

5PSQ-003

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BACKGROUND AND IMPORTANCE

- Few information are available about the performance of cold maintenance device.
- Within the framework of the implementation of a pneumatic system in a new university hospital, the feasibility of sending different types of medicines, **including cold products** with a pneumatic system was studied.

→ The **objective** of this study is to **evaluate the compliance** of a cold maintenance device within a pneumatic

METHODS

- Study led in a **French University Hospital**, 1495 beds and more than 80 care units, between May and September 2022.
- Analysis made with kits provided for the **cartridges dedicated to cold transport** and with **qualified electronic temperature recorders** Log-tags[®] (C.M.I France, Neung-sur-Beuvon).
- **Different conditions** tested, one condition per test, reproduced at **least 3 times**:
 - kits placed at room temperature
 - in the fridge (2/8°C)
 - in the freezer
 - presence or not of a secondary packaging
 - eutectic plate
 - putting the kit in the cartridge
- The supplier had certified on his commercial leaflet a duration of **50 min between 2 and 8°C** under the following conditions: 500 ml **infusion bag** stored at 5°C, with thermal recorder inside the bag, placed in the kit then in the cartridge (*Figure 1*).

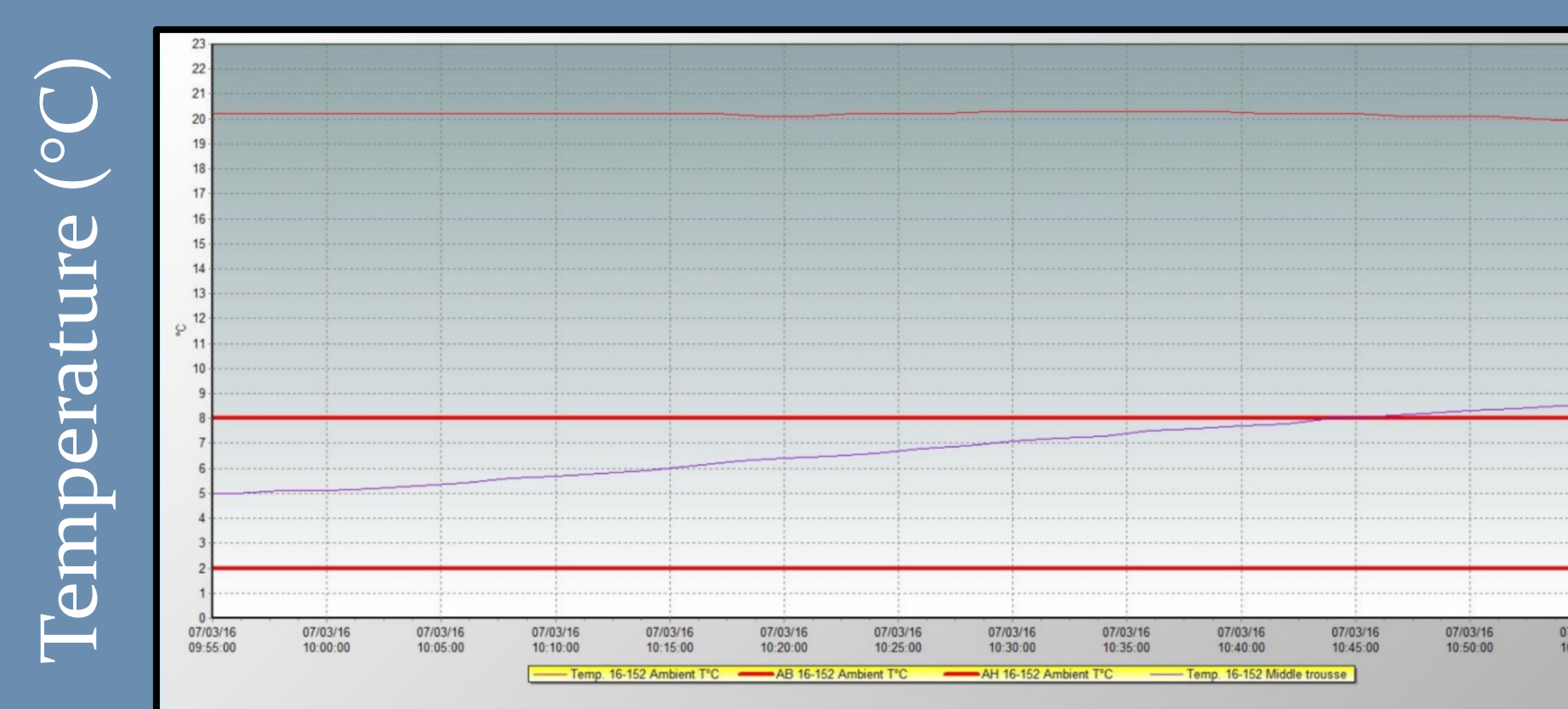
RESULTS

- The method applied by the supplier shows a mean duration between 2 and 8°C of **4.20min** [4;5] (*Figure 2*).
- Using the same starting conditions (*Table 1*):
 - freezing the kit, gave an average of 8.20min [7;9],
 - using a secondary packaging, the average was 6.40min [6;7],
 - outside the cartridge, the average was 4.40min [4;6],
 - and adding an eutectic plate, the average was 29.24min [11;60] but with a temperature below 0°C.

→ The average for all tests is **8.46min**.

All the results of the 9 different tests (one condition per test, reproduced at least 3 times) **do not meet the 50 min data** indicated by the supplier.

Figure 1: Curve obtained by the supplier



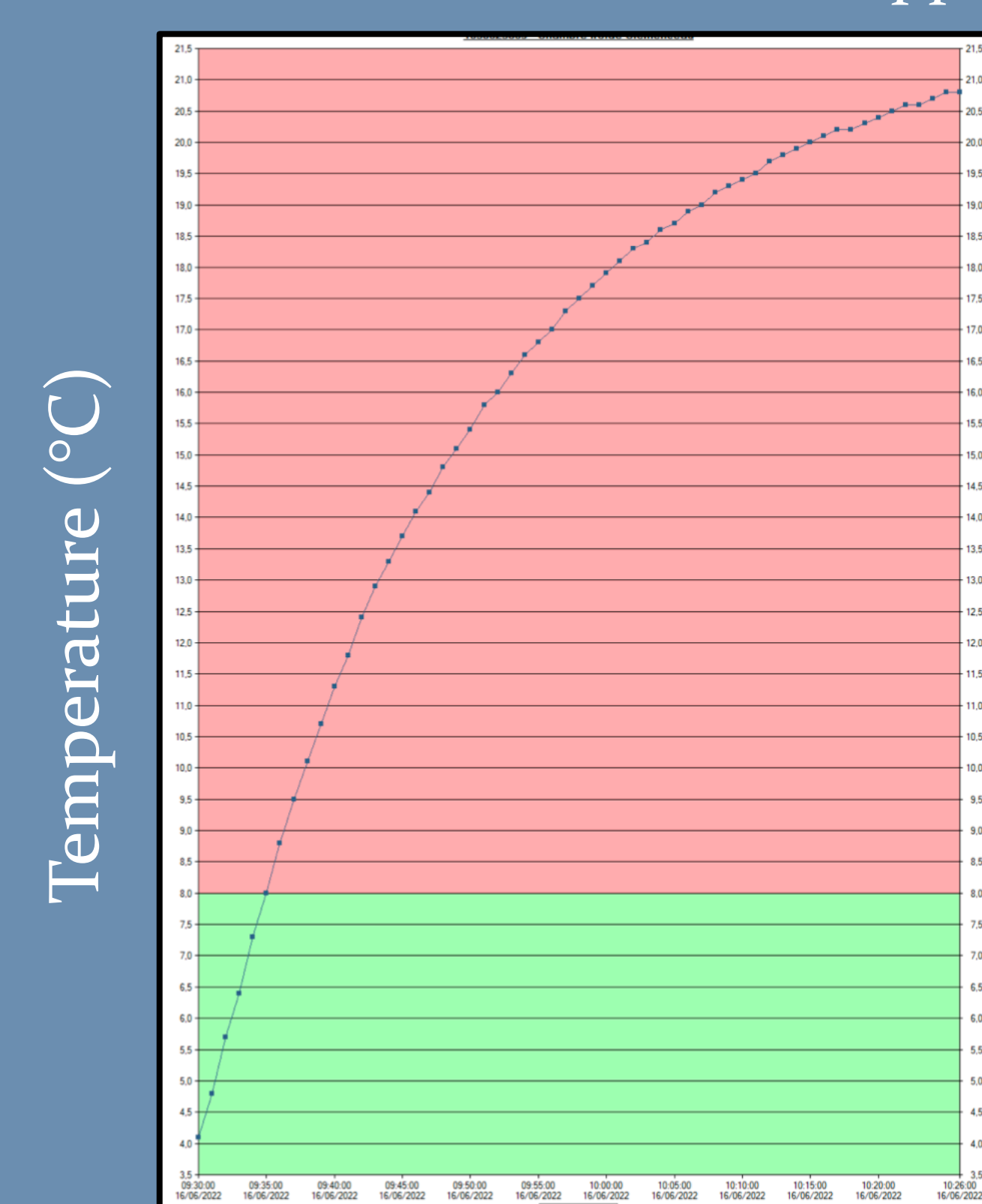
Duration between 2 and 8°C (min)

Table 1: Summary table of results per test

	Testing conditions				Results					Average (min)	Standard deviation (min)
	Presence of secondary packaging	Kits temperature	Presence of Eutectic plate	Kit placed in the cartridge	Test 1	Test 2	Test 3	Test 4	Test 5		
1	X	Room temperature	X	X	1	1	2			1.20	0.35
2	X	Fridge	X	X	5	4	6			4.45	0.58
3	Yes	Fridge	X	X	7	6	7			6.40	0.35
4	X	Fridge	X	Yes	4	5	4			4.20	0.35
5	X	Freezer	X	X	7	9	9			8.20	1.09
6	X	Fridge	Yes	X	12	15	7			11.20	4.02
7	Yes	Fridge	Yes	X	20	17	60	39	11	29.24	20.04
8	Yes	Freezer	X	X	7	8	8			7.40	0.34
9	X	Freezer	X	Yes	7	5	3			5.00	2.00

Temperature below 2°C and negative
Supplier conditions

Figure 2: Curve obtained under the same conditions as the supplier



Duration between 2 et 8 °C (min)

CONCLUSION

This study showed that the supplier's device and data **did not comply the good practices** concerning management of health products subject to cold chain and the patient safety.

Various studies undertaken at the level of the Hospital pharmacy and the cold supplier to improve the supplied isothermal enclosure.