

Bionova® Exchange Module – Developer's Manual

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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 Bionova incubators, so the sterilization process within such software remains incomplete.

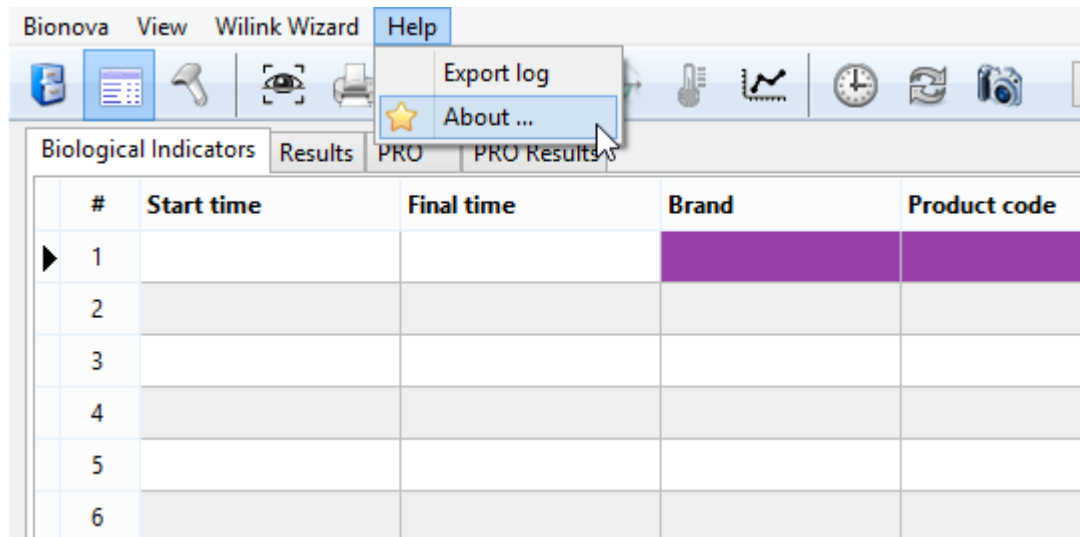
In order to meet such requirement, Bionova software incorporates (as of version 3.5) a new module named "Bionova Exchange". Such module acts as interface between the compatible incubators and the third parties software, using a system of XML files to implement the data exchange between both systems.

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 Bionova 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.

Activation process

When installing version 3.5 of Bionova software, the functionality "Exchange" is deactivated by default. In order to activate it and start the trial period, you should access the menu "About..."



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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.

A screenshot of a contact information form. The form is enclosed in a light gray border. It contains several labeled input fields. The first field is labeled "*Contact name" and contains the text "Juan Pérez". The second field is labeled "*Contact mail" and contains the text "jperez@email.com". The third field is labeled "*Repeat mail" and also contains the text "jperez@email.com". The fourth field is labeled "Contact Phone" and is currently empty. Below these fields is a label "*Required Fields". At the bottom center of the form is a button labeled "Start trial".

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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.



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\bionova\BionovaExchange

Inside this folder, a new folder is created for each incubator, with the format [LOT] [SERIES], being for this example the lot IC1020FR9999 and the series number 098. 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 integers.

▲ C:\ProgramData\bionova\BionovaExchange\	14,2 KB
▲ IC1020FR9999098	13,4 KB
▲ BI	9,5 KB
1.xml	887 Bytes
2.xml	887 Bytes
3.xml	887 Bytes
4.xml	887 Bytes
5.xml	887 Bytes
6.xml	887 Bytes
7.xml	887 Bytes
8.xml	887 Bytes
9.xml	887 Bytes
10.xml	888 Bytes
11.xml	888 Bytes
▲ PRO	3,9 KB
1.xml	824 Bytes
2.xml	798 Bytes
3.xml	798 Bytes
4.xml	798 Bytes
5.xml	781 Bytes
▲ MINIPRO1919001	824 Bytes
▲ PRO	824 Bytes
1.xml	824 Bytes

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

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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" />
```

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```
<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:sequence>
```

```
</xs:complexType>
```

```
</xs:element>
```

```
</xs:schema>
```

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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

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		3	STEAM (132)	
		4	STEAM (134)	
		5	STEAM (135)	
		6	EO (30)	
		7	EO (54)	
		8	FORM (60)	
		9	VH202 (27)	
		10	VH202 (45)	
		11	VH202 (50)	
DValue	FLOAT (.3)	#.###		Provides information about the resistance of that BI batch
SCBI_status	INDEX (INTEGER)	0	Positive	"Positive" (positive control, non-exposed)
		1	Expuesto	"Exposed" (to the sterilization cycle).
Result	INDEX (INTEGER)	0	Positive	Actual result given by the incubator
		1	Negative	
		2	Cancelled	
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

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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

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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" />
```

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```
<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:sequence>
```

```
</xs:complexType>
```

```
</xs:element>
```

```
</xs:schema>
```

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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 1 Negative	Protein test visual confirmation through color change interpretation

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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

Cleaning Indicator Result Schema

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

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

```
  <xs:element name="CI">
```

```
    <xs:complexType>
```

```
      <xs:sequence>
```

```
        <xs:element name="Date" type="xs:dateTime"/></xs:element>
```

```
        <xs:element name="GTIN" type="xs:int"/></xs:element>
```

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

```
        <xs:element name="Expiration_Date" type="xs:dateTime"/></xs:element>
```

```
        <xs:element name="Production_Date" type="xs:dateTime"/></xs:element>
```

```
        <xs:element name="Manufacturer" type="xs:string"/></xs:element>
```

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

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

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

```
        <xs:element name="Result" type="xs:int"/></xs:element>
```

```
        <xs:element name="Washer_ID" type="xs:string"/></xs:element>
```

```
        <xs:element name="Washer_Brand" type="xs:string"/></xs:element>
```

```
        <xs:element name="Washer_Serial" type="xs:string"/></xs:element>
```

```
        <xs:element name="Cycle" type="xs:int"/></xs:element>
```

```
        <xs:element name="Process_Time" type="xs:string"/></xs:element>
```

```
        <xs:element name="Temperature" type="xs:string"/></xs:element>
```

```
        <xs:element name="Location" type="xs:string"/></xs:element>
```

```
        <xs:element name="Concentration" type="xs:string"/></xs:element>
```

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```

<xs:element name="DetergentType" type="xs:string"></xs:element>

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

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

<xs:element name="Prog_number" type="xs:string"></xs:element>

<xs:element name="WaterPress" type="xs:string"></xs:element>

<xs:element name="WaterHard" type="xs:string"></xs:element>

<xs:element name="Image" type="xs:string"></xs:element>

<xs:element name="Observations" type="xs:string"></xs:element>

<xs:element name="Trazanto_serial" type="xs:string"></xs:element>

</xs:sequence>

</xs:complexType>

</xs:element>

</xs:schema>

```

Cleaning Indicator Result Data Detail

NodeName	DataType	VALUES	Description
DATE	DATETIME	YYYY-MM-DDThh:mm:ssTZD	Gives the exact date and time this file was generated
GTIN	STRING (32)		Global Trade Item Number of the indicator
Operator	STRING (16)		Name of user that was logged in during indicator analysis
Expiration_Date	DATETIME	YYYY-MM-DDThh:mm:ssTZD	Expiration date of the indicator
Production_Date	DATETIME	YYYY-MM-DDThh:mm:ssTZD	Production date of the indicator

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Manufacturer	STRING (32)		Manufacturer of the indicator
Brand	STRING (32)		Brand of the indicator
Product_code	STRING (32)		Product code of the indicator
Batch	STRING (32)		Batch number of the indicator
Result	INDEX (INTEGER)	0 SAFE 1 UNSAFE	Analysis result according to the incubator's information
Washer_ID	STRING (52)		Descriptive name of the Cleaning machine used in the process
Sterilizer	STRING (32)		Brand of the Cleaning machine used in the process
Steril_serial	STRING (24)		Serial number of the Cleaning machine used in the process
Cycle	INTEGER		Cycle number of the cleaning process.
Process_Time	STRING (16)		Time that the indicator was exposed to the cleaning process
Temperature	STRING (16)		Temperature of the sterilization or cleaning cycle
Concentration	STRING (16)		Percentage of concentration of the detergent utilized at the cleaning processes
Location	STRING (16)		Location of the chemical indicator inside the cleaning machine.
DetergentType	STRING (16)		The type of detergent utilized at the cleaning process
Book	STRING (16)		Number of the log book corresponding of the process.

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Sheet	STRING (16)		Number of the log page corresponding of the process.
Prog_number	STRING (16)		Number of the program that the machine uses for that cycle.
WaterPress	STRING (16)		Pressure of the water utilized at the cleaning cycle.
WaterHard	STRING (16)		Parameter that defines the quality of the water utilized at the cleaning cycle.
Image	Base64 Image		Digitized image of the indicator
Observations	STRING (200)		Any relevant information that has not been considered in other fields
Trazanto_serial	STRING (16)		Serial Number of the Trazanto reader used

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Sterilization Indicator Result Schema

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

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

```
  <xs:element name="SI">
```

```
    <xs:complexType>
```

```
      <xs:sequence>
```

```
        <xs:element name="Date" type="xs:dateTime"/></xs:element>
```

```
        <xs:element name="GTIN" type="xs:int"/></xs:element>
```

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

```
        <xs:element name="Expiration_Date" type="xs:dateTime"/></xs:element>
```

```
        <xs:element name="Production_Date" type="xs:dateTime"/></xs:element>
```

```
        <xs:element name="Manufacturer" type="xs:string"/></xs:element>
```

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

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

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

```
        <xs:element name="Result" type="xs:int"/></xs:element>
```

```
        <xs:element name="Sterilizer_ID" type="xs:string"/></xs:element>
```

```
        <xs:element name="Sterilizer_Brand" type="xs:string"/></xs:element>
```

```
        <xs:element name="Steril_serial" type="xs:string"/></xs:element>
```

```
        <xs:element name="Cycle" type="xs:int"/></xs:element>
```

```
        <xs:element name="Process_Time" type="xs:string"/></xs:element>
```

```
        <xs:element name="Temperature" type="xs:string"/></xs:element>
```

```
        <xs:element name="Package" type="xs:string"/></xs:element>
```

```
        <xs:element name="Concentration" type="xs:string"/></xs:element>
```

```
        <xs:element name="RH" type="xs:string"/></xs:element>
```

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

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

<xs:element name="Prog_number" type="xs:string"></xs:element>

<xs:element name="Image" type="xs:string"></xs:element>

<xs:element name="Observations" type="xs:string"></xs:element>

<xs:element name="Trazanto_serial" type="xs:string"></xs:element>

</xs:sequence>

</xs:complexType>

</xs:element>

</xs:schema>
```

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Sterilization Indicator Result Data Detail

NodeName	DataType	VALUES	Description
DATE	DATETIME	YYYY-MM-DDThh:mm:ssTZD	Gives the exact date and time this file was generated
GTIN	STRING (32)		Global Trade Item Number of the indicator
Operator	STRING (16)		Name of user that was logged in during indicator analysis
Expiration_Date	DATETIME	YYYY-MM-DDThh:mm:ssTZD	Expiration date of the indicator
Production_Date	DATETIME	YYYY-MM-DDThh:mm:ssTZD	Production date of the indicator
Manufacturer	STRING (32)		Manufacturar of the indicator
Brand	STRING (32)		Brand of the indicator
Product_code	STRING (32)		Product code of the indicator
Batch	STRING (32)		Batch number of the indicator
Result	INDEX (INTEGER)	0 SAFE 1 UNSAFE	Analysis result according to the incubator's information
Sterilizer_ID	STRING (52)		Descriptive name of the Sterilizer machine used in the process
Sterilizer	STRING (32)		Brand of the Sterilizer used in the process
Steril_serial	STRING (24)		Serial number of Sterilizer used in the process
Cycle	INTEGER	#	Cycle number of the sterilization process.

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Process_Time	STRING (16)		Time that the indicator was exposed to the sterilization process
Temperature	STRING (16)		Temperature of the sterilization cycle
Package	STRING (16)		The number of the packet which contained the chemical indicator during the sterilization process.
Concentration	STRING (16)		Percentage of concentration of the sterilization agent used in the sterilization processes.
RH	STRING (16)		Relative humidity condition, given in percentage, at the moment the sterilization process was made.
Book	STRING (16)		Number of the log book corresponding of the process.
Sheet	STRING (16)		Number of the log page corresponding of the process.
Prog_number	STRING (16)		Number of the program that the sterilizer uses for that cycle.
Image	Base64 Image		Digitized image of the indicator
Observations	STRING (200)		Any relevant information that has not been considered in other fields
Trazanto_serial	STRING (16)		Serial Number of the Trazanto reader used

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Appendix – Examples

Biological Indicator Example

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

<IB>

  <Slot>4</Slot>

  <Serial>98</Serial>

  <Lot>IC1020FR9999</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>
```

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```
<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>  
</IB>
```

Protein test Example

```
<?xml version="1.0" encoding="utf-8"?>  
<PRO>  
  <Slot>1</Slot>  
  <Serial>1</Serial>  
  <Lot>IC1020FR0001</Lot>  
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  <Protein_Level>7.1</Protein_Level>  
  <Avg_temp>59.9</Avg_temp>  
  <Book>Book</Book>  
  <Sheet>Page</Sheet>
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TERRAGENE®

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<Cycle>1555</Cycle>
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<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>
</PRO>
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Cleaning Indicator Example (CI) – The image field has a smaller font in order to save space in this document

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  <GTIN>07798164676799</GTIN>
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  <Production_Date>2019-07-19T00:00:00-03:00</Production_Date>
  <Manufacturer>TERRAGENE</Manufacturer>
  <Brand>CHEMDYE</Brand>
  <Product_code>CDWA4</Product_code>
  <Batch>CDWA4030719</Batch>
  <Result>1</Result>
```