GX Solutions -35°C Plasma Freezer – Temperature Performance

Helmer Scientific
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INTRODUCTION

The storage of blood products is highly regulated, with the goal of ensuring that proper storage conditions are maintained for these life-saving therapies. Different blood components, such as platelets, plasma, and red blood cells, require storage within different temperature ranges. Compliance becomes more complex than just considering required temperatures for the specific blood product as storage regulations may also vary depending on the region or country.

Blood plasma and cryoprecipitate for transfusion are stored at frozen temperatures to preserve clotting factors and optimize shelf life. This white paper will describe several examples of various regulations related to plasma storage requirements and will conclude by describing freezer performance that can support blood centers and transfusion services in their efforts to meet a range of storage requirements.

EXAMPLES OF PLASMA STORAGE REQUIREMENTS

Global and regional guidelines for the storage of Fresh Frozen Plasma (FFP) and cryoprecipitate vary. Two examples can be found from the World Health Organization (WHO) and the Council of Europe:

World Health Organization (WHO)
In the *Manual on the management, maintenance and use of blood cold chain equipment*, the World Health Organization (WHO) states that operating temperature of the freezer should be at -35 °C or colder, and the optimal storage temperature for Fresh Frozen Plasma (FFP) is below –30 °C. Cryoprecipitate is to be stored within the same temperature range as FFP. In addition, the guidance recommends that automatic defrost systems keep the cabinet in a safe range and that high temperature alarms should be activated at -25 °C.[1]

Council of Europe

The *Guide to the preparation, use and quality assurance of BLOOD COMPONENTS* specifies the storage temperature and duration for fresh frozen plasma (FFP) and cryoprecipitate as follows:[2]

> The following storage times and temperatures are permitted:
> - 36 months at below –25 °C
> - 3 months at between –18 °C and –25 °C

Individual countries may also adopt country-specific regulations that differ from global and regional guidelines. Germany, Australia, and the United States are just three examples of country-specific requirements for the storage of frozen plasma:

Germany

The German standard *DIN 58375* requires that blood plasma storage devices ensure the following conditions:[3]

- Frozen plasma is stored at temperatures ≤ -30 °C.
- The storage device must ensure that the product temperature does not exceed -27 °C at any point in time.

Australia

The Australian standard *AS 3864.1—2012* requires that a blood plasma and plasma products be stored at or below -25 °C, however, the freezer's high temperature alarm must activate at -27 °C.[4]

United States

AABB *Standards for Blood Banks and Transfusion Services* specifies that frozen plasma and cryoprecipitate be stored at -18 °C or colder with an expiration 12 months from collection.[5]

PLASMA FREEZER PERFORMANCE DURING NORMAL OPERATION and AUTO-DEFROST CYCLES

In the interest of meeting various regional and country-specific regulations, Helmer Scientific has developed GX Solutions upright plasma freezers. These freezers are designed to:

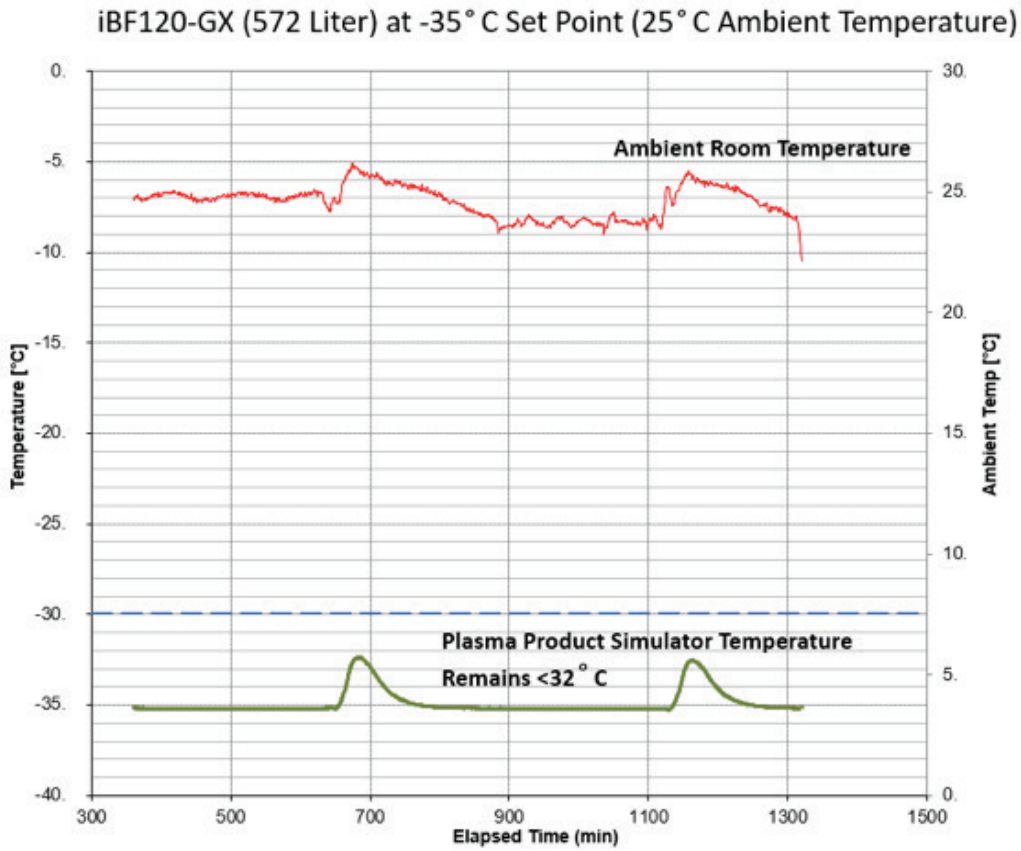
- Allow for an operating setpoint of -35 °C
- Achieve tight uniformity of +/-2°C to ensure all storage locations across the cabinet remain safe for plasma storage
- Avoid alarms that can be a nuisance or regulatory risk by maintaining product temperature below -30 °C even during automatic defrost events

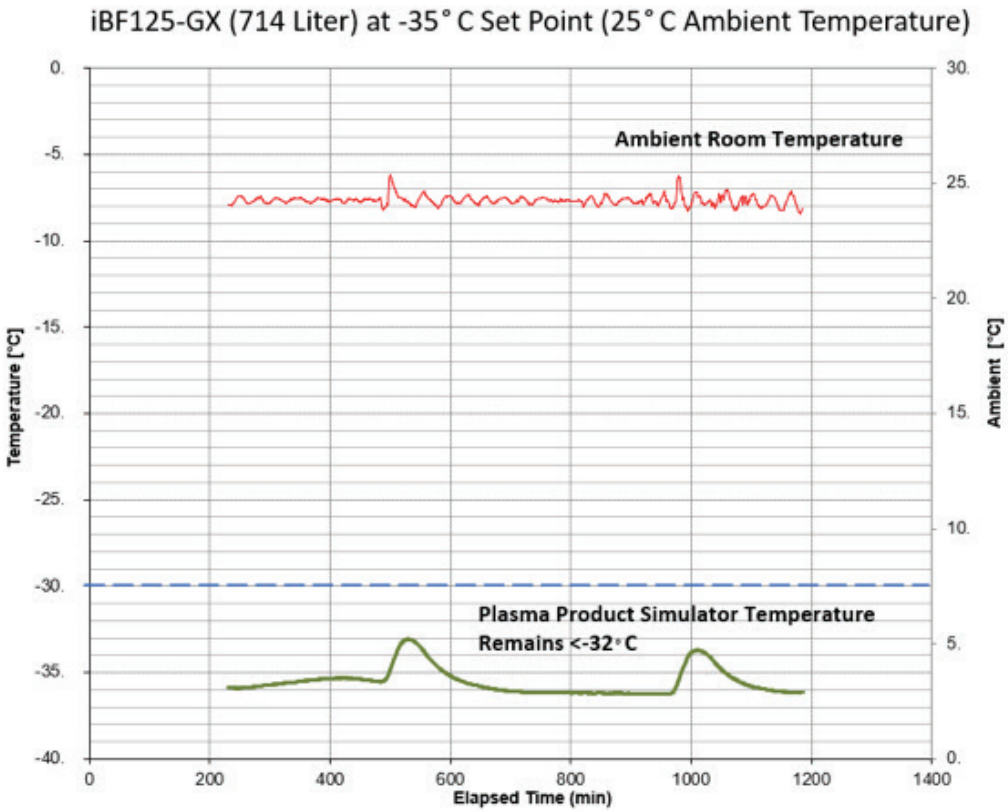
The following evaluation data demonstrates the temperature performance of GX Solutions upright plasma freezers for plasma storage based on various regional guidelines. All the tests were conducted on units with the standard plasma storage configuration of solid stainless-steel drawers. To fully challenge temperature performance by not including frozen mass that would artificially lower cabinet temperature during defrost events, GX Solutions upright freezers units were tested without product loaded in the drawers. The operating temperature of the freezer was set to -35 °C. Two different size freezers (572 liters / 20.2 cu ft and 714 liters / 25.2 cu ft) were tested at a normal ambient temperature of 25 °C.

SIMULATED PRODUCT TEMPERATURE REMAINED BELOW -30 °C

The following graphs illustrate the temperature of a small 120 ml (4 oz) water bottle, which simulates the product temperature of a frozen plasma bag. As the product simulator used in these evaluations contains less volume than a typical plasma bag, the product simulator will be more reactive to temperature increases. The product simulator was placed in the warmest location inside the cabinet and therefore represents worst-case scenario or the highest temperature within the cabinet. Each graph shows performance during normal operation as well as during two automatic defrost cycles. All evaluations used the standard plasma freezer confi guration, which includes 8 stainless steel blood bank drawers without frozen product mass loads, to determine peak temperatures during a worst-case inventory load condition.

<u>The iBF120-GX and iBF125-GX Plasma Freezers Maintained Product Temperature below -30 °C (with 2 automatic defrost events)</u>





RESULTS AND DISCUSSION

Tests of temperature performance of both sizes of the upright plasma freezers, conducted at a typical room temperature of 25 °C, showed that simulated product temperature always remained colder than -30 °C when the plasma freezer was set at an operating temperature of -35 °C. In fact, in this evaluation, the measured temperatures of the plasma product simulator never exceeded -32 °C during normal operation and automatic defrost events, even though the product simulator was placed in the warmest part of the cabinet. The temperature uniformity of the freezer has also been confirmed to be within a tight range of +/- 2 °C, ensuring safe storage throughout the cabinet. In addition to safeguarding plasma, this evaluation demonstrates that the performance of the -35 °C upright plasma freezer supports limiting high temperature alarms across regional requirements.

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CONCLUSION

Maintaining the acceptable temperature range for frozen plasma storage is critical for supporting compliance with regulatory requirements that vary across different regions. In this evaluation, the product simulator was placed in the warmest location within the cabinet to record the highest possible temperature and simulated product temperature remained below -30 °C. The temperature uniformity of the freezer has been confirmed to be +/- 2 °C, which means that plasma can safely be stored across any location within the cabinet.

In this evaluation simulated product temperature remained below -30 °C in Helmer Scientific GX Solutions upright plasma freezers with a -35° C setpoint, even during automatic defrost events, across all locations within the storage cabinet. In addition, this data demonstrates how a Helmer Scientific upright plasma freezer can support various global and regional requirements related to temperature performance, including guidance from the World Health Organization and Council of Europe.

REFERENCES

[1] World Health Organization (WHO), Manual on the management, maintenance and use of blood cold chain equipment (2005)
[2] Guide to the preparation, use and quality assurance of BLOOD COMPONENTS, European Committee (Partial Agreement) on Blood Transfusion (CD-P-TS), EDQM, Council of Europe, 20th Edition, 2020
[3] German Standard DIN 58375, Plasma storage - Definitions, requirements, testing (2004)
[4] Australian Standard® AS 3864.1—2012, Medical refrigeration equipment—For the storage of blood and blood products, Part 1: Manufacturing requirements (2012)
[5] AABB Standards for Blood Banks and Transfusion Services, 32nd Edition (2020)

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