Roberto Gobita

Tectronik srl, Limena (PD) - Italy

F_{value} DRIVEN RETORT FOR CANNED FOOD STERILIZATION → ACCEPTANCE BY THE US FDA ?

Jan 2018

Tectronik srl

- Validation company (Hospital and Pharma industries - pertinent EN norms).
- *Ebro* logger distributor in Italy.

Act as **Process Authority** (Small Medium Sized food processors) and **FFR**, and **SIDs** management.

Economic tissue at present in Europe

Which Companies (small companies):

- 10 employees
- a annual turnover up to 2 milions Euro

How many:

over 4.100.000 : 95% of the total of enterprises in Italy; about 93,2% of the total European (19 countries) enterprises (about 18 million units)

Occupated personnel:

47% of total private employees- no agricoltural-, in Italy; 39% into the European Union (UE based on 19 countries); 11% in the United States

Their trend:

absolutely increasing in the last 10 years; Italy : highest number

These numbers = General + Food related Companies

situation:

- **Small**
- forced to **manufacture "niche" products** and **export** them (USA).

They have limited resources (money and personnel) : different from the USA **SME** definition!

The purchase of a retort for a European SME represents an important investment : the local market offers a variety of choice.

More and more Manufacturer have implemented into their retort PLCs

<u>the F0 functions</u>

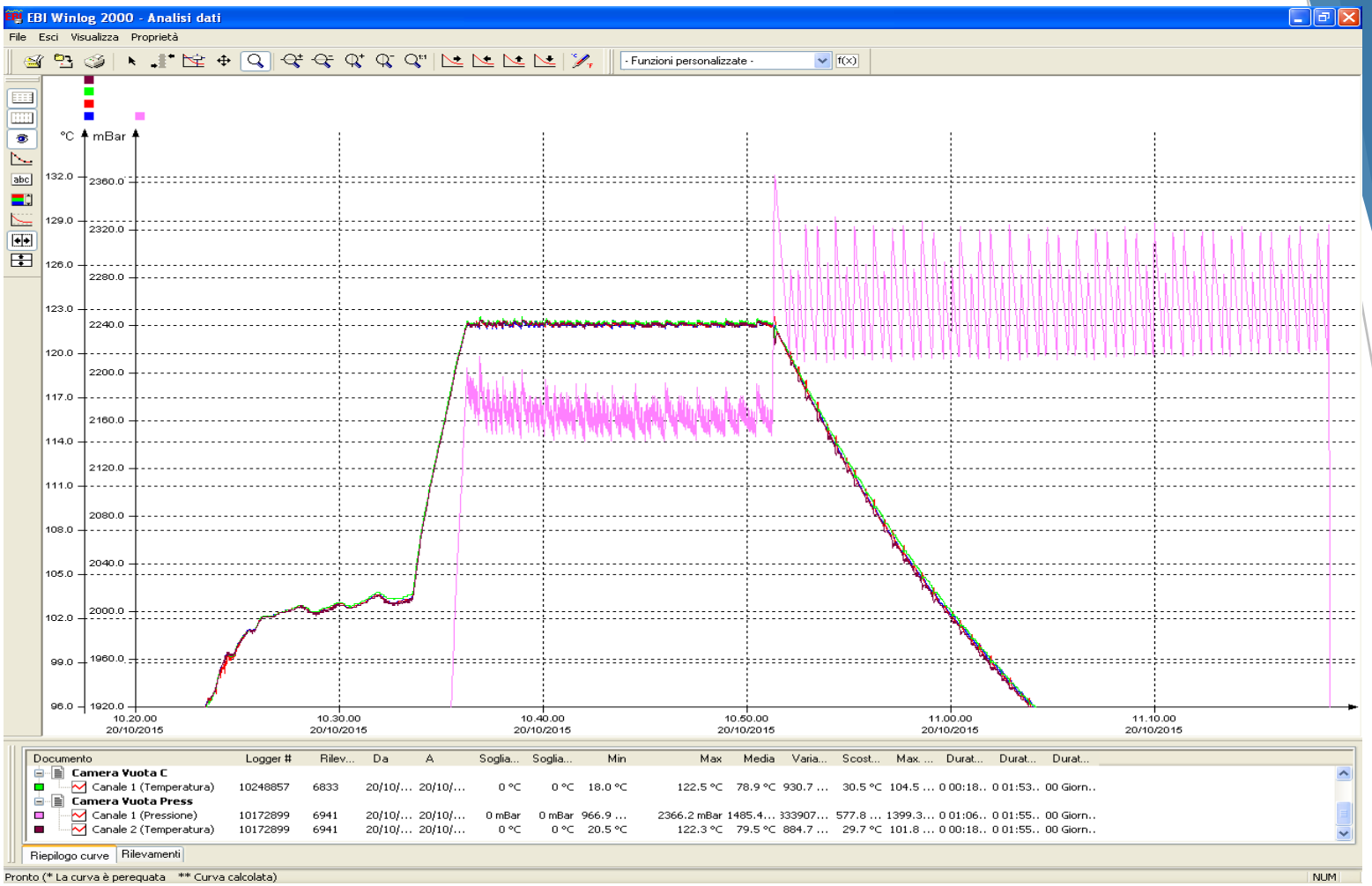
for the production batch control of sterilized foods.

As most of you know, F0 is:

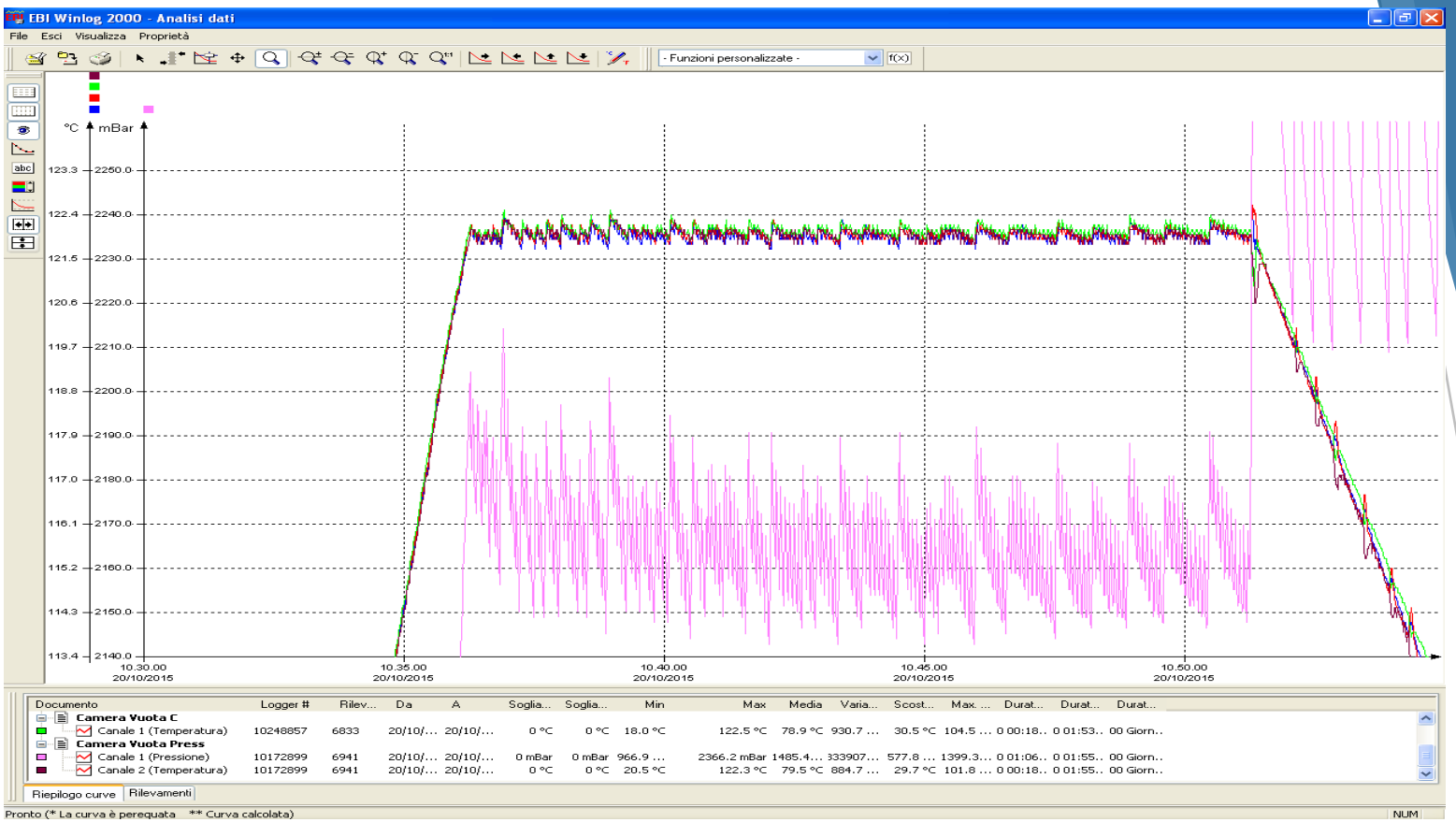
$$F_0 = \sum \Delta t \times 10^{\left(\frac{T - 121.11}{z}\right)}$$

Where:
T = Temperature
Δt = Dwell time at the considered Temperature (e.g. 1 min)
z = Temperature coefficient = 10 °C

Which in practice is a calculation which means a “equivalent” cooking time at 121,1°C.



A typical sterilization plateau shows always small fluctuations at 121,1°C.

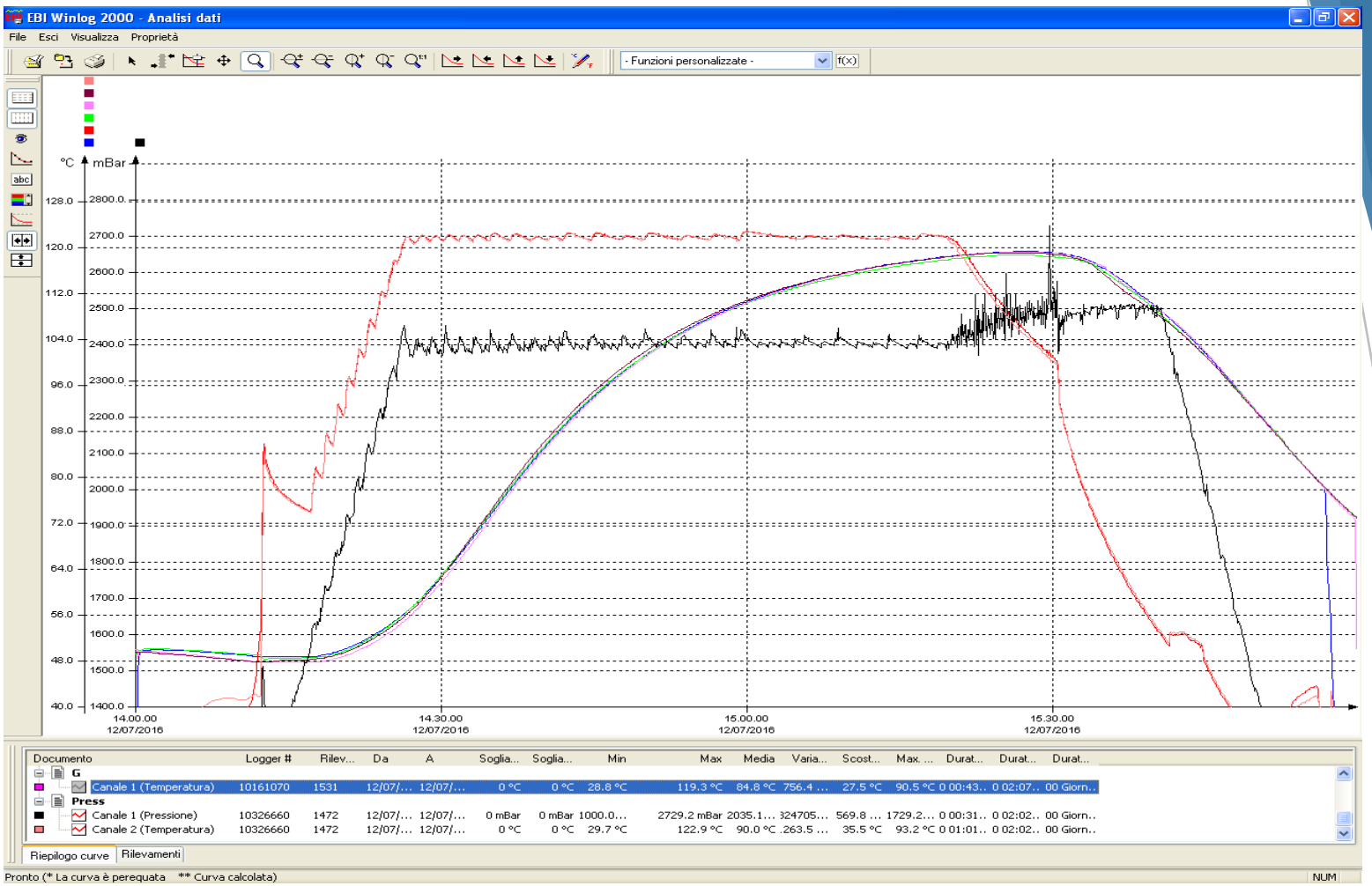


Time/temperature settings → different studies

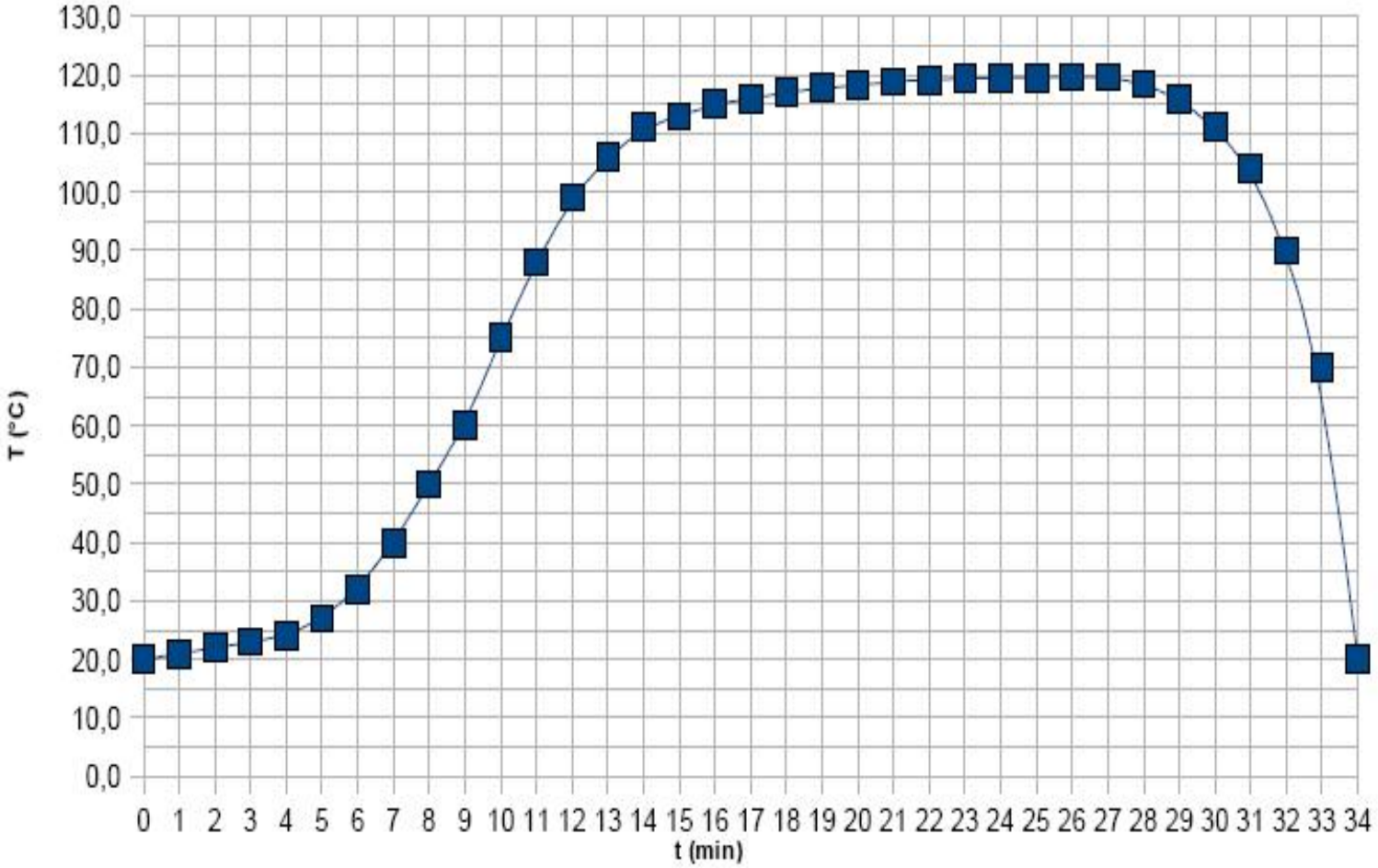
- different behaving products
- different can/jar sizes

to set up sterilization programs to achieve commercial sterility whilst preserving organoleptic characteristics.

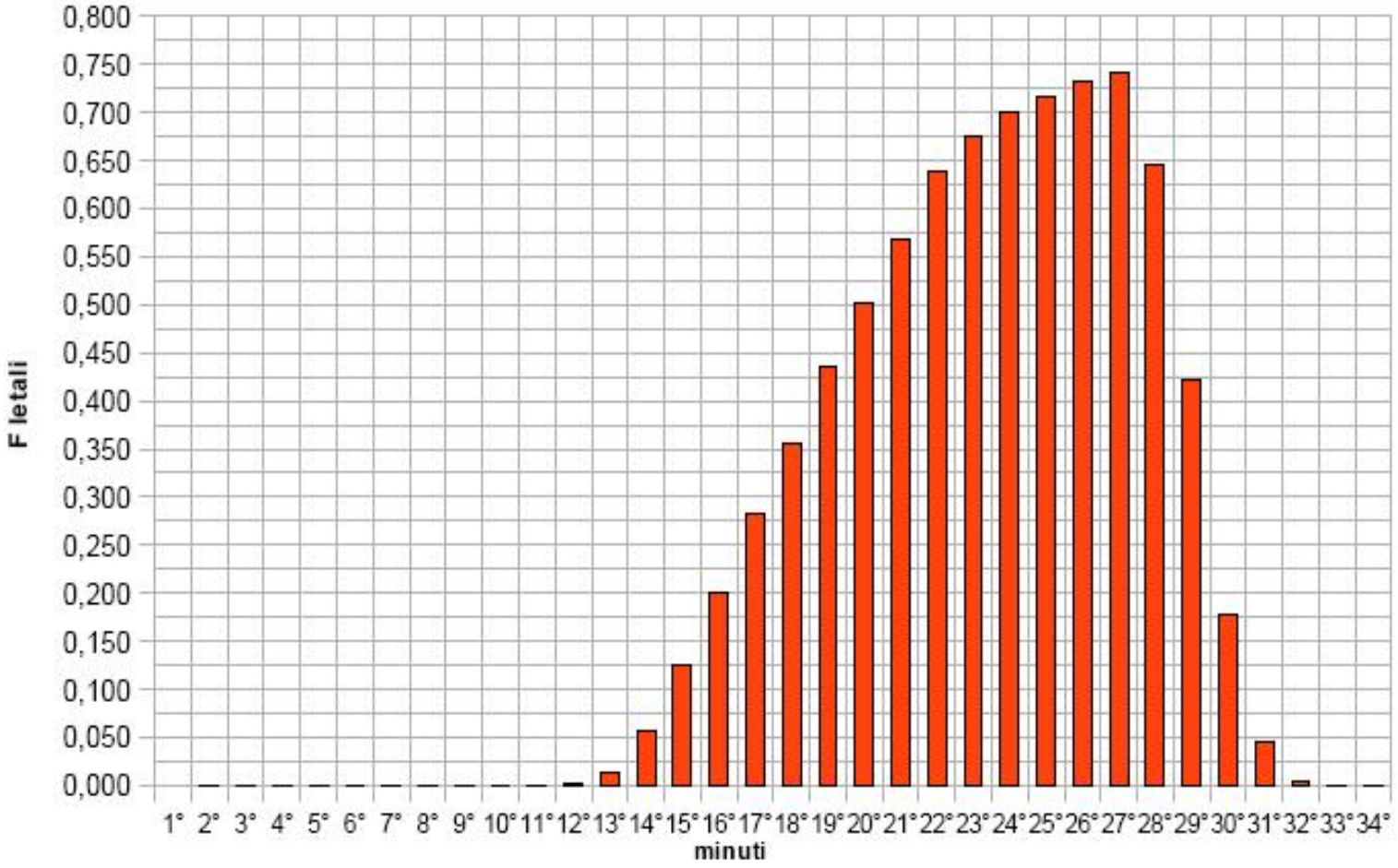
Typically, when applying for a SID to the US FDA, above means a program change (evaluated and documented by appropriated studies).



Outside temperature…. Pressure….. Inside temperature…

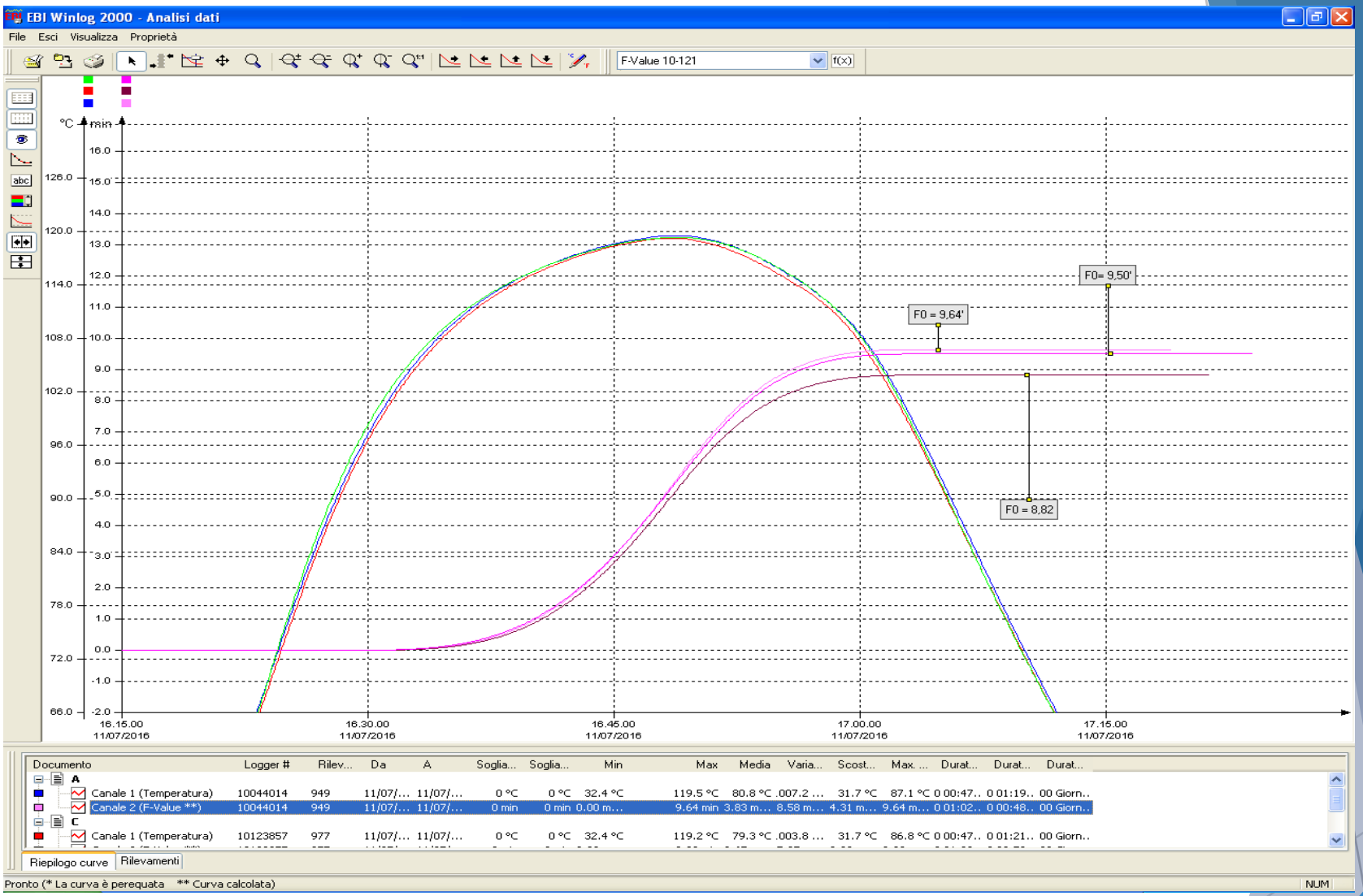


Curve progression in relative time

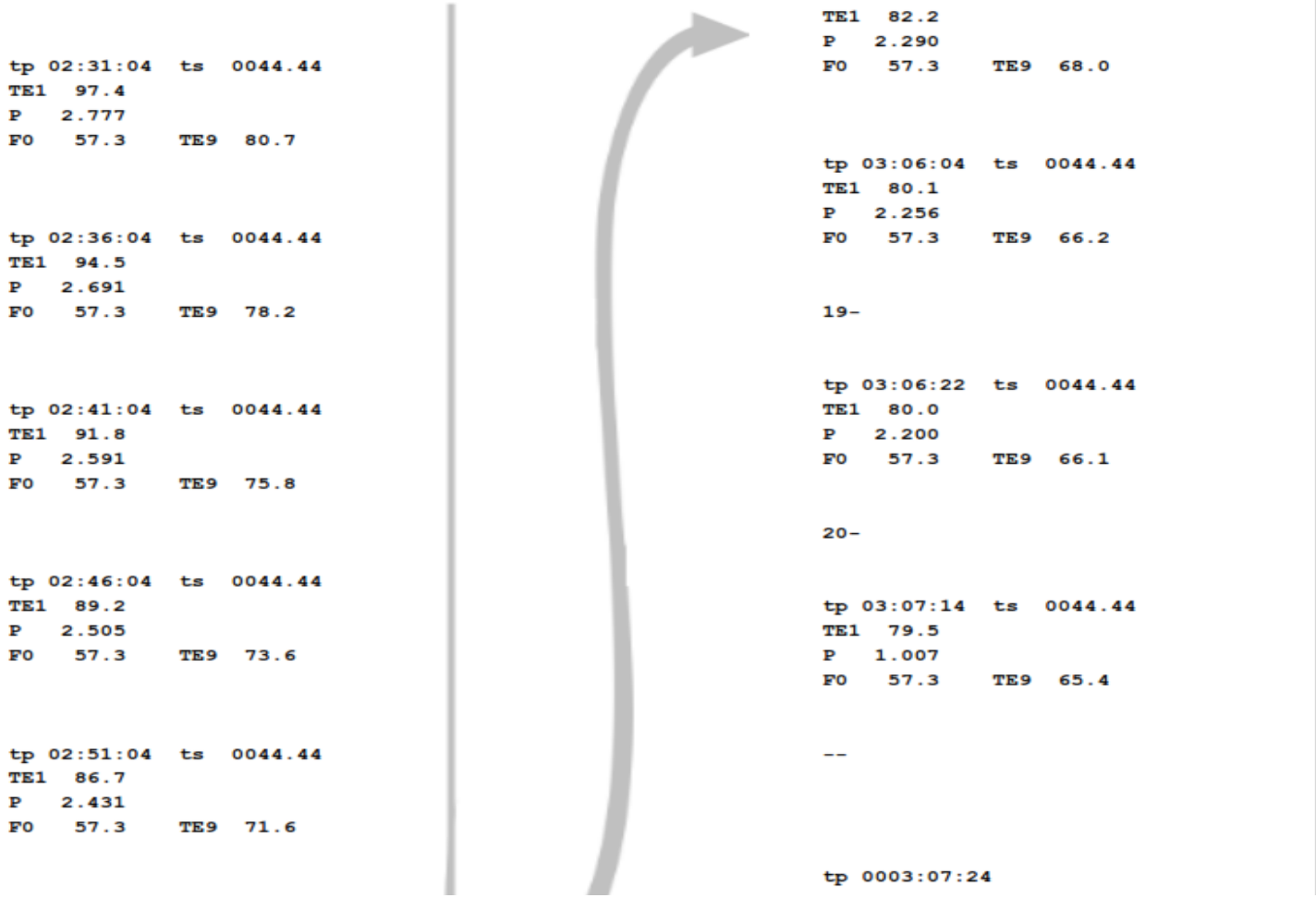


Thermal contribution during a sterilization process.

F0 = the last (and most important) value to be obtained in a food thermal process



Inside curves + F_{value} on a «*nice*» process



F0 implementation dramatically reduces the number of studies required for “traditional” time /temperature based processes.

When enhancing a food sterilization activity :

- **TD**, Temperature Distribution
- (and/or) **HTD**, Heat Transfer Distribution

Homogeneity of F0 studies into the different points of the retorts could represent a shorter procedure.

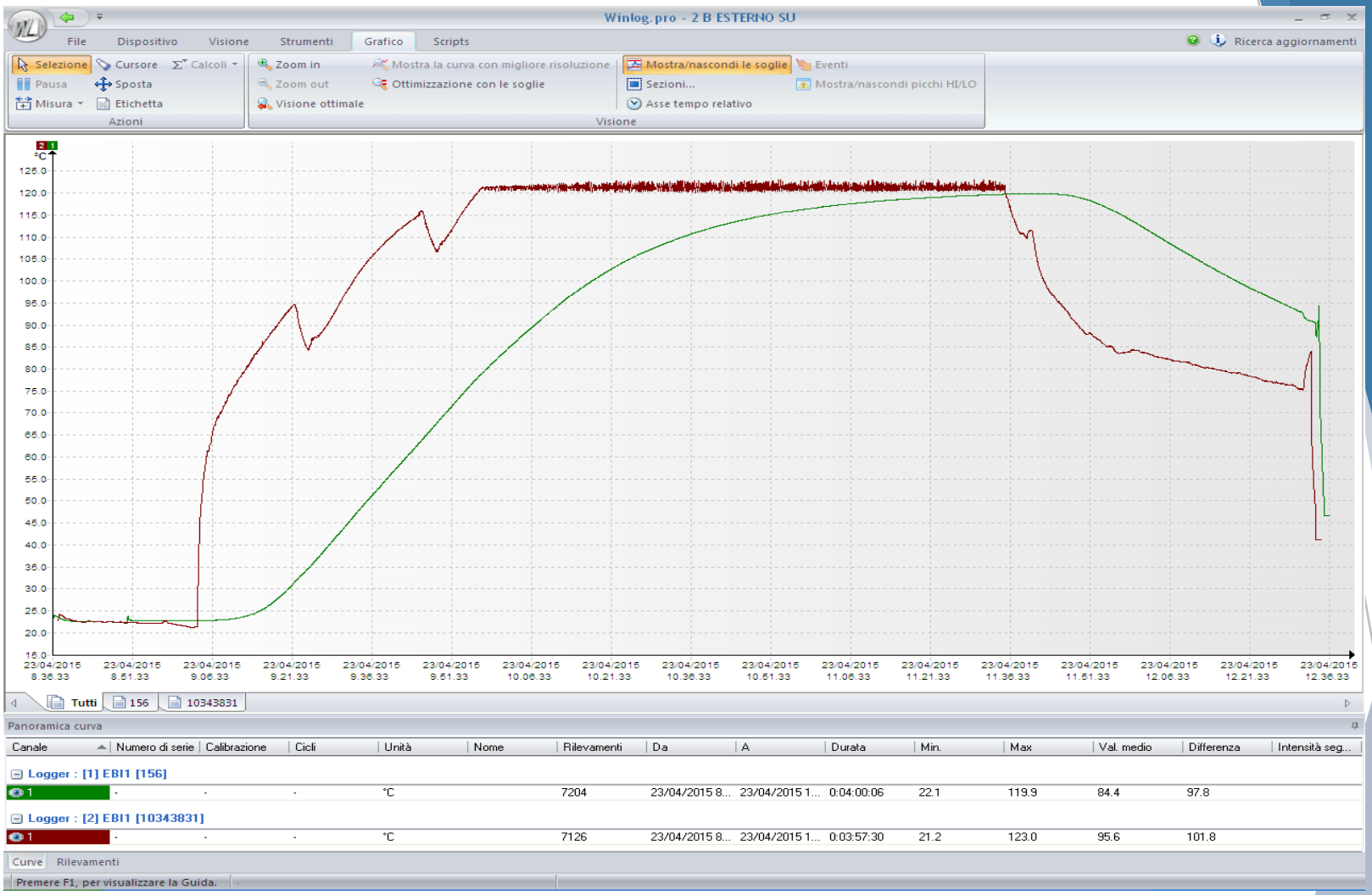
IQ, OQ, PQ

According to *EN norms*, a **validation** of a device is the final document which includes :

the **I**nstallation **Q**ualification, the **O**perational **Q**ualification and the **P**erformance **Q**ualification.

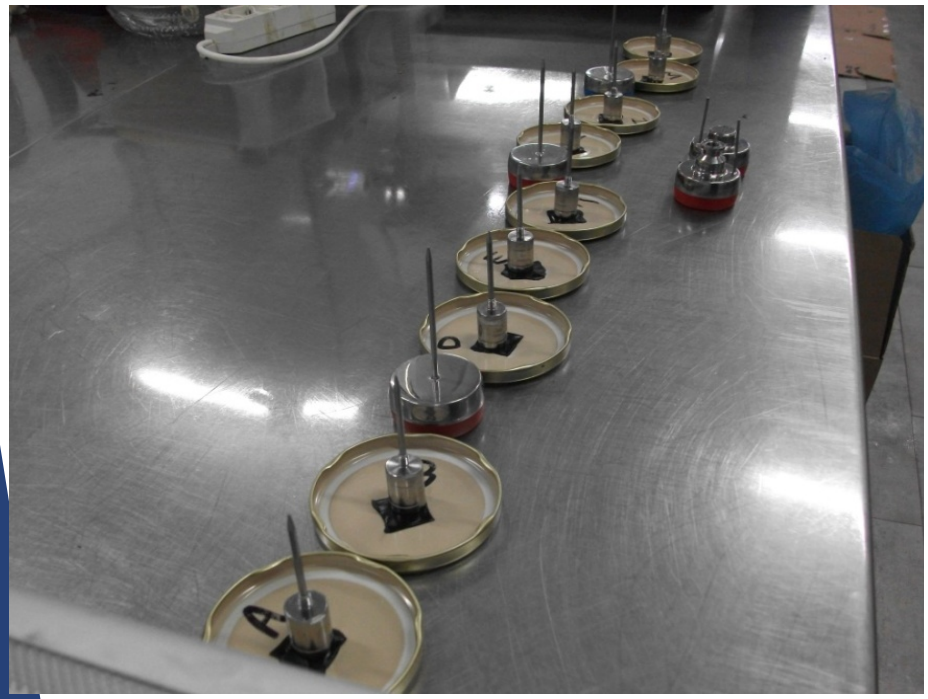
- A **TD** or a **HTD** study (in case of air/steam) could be offered as a part of the OQ.
- Heat penetration will be then delegated to third party for the product tests and the final **validation** document.

..Open discussion on this subject!



HTD : Inhert material run external/internal

«Inside» loggers for HP studies into truffles sauce



N° of loggers ready for the process

Outside loggers into creamy truffles

F0 control probe

F0 target values are available :

- in literature
- by expert (public) institutions in the European Countries;

The identification of required target (for a specific process) makes the tests repetition in each different product meaningless.

- according to F0 based program setting, Heat Penetration studies are the most important to be performed as a demonstration of success.

In fact,

a **TID** (placed *in the cold spot inside a can/jar specimen*, located in *identified cold spot of the retort - could be also determined by multiple HP studies…*), stops the program plateau only once the targeted F_{value} has been reached,

regardless of :

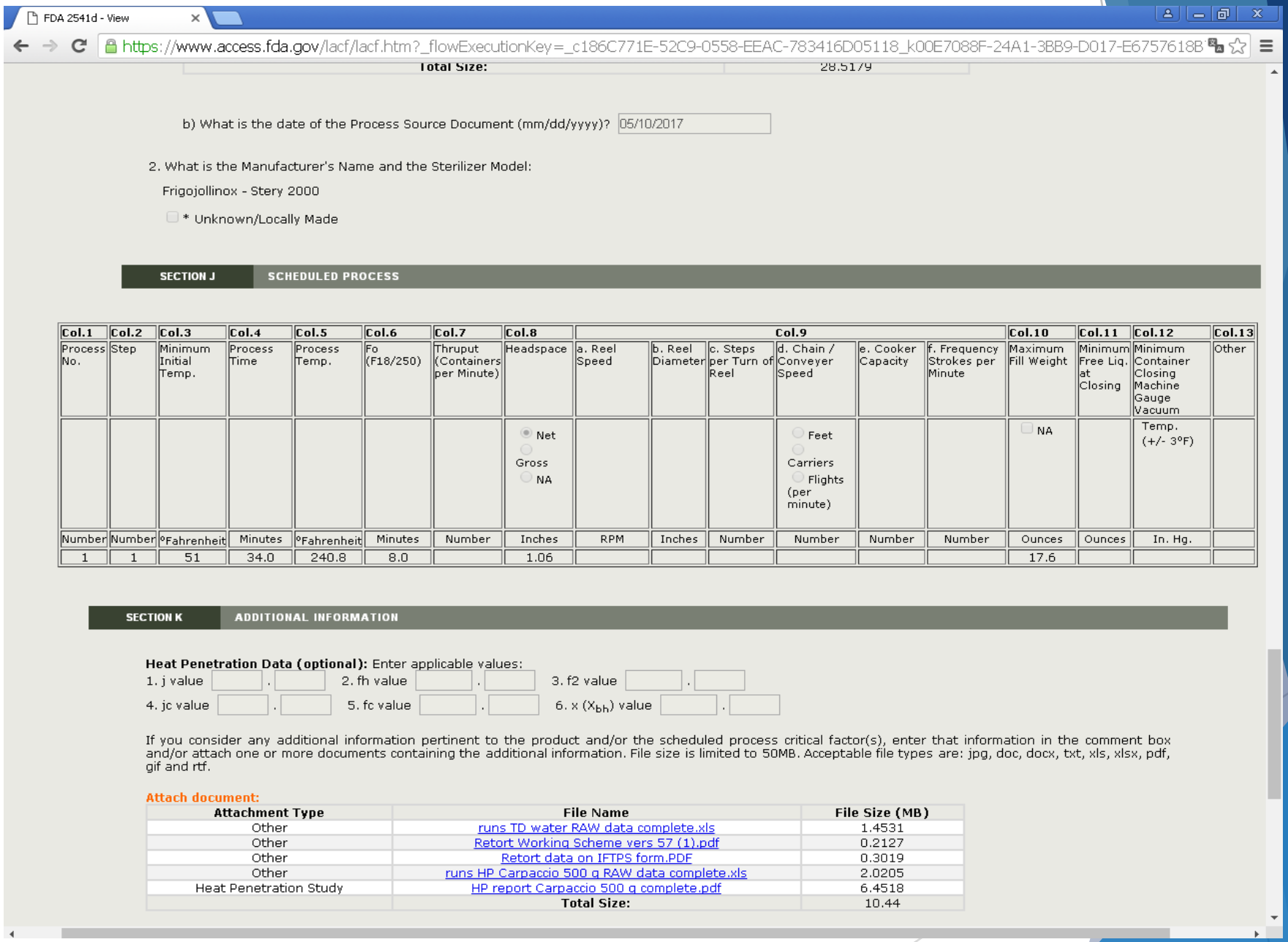
- size of the can/jar
- product canned nature and its starting temperature

According to form **2541d**,

(which is the one where LACF processors should upload to get the SID) the missing of :

- start temperature
- process time
- Temperature

are “blocking” elements which will cause blocking of the uploading procedure as well as “inquiry” by the officer in case of incorrect declarations.


FDA 2541d - View
https://www.access.fda.gov/lacf/lacf.htm?_flowExecutionKey=_c186C771E-52C9-0558-EEAC-783416D05118_k00E7088F-24A1-3BB9-D017-E6757618B
Total Size: 28.5179
b) What is the date of the Process Source Document (mm/dd/yyyy)? 05/10/2017
2. What is the Manufacturer's Name and the Sterilizer Model:
Frigojollinox - Stery 2000
* Unknown/Locally Made
SECTION J SCHEDULED PROCESS
Col.1 Process No. | Col.2 Step | Col.3 Minimum Initial Temp. | Col.4 Process Time | Col.5 Process Temp. | Col.6 Fo (F18/250) | Col.7 Thruput (Containers per Minute) | Col.8 Headspace | Col.9 a. Reel Speed | b. Reel Diameter | c. Steps per Turn of Reel | d. Chain / Conveyer Speed | e. Cooker Capacity | f. Frequency Strokes per Minute | Col.10 Maximum Fill Weight | Col.11 Minimum Free Liq. at Closing | Col.12 Minimum Container Closing Machine Gauge Vacuum | Col.13 Other
Net Gross NA | Feet Carriers Flights (per minute) | NA | Temp. (+/- 3°F)
Number | Number | °Fahrenheit | Minutes | °Fahrenheit | Minutes | Number | Inches | RPM | Inches | Number | Number | Number | Number | Ounces | Ounces | In. Hg.
1 | 1 | 51 | 34.0 | 240.8 | 8.0 | | 1.06 | | | | | | | 17.6
SECTION K ADDITIONAL INFORMATION
Heat Penetration Data (optional): Enter applicable values:
1. j value . 2. fh value . 3. f2 value .
4. jc value . 5. fc value . 6. x (X_{bh}) value .
If you consider any additional information pertinent to the product and/or the scheduled process critical factor(s), enter that information in the comment box and/or attach one or more documents containing the additional information. File size is limited to 50MB. Acceptable file types are: jpg, doc, docx, txt, xls, xlsx, pdf, gif and rtf.
Attach document:
Attachment Type | File Name | File Size (MB)
Other | runs TD water RAW data complete.xls | 1.4531
Other | Retort Working Scheme vers 57 (1).pdf | 0.2127
Other | Retort data on IFTPS form.PDF | 0.3019
Other | runs HP Carpaccio 500 g RAW data complete.xls | 2.0205
Heat Penetration Study | HP report Carpaccio 500 g complete.pdf | 6.4518
Total Size: 10.44

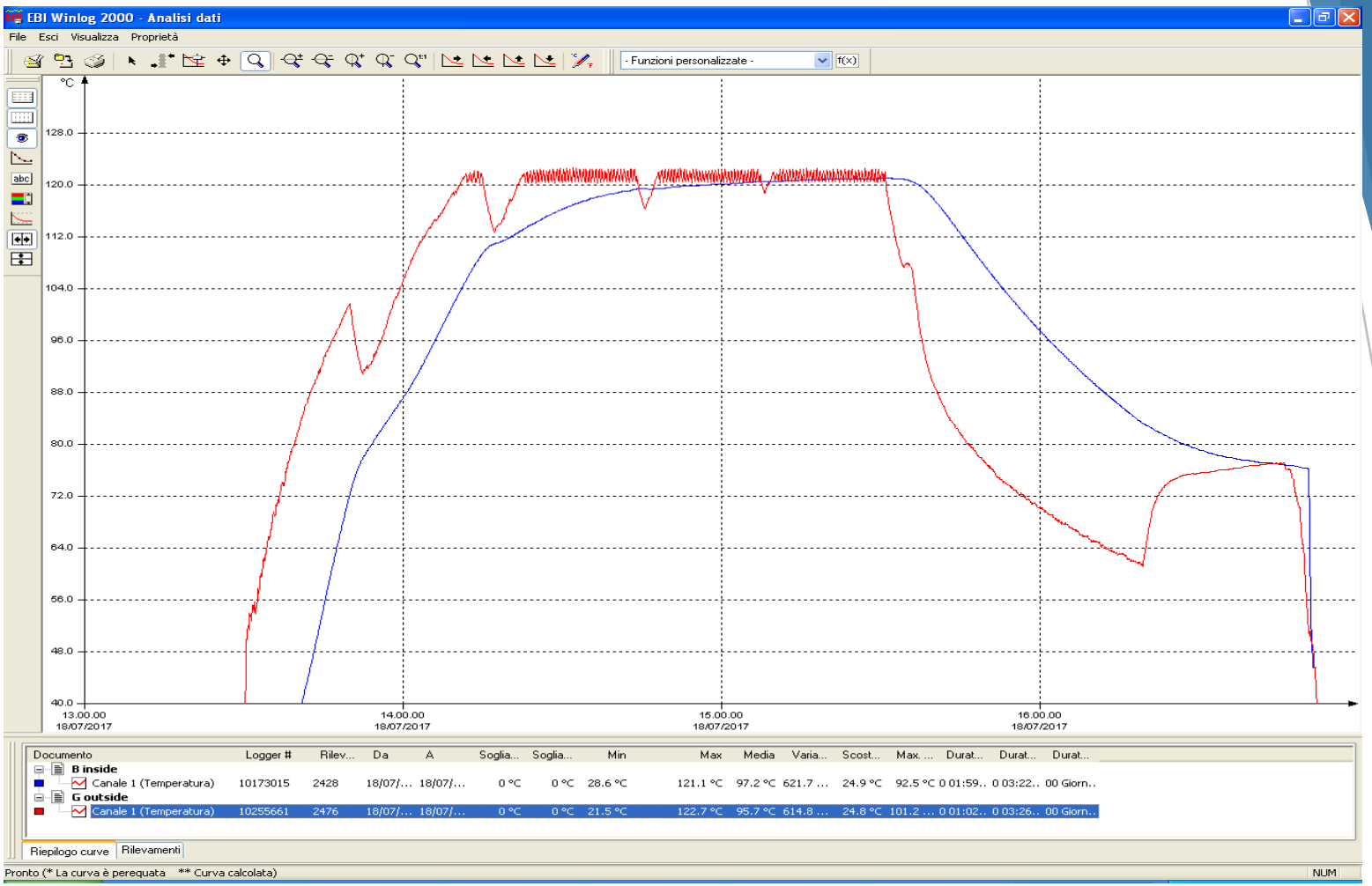
F0 driven retorts make all the variables like *size of the can/jar, start temperature*, etc… elements which influence only the process duration.

Note: during the cooling phase F0 still will increase of some before it lowers below 100C°.

When setting the target value,
It is necessary to consider to avoid both:

too short cooking time ↙ ↘ too long exposure

When something goes wrong?



Error in maintain of steam into the chamber, but process ends at the achieving of the F value targeted.

In the previous presentation the retort printout records the alarm but at the end of the cycle also considers the cooking as successful.

- Is it acceptable?

Even if the retort condition are definitely not acceptable,

the thermal contribution to the food has been granted anyhow (see the inside curve) and F value has also been achieved

so the current load could be released as “safe”

Please comments on this step!

Human Factors

A further *objection* :

- internal probe placement

The person in charge of this task must be trained and well conscious of this action responsibility.

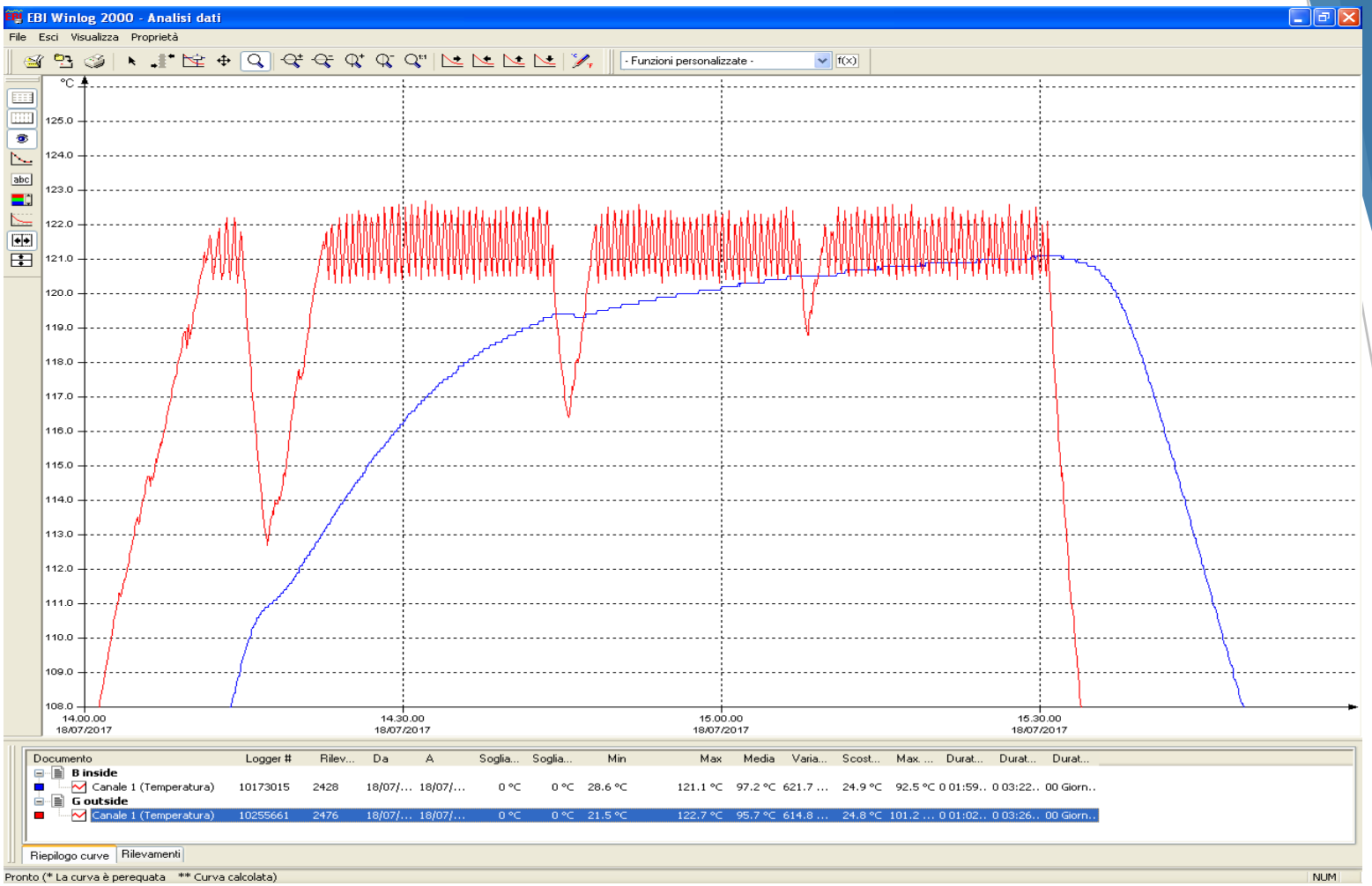
A separate data logger into a “second” container = help to match result.

Moreover,

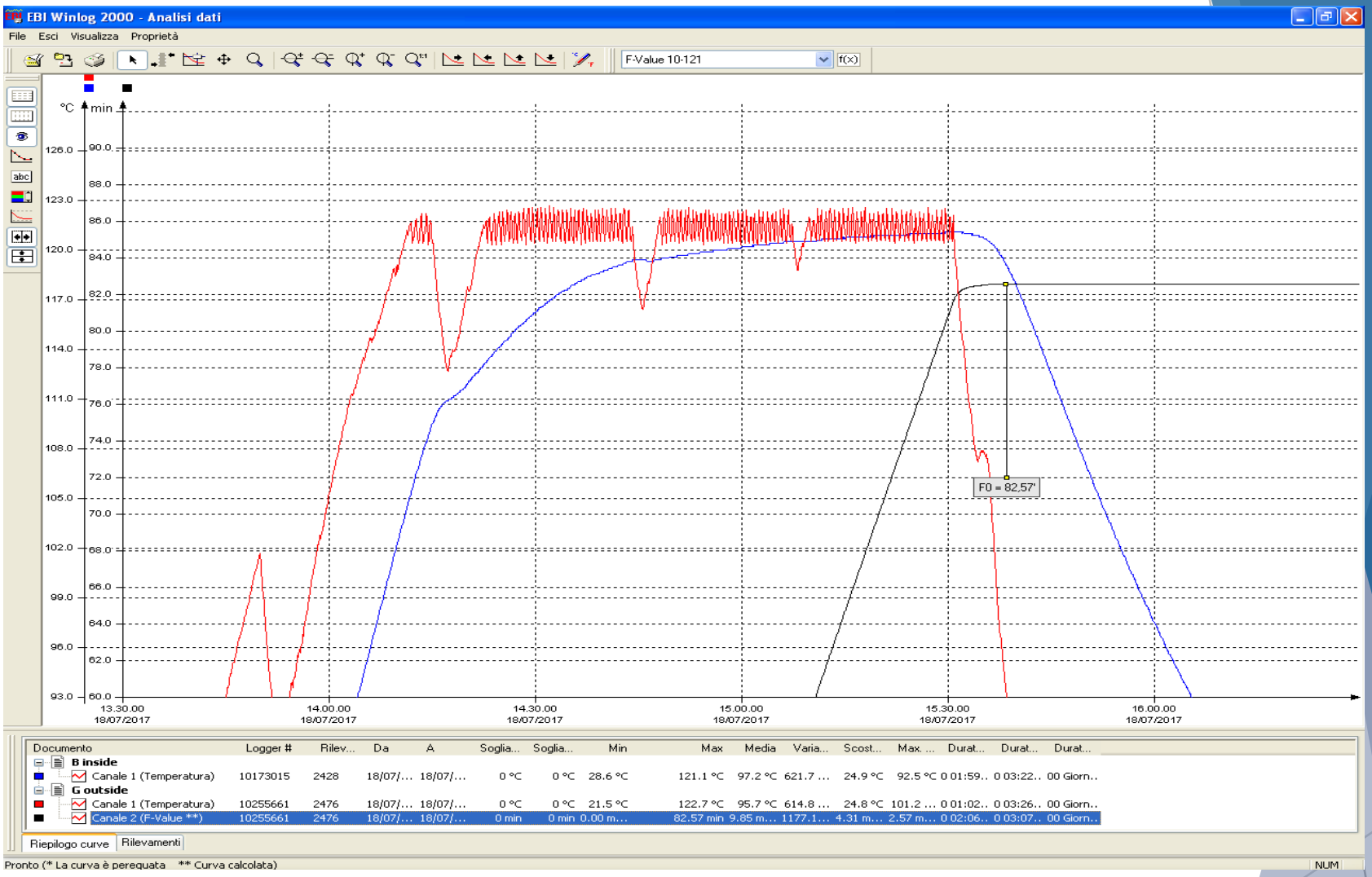
- BRC (*british*) of IFS (*german*) rule
- protocols issued by supermarket chains (Europe)

require a sterilization proof by independent measuring device

Your opinions are most welcomed on this subject !



Larger errors during cooking



… but F0 achieved!

Could it be a future discussion (?) that :

IFTPS
(by the protocols point of view)

FDA
(by the LACF SID " form" point of view)

would consider the possibility to amend the protocols/forms accordingly to allow this increasing technology as well to the form filling options.

Thanks for your attention

Roberto Gobita

Special thanks to Stefano Virgone

(IFTPS Member)