThh:mm:ssTZD	Gives the exact date and time of finalization of readout
Brand	STRING (32)		Brand of the BI
Product_code	STRING (32)		Product code of the BI
Batch	STRING (24)		Batch number of the BI
Mode	INDEX (INTEGER)	1 3h / 60°C 2 4h / 37°C 3 1h / 60°C 4 1/2h / 60°C 5 2h / 60°C 6 1/3h / 60°C	Program (time/temperature) set in the incubator
Process	INDEX (INTEGER)	1 STEAM (121) 2 STEAM (128)	Conditions for calculation of the D-Value

		3 STEAM (132) 4 STEAM (134) 5 STEAM (135) 6 EO (30) 7 EO (54) 8 FORM (60) 9 VH2O2 (27) 10 VH2O2 (45) 11 VH2O2 (50)	
DValue	FLOAT (.3)	#.###	Provides information about the resistance of that BI batch
SCBI_status	INDEX (INTEGER)	0 Positive 1 Expuesto	"Positive" (positive control, non-exposed) "Exposed" (to the sterilization cycle).
Result	INDEX (INTEGER)	0 Positive 1 Negative 2 Cancelled	Actual result given by the incubator
Avg_temp	FLOAT (2)	#.##	Average temperature during the incubation period of that BI
Book	STRING (16)		Logbook information (book where you keep your records, including the incubator´s printed ticket)
Sheet	STRING (16)		Complete with logbook page number corresponding to sterilization process.
Cycle	INTEGER	#	Cycle number, provided in the sterilizer screen and/or ticket
Steril_ID	STRING (52)		Descriptive name of the sterilizer used for the process

Sterilizer	STRING (32)		Brand of the sterilizer
Steril_serial	STRING (24)		Serial number of the sterilizer, in case you have 2 or more of the same brand
Load_number	STRING (16)		Load number of the day.
Prog_number	STRING (16)		Program of the sterilizer used for that cycle.
Conditions	STRING (32)		You can fill this box with details about the cycle (not mandatory information).
Observations	STRING (200)		You can fill this box with any information you consider relevant and it is not already considered in the other fields
Archive_time	DateTime	YYYY-MM-DDThh:mm:ssTZD	Gives the exact date and time this file was generated
TicketId	INTEGER	#	Indicates the ticket number of the unit.

Protein Pen Result Schema:

```
<?xml version="1.0" encoding="utf-8" ?>

<xs:schema attributeFormDefault="unqualified" elementFormDefault="qualified"
xmlns:xs="http://www.w3.org/2001/XMLSchema">

  <xs:element name="PRO">

    <xs:complexType>

      <xs:sequence>

        <xs:element name="Slot" type="xs:integer" minOccurs="0" />

        <xs:element name="Serial" type="xs:integer" minOccurs="0" />

        <xs:element name="Lot" type="xs:string" minOccurs="0" />

        <xs:element name="Operator" type="xs:string" minOccurs="0" />

        <xs:element name="Start_time" type="xs:dateTime" minOccurs="0" />

        <xs:element name="Finish_time" type="xs:dateTime" minOccurs="0" />

        <xs:element name="Brand" type="xs:string" minOccurs="0" />

        <xs:element name="Product_Code" type="xs:integer" minOccurs="0" />

        <xs:element name="Batch" type="xs:string" minOccurs="0" />

        <xs:element name="Result" type="xs:integer" minOccurs="0" />

        <xs:element name="Visual_Result" type="xs:integer" minOccurs="0" />

        <xs:element name="Protein_Level" type="xs:decimal" minOccurs="0" />

        <xs:element name="Avg_temp" type="xs:decimal" minOccurs="0" />

        <xs:element name="Book" type="xs:string" minOccurs="0" />

        <xs:element name="Sheet" type="xs:string" minOccurs="0" />

        <xs:element name="Cycle" type="xs:integer" minOccurs="0" />

        <xs:element name="Prog_Number" type="xs:string" minOccurs="0" />

        <xs:element name="Surface" type="xs:string" minOccurs="0" />
```

```
            <xs:element name="Identification" type="xs:string" minOccurs="0" />
            <xs:element name="Washer" type="xs:string" minOccurs="0" />
            <xs:element name="Washer_Serial" type="xs:string" minOccurs="0" />
            <xs:element name="Observations" type="xs:string" minOccurs="0" />
            <xs:element name="Treshold" type="xs:decimal" minOccurs="0" />
            <xs:element name="Archive_time" type="xs:dateTime" minOccurs="0" />
            <xs:element name=" TicketId" type="xs:integer" minOccurs="0" />
          </xs:sequence>
        </xs:complexType>
      </xs:element>
    </xs:schema>
```

Protein Pen Result Data Detail

NodeName	DataType	VALUES	Description
Slot	INTEGER	MIN=1 MAX= 12	Shows the position in which the protein incubation process is being performed
Serial	INTEGER	MIN=0 MAX= 999	Serial number of the incubator
Lot	STRING (32)		Lot number of the incubator
Operator	STRING (16)		Name of user that was logged in during incubation of this protein test
Start_time	DATETIME	YYYY-MM-DDThh:mm:ssTZD	Gives the exact date and time of beginning of the incubation
Finish_time	DATETIME	YYYY-MM-DDThh:mm:ssTZD	Gives the exact date and time of finalization of readout
Brand	STRING (32)		Brand of the protein test
Product_Code	INDEX (INTEGER)	0/1 PRO1 micro 2 PRO1 VTP 3 PRO1 VTN	Product code of the protein test
Batch	STRING (24)		Batch number of the protein test
Result	INDEX (INTEGER)	0 Positive 1 Negative 2 Cancelled 3 Positive	Protein test result according to the incubator´s information
Visual_Result	INDEX (INTEGER)	-1 --- 0 Positive	Protein test visual confirmation through color change interpretation

		1 Negative	
Protein_Level	STRING	>10 1,00 ~ 9,90 <1 0	Quantitative Protein test result according to the incubator's information. This result is given in micrograms (µg) of protein
Avg_temp	FLOAT	#.##	Average temperature during the incubation period of that protein test
Book	STRING (16)		Complete with the logbook number corresponding to the washing process.
Sheet	STRING (16)		Complete with the logbook page number corresponding to the washing process.
Cycle	INTEGER	#	Cycle number, provided in the washer ticket or display
Prog_Number	STRING (16)		Program used for that specific washing cycle.
Surface	STRING (32)		Gives information about the item that has been sampled.
Identification	STRING (32)		Descriptive name of the washer machine used for the process
Washer	STRING (32)		Washer´s brand
Washer_Serial	STRING (24)		Serial number of the washer
Observations	STRING (200)		You can fill in this box with any relevant information that has not been considered in other fields
Threshold	FLOAT	#.##	Defines the protein level (µg) from which the hygiene indicator result will be considered as positive.
Archive_time	DATETIME	YYYY-MM-DDThh:mm:ssTZD	Gives the exact date and time this file was generated

TicketId	INTEGER	#	Indicates the ticket number of the unit.

Appendix – Examples

Biological Indicator Example

```
<?xml version="1.0" encoding="utf-8"?>
<IB>
 <Slot>4</Slot>
 <Serial>98</Serial>
 <Lot>Bix129999</Lot>
 <Operator>admin</Operator>
 <Start_time>2019-08-30T10:26:29-03:00</Start_time>
 <Finish_time>2019-08-30T10:29:00-03:00</Finish_time>
 <Brand>PRODBRAND</Brand>
 <Product_code>PRODCODE</Product_code>
 <Batch>PRODBATCH</Batch>
 <Mode>6</Mode>
 <Process>7</Process>
 <DValue>3.000</DValue>
 <SCBI_status>0</SCBI_status>
 <Result>0</Result>
 <Avg_temp>59.9</Avg_temp>
 <Book>LIBRO</Book>
 <Sheet>FOLIO</Sheet>
 <Cycle>15555</Cycle>
 <Steril_ID>STERILIZERID</Steril_ID>
 <Sterilizer>STERILBRAND</Sterilizer>
```

<Steril_serial>STERILSERIAL</Steril_serial>

<Load_number>LOADN</Load_number>

<Prog_number>PROGN</Prog_number>

<Conditions>SOME CONDITIONS</Conditions>

<Observations></Observations>

<Archive_time>2019-08-30T10:32:09-03:00</Archive_time>

<TicketId>10</TicketId>

</IB>

Protein test Example

<?xml version="1.0" encoding="utf-8"?>

<PRO>

<Slot>1</Slot>

<Serial>1</Serial>

<Lot>Bix120001</Lot>

<Operator>admin</Operator>

<Start_time>2019-08-30T10:12:01-03:00</Start_time>

<Finish_time>2019-08-30T10:27:00-03:00</Finish_time>

<Brand>Brand</Brand>

<Product_Code>1</Product_Code>

<Batch>LOT</Batch>

<Result>3</Result>

<Visual_Result>0</Visual_Result>

<Protein_Level>7.1</Protein_Level>

<Avg_temp>59.9</Avg_temp>

<Book>Book</Book>

<Sheet>Page</Sheet>

<Cycle>1555</Cycle>

<Prog_Number>NroProg</Prog_Number>

<Surface>Instrument</Surface>

<Identification>IDENTIF</Identification>

<Washer>WasherBrand</Washer>

<Washer_Serial>WasherSerial</Washer_Serial>

<Observations>This is an observation</Observations>

<Treshold>1.0</Treshold>

<Archive_time>2019-08-30T10:28:56-03:00</Archive_time>

<TicketId>52</TicketId>

</PRO>