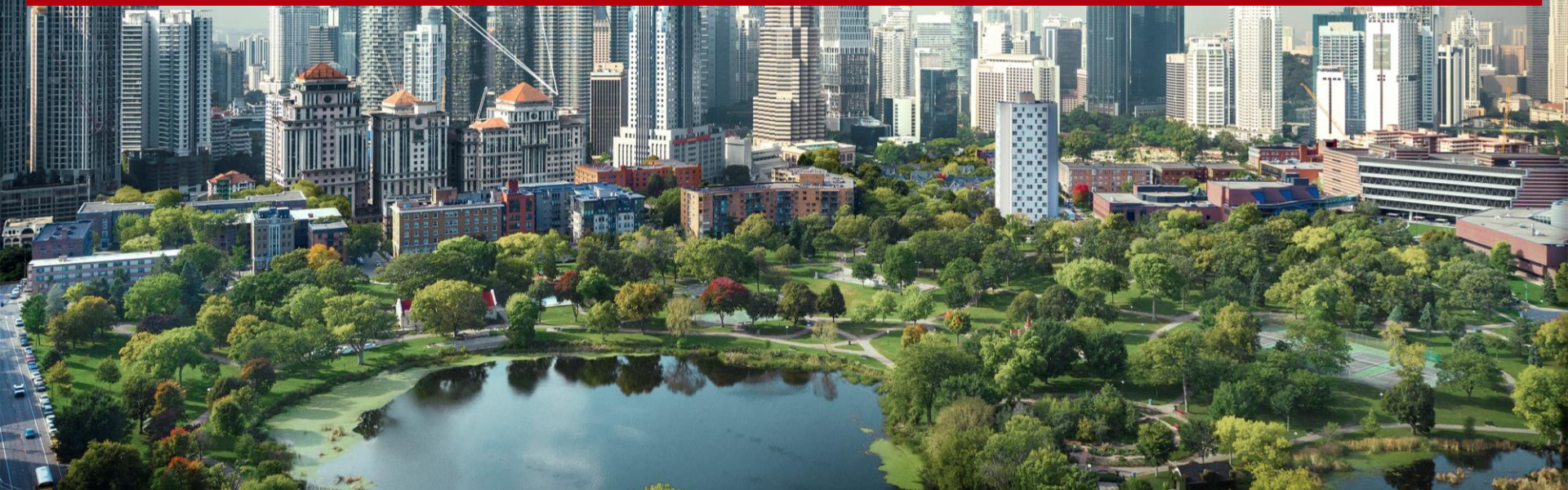
ENGINEERING TOMORROW

Case Study
Protection of Pharmaceutical Vials at Stevanato Group

Antonio Terio, Sales & Business Development Manager, Danfoss Fire Safety

Thursday 22nd of October 2020 - IWMA Webinar



Presenter's BIO profile

Who I am

Antonio Terio
Sales & Business Development Manager
Cyprus, Israel, Italy, Malta

ate@danfoss.com

+39 340 325 33 12

Who I represent

Danfoss Fire Safety A/S is a leader in the sale, development, production and service/commissioning of certified fixed fire fighting systems under the brand name SEM-SAFE®.

Innovation is our approach.
We have been engineering and pioneering SEM-SAFE® fire fighting systems for decades.

This gives us the experience and technological knowledge to provide complete solutions of SEM-SAFE® fire fighting systems based on two key technologies: high-pressure water mist and low-pressure CO_2.

Working experience

About 15 years experience in technical sales for high value products, systems and applications.

Deep technical knowledge of the most important active fire-fighting technologies, systems and products.

I am engaged and passionate about what I am doing.

Company contact details

Danfoss Fire Safety A/S
Middelfartvej 9, DK-5000 Odense C, Denmark | +45 7488 7800

General: firesafety@danfoss.com
Customer Centre: firesafety.customer@danfoss.com
Service enquiries: firesafety.service@danfoss.com
Spare parts: firesafety.spareparts@danfoss.com

www.semsafe.danfoss.com

Stevanato Group

Working together towards a common goal: to help people live a better life

What are they doing

The world's largest designer and producer of glass primary packaging for the pharmaceutical and healthcare industry:

- 14 production sites located on different continents
- Wide set of capabilities dedicated to serving the biopharmaceutical and diagnostic industries
- Own glass converting technology to ensure the highest standards of quality
- Faster time to market

High-quality glass containers

24 h / 7 days playing with fire

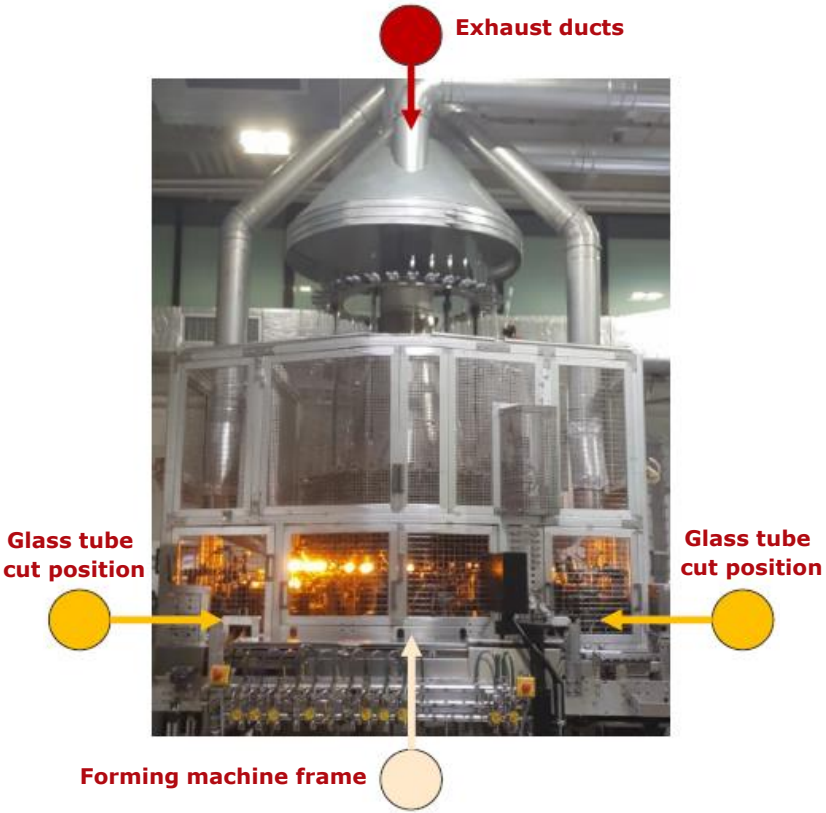
YouTube

https://www.youtube.com/watch?v=fHJxfFTbT9Q&list=PLIdOwaTeQrYgFbDDi8ZGKEQcGT-FIjJIu

Broad range of glass vials

Risk assessment on general fires

Typical Working Center (main zones of ignition)



Forming machine frame

- Probability is high
- Severity is low
- Containment measures can be implemented through fire extinguishers and HSE operating procedures

Glass tube cut position

- Probability is high
- Severity is medium
- Containment measures can be implemented through fire extinguishers and HSE operating procedures

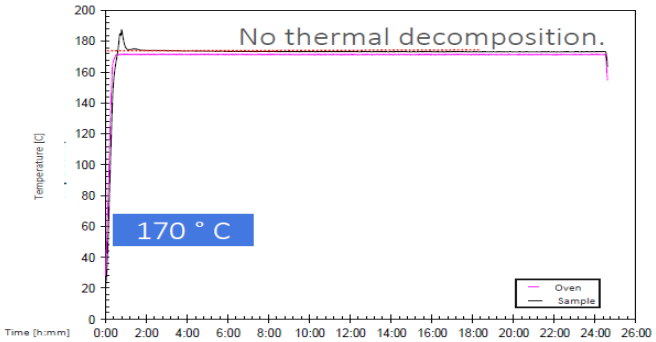
Exhaust ducts

- Probability is low
- Severity is high
- No accessibility for fire extinguishers, a fire prevention and protection system for vials was suggested as a mitigation of the risk

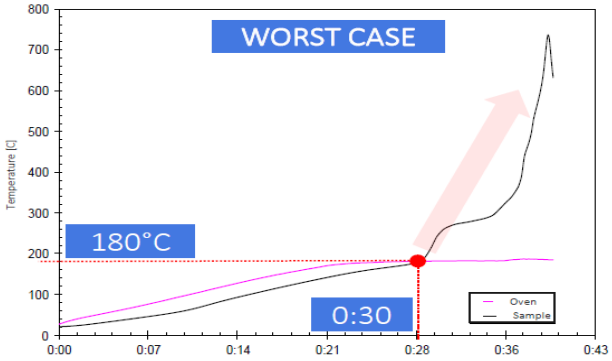
Risk assessment on exhaust ducts fires

Tests conducted in oven during 24h identified that a thermal decomposition of substrate starts at high temperature

Behavior at high T of powder sample at 170 ºC



Behavior at high T of powder sample at 180 ºC



Powder sample

Powders from lines hoods
(maintenance spring 2017)

Cause / Condition / Solutions

Cause: Thermal decomposition of substrate in the exhaust ducts

Condition: An exothermic phenomenon occurs and generates an auto-ignition in about 30’ at 180 ºC (but not at 170 ºC)

Solutions:

- 1) Cleaning procedures
- 2) Keep the temperature of the exhaust air low
- 3) Preventive and corrective actions

How to design the high-pressure water mist

The base function of the water mist system can be documented through the fire test report issued by an international recognized third-party laboratory and/or through the approval certificate issued by an international notified body.

Client Requirements

- To refer to a fire test protocol to be used for all foreign plants (internationally)
- To refer to a fire test report to be used for all foreign plants (internationally)
- To verify possible deviations by CFD-calculations

Available fire test protocols

- **ISO 15371** *Ships and marine technology — Fire extinguishing systems for protection of galley cooking equipment*
- **UL 300** *Fire Testing of Fire Extinguishing Systems for Protection of Commercial Cooking Equipment*
- **CEN TS 14972 Annex A.4** *Test protocol for the firefighting performances in commercial kitchen of type deep fat fryers*

Available fire test report

- A full-scale fire test was conducted at DBI (Danish Institute of Fire and Security Technology) according to UL 300 fire test protocol for ducts

CFD (computational fluid dynamics) simulations

- The client hired a global fire consultant

Water mist systems & FDS (Fluid Dynamic Model)

From fire test to real case

www.idfstudio.it

IDF
INGEGNERIA DEL FUOCO

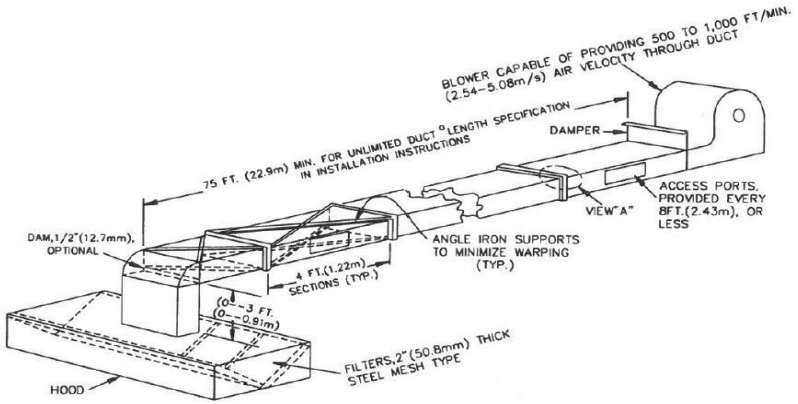
Objectives for CFD analysis

- In facts, the safe implementation of a water mist system is limited to specifically tested applications, where the parameters of the tests define the design boundaries.
- These limitations made it necessary to identify and quantify potential effect differences that may occur for the real installation, through a fluid-dynamic model.
- The purpose of the assessment was not to proof the system's effectiveness, but to identify and quantify potential deviations that may occur between the fire test scenario and the real installation
- To give exhaustive information regarding the replicability of the system as it was tested

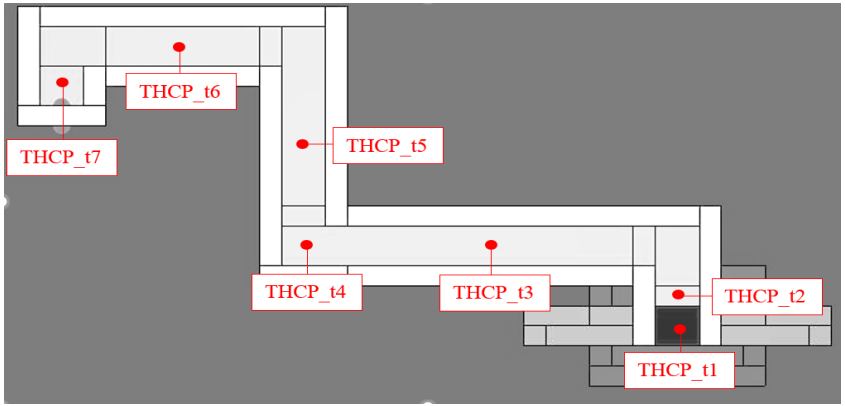
Water mist systems & FDS (Fluid Dynamic Simulation)

Comparison of the fire scenarios

UL 300 duct fire test



FDS Model represents the real application to be assessed



Design parameters

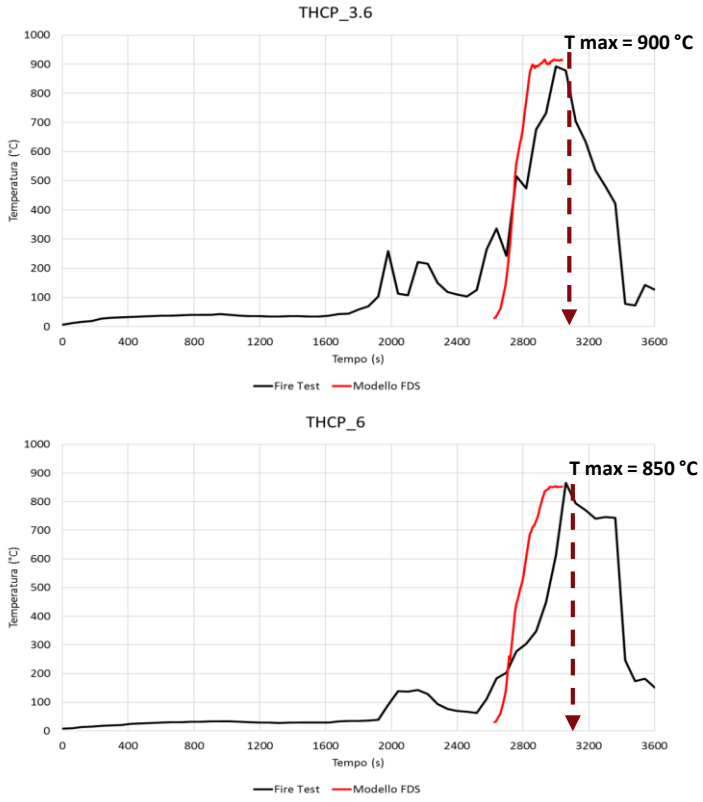
- Rectangular hood above "deep fat fryer"
- Horizontal Pipe L=23m – 90° bend
- Pipe Section A=0.32m^2
- Flow rate fan 0.96 cm/s.
- N.2 Vegetable oil trays – 9lt
- Nozzle flow rate: 2 x 0.06 l/s.

Main deviations

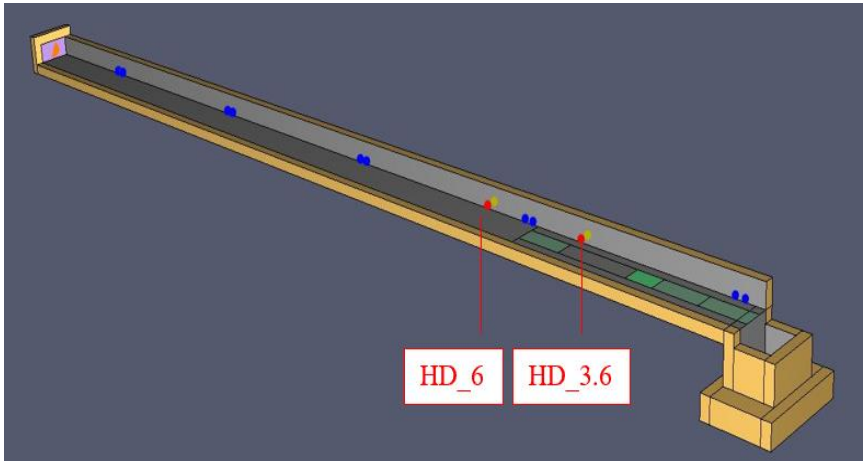
- Main impeller on which the tools are positioned in a circumferential direction
- Burners powered by methane and oxygen for glass cutting and processing
- Material layers: mineral oil and glass powder
- Vertical & Horizontal pipes L= 13m (average) – 45° and 90° bends
- Circular pipe section A= 0.5m^2

Fire test validation through the FDS model

Experimental activation of the water mist system (HD_3.6, HD_6)



Recreates the environment for the system originally tested



Conditions for water mist activation according to UL 300 duct test:

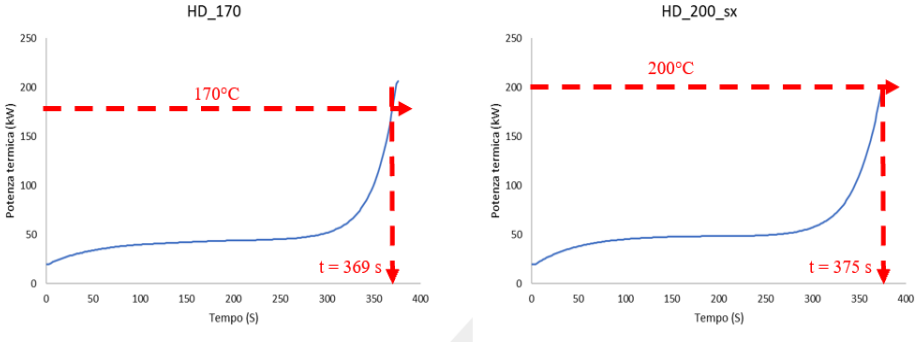
- HD_3.6 (located inside the pipe at 3.6m from the duct inlet) → 871°C
- HD_6 (located inside the pipe at 6.0m from the duct inlet) → 649°C

The graphs represent the temperatures of the two thermocouples both in the Fire Test and in the FDS Model.

The graphs show that the fire development in the FDS Model is similar to the one of the Fire Test: for both the thermocouples there is a gradual increase of the temperatures inside the duct until the peak at 850-900°C.

Real case & FDS model

FDS Model activation of the water mist system (HD_170, HD_200)

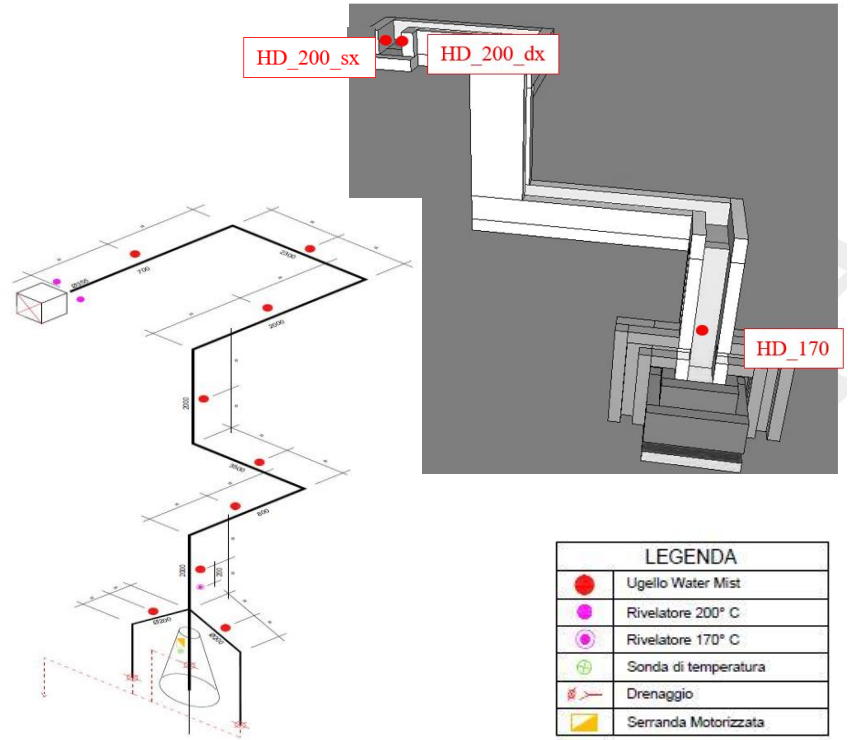


The FDS Model was characterized with the same devices placed in the fire test model, to compare le results of the two simulations.

The graphs represent the temperatures of two thermocouples located in the in the FDS Model real case.

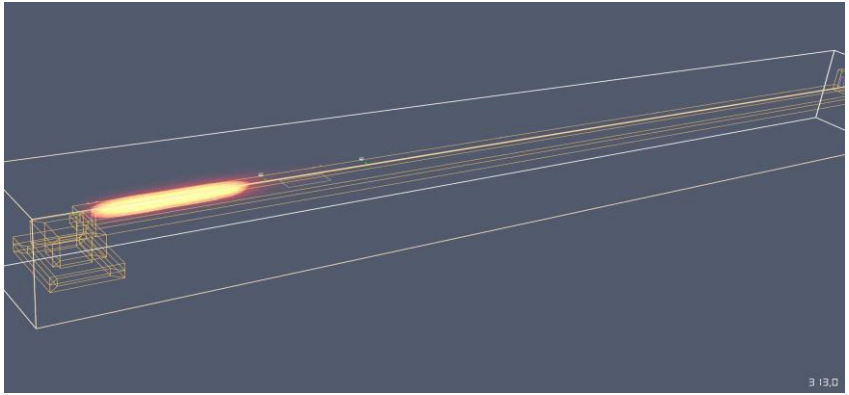
The FDS Model shows the fire evolution inside the duct and consequently the water mist activation after 369 s (HD_170) since the ignition.

Recreates the real application that needs to be assessed

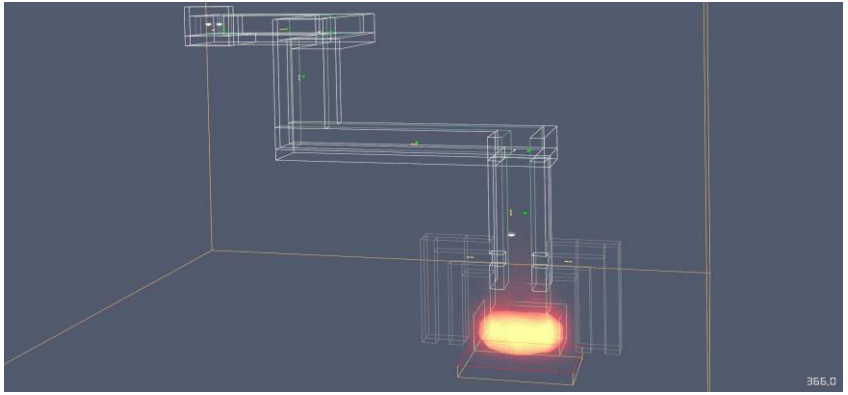


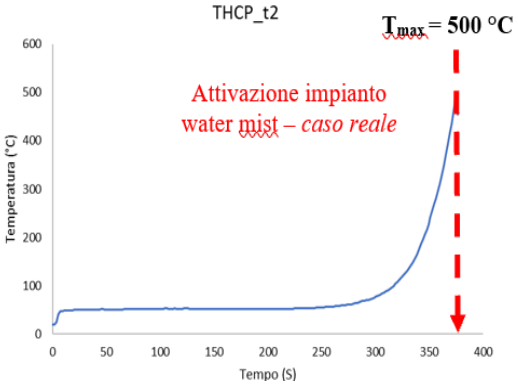
FDS model conclusions

Instant of activation for the UL 300 duct test



Instant of activation for the real case

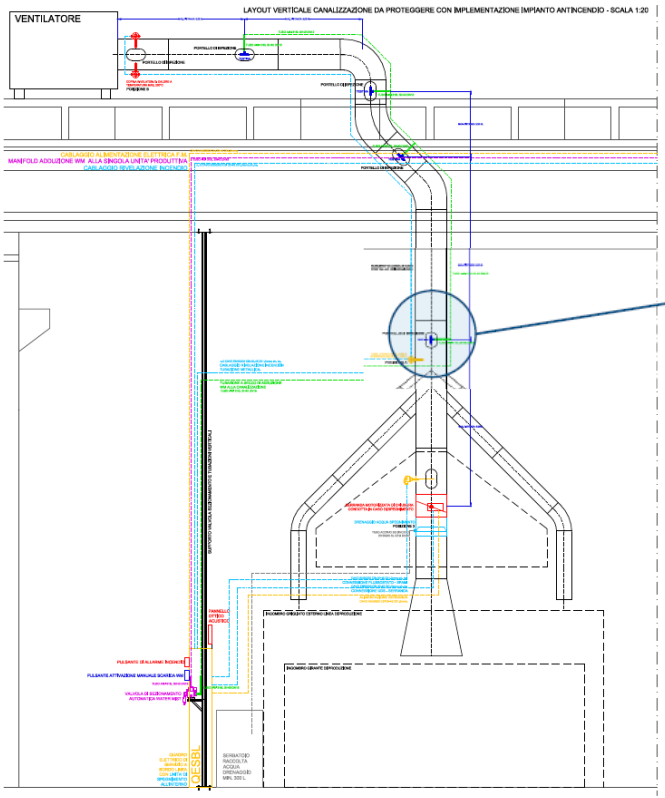


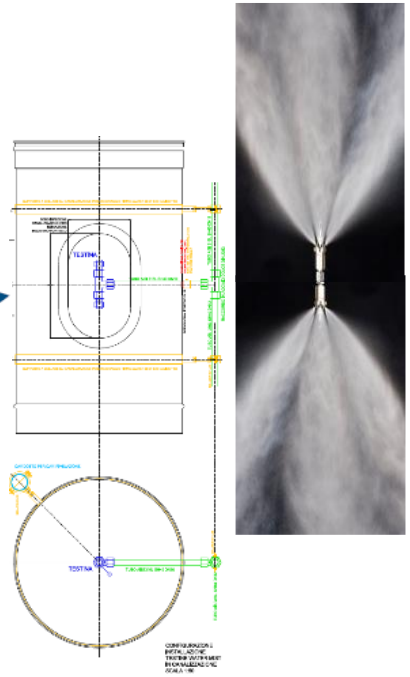


FDS real dimension-based simulation's output is more conservative than the fire test, considering the earlier water mist activation and the consequently lower thermal peak inside the pipe.

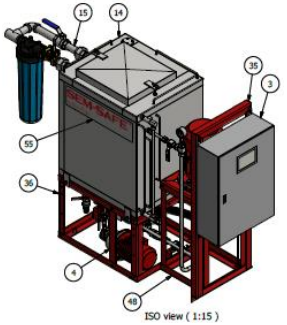
High-pressure water mist system for vials work centers

Main components & Nozzles layout

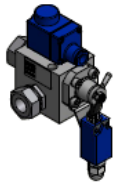




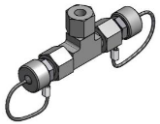
Pump Unit



Solenoid block valve



Duct nozzles with protection cup



High-pressure water mist system for vials work centers

Photos from the on-site installation

External

Internal

the Coalition for Epidemic Preparedness Innovations

What are they doing

An innovative partnership between public, private, philanthropic, and civil organizations, launched at Davos in 2017, to develop vaccines to stop future epidemics.

- Before the emergence of COVID-19 CEPI's priority diseases included Ebola virus, Lassa virus, Middle East Respiratory Syndrome coronavirus, Nipah virus, Rift Valley Fever virus and Chikungunya virus.
- CEPI also invested in platform technologies that can be used for rapid vaccine and immunoprophylactic development against unknown pathogens (Disease X)

Urgent response to the emergence of COVID-19

- Coordination with WHO
- Investing up to US $829 million and nine COVID-19 vaccine candidates
- Built on the principles of speed, scale and access
- Increase the world's chances of finding a safe, effective and globally accessible vaccine

The most crucial element

is the worldwide supply of

medical-grade glass vials to deliver

the billions of doses of vaccines

needed to fight the virus

Without medical glass vials,

vaccines cannot be stored or delivered,

and patients cannot be vaccinated

On June 25th, 2020

Working with partners around the world to begin the manufacture of millions of vaccine doses so that, should a candidate be proven to be safe and effective, it will be available to those in need without delay.

Signed an agreement for the supply

of **100 million** glass vials

to hold up

to **2 billion** doses of COVID-19 vaccines under development

Playing a key role in this global challenge of scaling up the industrialization of glass vials, proactively increasing the global capacity and sharing the same deep sense of responsibility and commitment to successfully address this public health challenge, ensuring no patient is left behind.

Water mist technology was chosen to reduce any potential **business interruption** in case of fire.

We can be proud to say that the **small droplets** will give their contribution to bring this pandemic to an end as soon as possible!

ENGINEERING
TOMORROW

Danfoss Fire Safety A/S
+45 7488 7800 | firesafety@danfoss.com | www.semsafe.danfoss.com

Antonio Terio
+39 340 325 33 12 | ate@danfoss.com