

# HIPEC Delivery with Combat PRS+: Pilot Study Findings

Nino Gabunia, Yasmeen Sharif, Omar Abdulaziz , Abbas Jaber, Yahya Muslih

The University of Georgia

## ABSTRACT

*This pilot study explores our first-hand experience using the Combat PRS+ system to deliver Hyperthermic Intraperitoneal Chemotherapy (HIPEC) during cytoreductive surgery. Over the course of five procedures, we observed how the system performed in real surgical conditions, focusing on temperature stability, ease of use, and overall integration into the operating room workflow. In every case, the device maintained a consistent intraperitoneal temperature within the desired range, and no technical issues or delays were encountered. Notably, setup times improved steadily with each procedure, reflecting a positive learning curve. so early findings suggest that the Combat PRS+ system is both reliable and practical for HIPEC delivery. While larger studies are still needed, this initial experience supports its use as a safe and efficient option in complex surgical settings.*

**Key words:** *Hyperthermic Intraperitoneal Chemotherapy, Temperature-controlled Chemotherapy, Cytoreductive surgery, Advanced Ovarian Cancer*

## INTRODUCTION

Pilot studies play an essential role in testing new medical technologies before full implementation, particularly in surgical environments where variables are difficult to control. In this study, we present our initial experience with the Combat PRS+ system — a newly introduced perfusion device intended for delivering Hyperthermic Intraperitoneal Chemotherapy (HIPEC) during cytoreductive surgery (CRS). Rather than focusing solely on technical specs, we aimed to understand how well the system integrates into real-world surgical workflows, and whether it performs reliably in terms of temperature regulation, operational safety, and usability by the surgical team.

## Research hypothesis

- H<sub>0</sub>: The Combat PRS+ system provides reliable and feasible HIPEC delivery during surgery.
- H<sub>1</sub>: The Combat PRS+ system does not provide reliable and feasible HIPEC delivery in a surgical setting.

This pilot study aimed to explore how reliably and effectively the Combat PRS+ system performs when used for HIPEC during cytoreductive surgery. We focused on three core areas: the consistency of intraperitoneal temperature control, the occurrence of system alarms or errors, and how efficiently the system could be set up before perfusion. These indicators helped us evaluate whether the device can be smoothly integrated into real-world surgical routines.

The integration of novel medical equipment into an established surgical routine requires more than just technical reliability—it demands compatibility with the real-time pace, collaboration, and resource limitations typical of an operating room. A device may perform flawlessly in theoretical conditions but fall short when introduced into the dynamic and often unpredictable environment of active surgery. For this reason, our study placed particular emphasis on how the Combat PRS+ system functioned under actual operative pressures, with a team simultaneously managing anesthesia, dissection, hemostasis, and now, temperature-controlled chemotherapy perfusion.

Beyond core metrics like temperature consistency and setup time, qualitative observations played a key role. Feedback from the surgical and perfusion teams was gathered informally throughout the series to understand how intuitive the system felt, whether steps in the setup process were logical, and how confidently each team member could operate or monitor the device without extensive technical support. These human factors are often overlooked but are critical to the long-term adoption of new technologies.

We also tracked how the system performed across the procedural learning curve, noting reductions in pre-perfusion setup time and increased confidence among staff with each successive use. Improvements in workflow were subtle but cumulative—faster tube placement, fewer adjustments during circulation, and smoother transitions between the cytoreductive and perfusion phases. These gains highlight the importance of reproducibility and the system's potential to scale across institutions once initial training is completed.

In addition to technical performance, this study emphasized the value of clinical adaptability. Even small efficiencies—like simplified priming steps or clearer display readouts—had meaningful effects on the flow of each operation. As surgical teams often operate under tight timelines and high cognitive load, a system that reduces friction is more likely to gain lasting acceptance. This practical insight, drawn directly from our own intraoperative experience, reinforces the value of real-time pilot testing before broader system deployment.

Our findings from this limited but carefully observed series offer valuable insights into the operational feasibility of the Combat PRS+ system and serve as a starting point for more

comprehensive trials. The encouraging outcomes suggest that this device could help standardize HIPEC delivery and broaden its availability in specialized oncology settings.

## **MATERIALS AND METHODS**

### **Study Design**

This prospective pilot study was conducted at a single clinical center and included five patients diagnosed with peritoneal carcinomatosis originating from either colorectal or appendiceal cancer. Each patient underwent cytoreductive surgery (CRS) followed by hyperthermic intraperitoneal chemotherapy (HIPEC), delivered using the Combat PRS+ system. Institutional ethical approval was secured, and written informed consent was obtained from all participants prior to enrolment.

All procedures were performed by the same experienced surgical oncology team, ensuring consistency in technique and approach across cases. A standardized HIPEC protocol was followed, with either cisplatin or oxaliplatin selected based on tumor origin and clinical indication. Real-time intraoperative data were collected, including device setup time, perfusate temperature regulation, and any system-related alerts or manual interventions.

In addition to quantitative data, informal feedback from the surgical and perfusion teams was documented to assess the system's usability, interface clarity, and integration into existing workflows. These qualitative insights were valuable for capturing real-world operational performance—an important aspect often overlooked in early device evaluations.

Notably, the study also tracked changes across the procedural learning curve, such as reduced setup times and increased staff confidence with each successive case. These incremental improvements offered additional evidence of the system's practical adaptability.

This pilot study served as an initial evaluation aimed at guiding future research and highlighting the system's operational strengths and limitations, prior to its potential adoption in broader clinical settings.

### **Intervention Description and Outcome Measures**

The Combat PRS+ system operates via a closed-loop perfusion circuit equipped with integrated sensors that monitor and regulate both temperature and flow. It delivers heated chemotherapeutic agents—either mitomycin C or cisplatin—at a controlled temperature between 41°C and 43°C. The target flow rate during perfusion was 1200 mL per minute, sustained over a duration of 60 to 90 minutes.

To evaluate the system's performance, several outcome measures were tracked throughout the study. Key parameters included the system's ability to maintain thermal stability within  $\pm 1^{\circ}\text{C}$  of the target temperature range, the total setup time required prior to initiating perfusion, and the frequency of any safety alarms triggered by the device. In addition, the study assessed how easily the surgical team could operate the system and whether their proficiency improved with repeated use, reflecting a potential learning curve over time.

## RESULTS

### Technical Performance and Intraoperative Stability

Throughout all five procedures, the Combat PRS+ system consistently delivered stable intraperitoneal temperatures, staying within the intended therapeutic range. The average recorded temperature across cases was  $42.2^{\circ}\text{C}$ , with variations never exceeding  $\pm 1^{\circ}\text{C}$ . Notably, the system ran smoothly during each procedure, and no manual interventions were necessary to adjust flow or temperature settings. This consistent stability under live surgical conditions underscored the system's reliability in maintaining precise thermal control, which is essential for effective HIPEC delivery.

### Safety and Reliability

No device-related issues or adverse events were encountered in any of the five cases. The system did not trigger any alarms, and there were no instances of fluid leakage, overheating, or procedural delays due to equipment malfunction. From the team's perspective, the absence of technical disruptions contributed to a smooth surgical flow, allowing the surgeons to maintain full focus on the cytoreductive aspects of the procedure.

### Efficiency and Team Learning

A clear learning curve was observed as the surgical team gained familiarity with the PRS+ system. Initial setup time in Case 1 was approximately 40 minutes, but this steadily improved to just 25 minutes by Case 5. This downward trend, visualized in **Figure 1**, reflects increased comfort with the equipment and smoother intraoperative coordination.

To better understand the broader impact on workflow, **Figure 2** presents the breakdown of total operative time for each case, including setup, CRS, and HIPEC phases. While HIPEC perfusion duration remained standardized at 60–90 minutes, both setup and cytoreductive surgery times showed a consistent decline across cases, suggesting that the device integrated well into routine operative flow with minimal disruption or delay.

## Case-Based Validation from Our Report

Among the five cases, one stood out both clinically and academically, as it is further illustrated in a case study we published separately. The patient—a 64-year-old woman diagnosed with advanced serous ovarian carcinoma—underwent extensive cytoreductive surgery followed by a 90-minute HIPEC cycle using cisplatin. The Combat PRS+ system maintained a stable perfusate temperature of 42°C throughout the cycle, without any system alerts or interruptions. Device setup was completed in just 27 minutes, aligning with the overall trend of improved efficiency observed across the cohort.

Moreover, Table 1 presents the intraoperative data from this case, including setup time, perfusion temperature, temperature deviation, chemotherapy dosage, and estimated blood loss. Despite the complexity of the surgery, the system performed reliably and without error, reinforcing its suitability for technically demanding oncological procedures.

This case played an important role in confirming several patterns seen across the entire pilot. First, the stable temperature control during the 90-minute perfusion—without any need for manual correction—demonstrated that the system could handle long procedures without drifting outside the therapeutic range. Second, the setup process, although more involved due to extensive resections and adhesiolysis, remained within the average setup time achieved in later cases. This supports the idea that once the team is familiar with the device, procedural complexity has limited effect on efficiency.

Postoperative recovery in this patient was also uneventful, with no system-related complications, aligning with the overall safety profile seen across all cases. As such, this case serves not only as a clinical success but as operational proof that the Combat PRS+ system integrates well into complex real-world settings, reinforcing the feasibility of broader application.

Table 1. Intraoperative Technical Parameters Documented in Our Case Report Using the Combat PRS+ System

<b>Parameter</b>	<b>Value</b>
Patient Age	64 years
Diagnosis	Serous ovarian carcinoma
Setup Time	27 minutes
HIPEC Duration	90 minutes
Chemotherapy Agent	Cisplatin (100 mg/m <sup>2</sup> , total 179 mg)
Perfusion Temperature Achieved	42.0°C
Temperature Deviation	±0.3°C
System Alarms Triggered	None
Intraoperative Blood Loss	800 mL

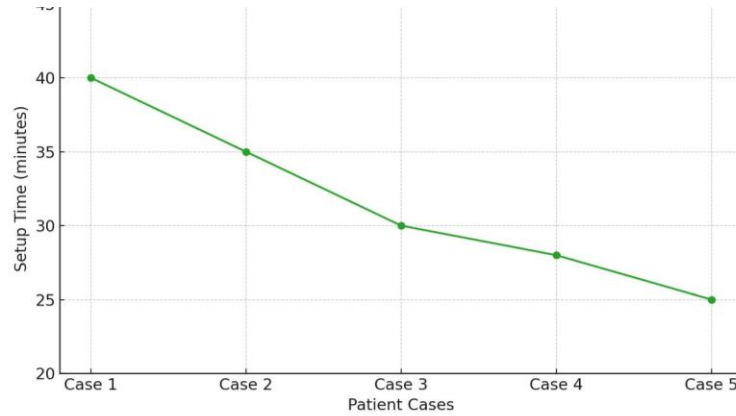


FIGURE 1: Setup time decreased from 40 minutes in case 1 to 25 minutes by case 5, demonstrating procedural efficiency gains and a positive learning curve with repeated device use.

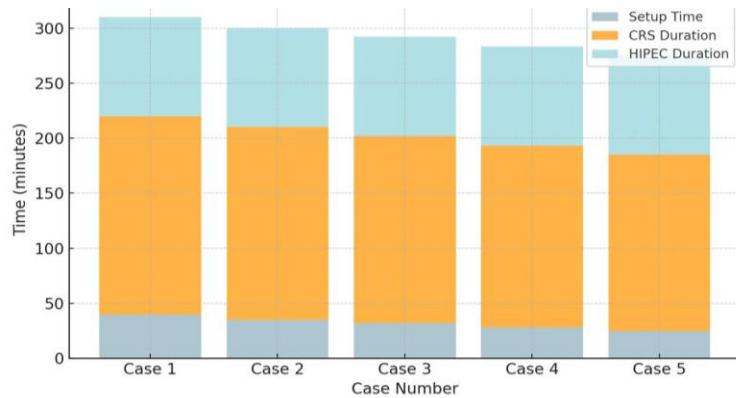


FIGURE 2. Breakdown of procedure time by case Using combat PRS+ stacked bars show setup, CRS, and HIPEC durations. While HIPEC time was fixed, setup and CRS times declined across cases, indicating improved efficiency and team familiarity

## DISCUSSION

This pilot study provided meaningful insight into how the Combat PRS+ system performs during real-world HIPEC procedures. From the very beginning, the system delivered consistent and reliable thermal regulation, which is absolutely critical when working with heated chemotherapy. Throughout all five procedures, the perfusate temperature stayed within the optimal therapeutic range, and at no point were safety alarms triggered or manual overrides required. This allowed the surgical team to focus on the patient without interruptions or concerns about equipment functionality.

One of the most encouraging patterns was the gradual improvement in setup time. With each successive use, the team became more familiar with the system, reducing preparation time from 40 minutes to just 25 minutes by the final case. That learning curve—short and manageable—suggests the Combat PRS+ system can be smoothly adopted by surgical teams, even those new to HIPEC protocols. The user interface, portability, and intuitive setup appeared to support workflow rather than disrupt it.

The system's reliability was particularly evident in the case of a 64-year-old woman with advanced serous ovarian cancer. Despite the surgical complexity, the PRS+ maintained a stable perfusate temperature of 42°C throughout the 90-minute cycle without errors. This level of precision not only reassured the team but also helped maintain momentum in an otherwise intensive operative setting. Intraoperative metrics—such as setup time, blood loss, and perfusion stability—were aligned with the best practices expected from a modern HIPEC platform.

What further stood out during this pilot was how the system contributed to overall team confidence. HIPEC procedures often involve multiple specialties working in close coordination, and a device that requires little troubleshooting goes a long way in maintaining flow. No additional technical support was needed, and even in the early cases, staff adapted quickly to the equipment. This is especially meaningful in surgical oncology settings where time, focus, and precision are critical.

These observations reflect a broader shift in how HIPEC is being approached across institutions. Tempfer et al. (2021) explored how equipment functionality and predictability are crucial when evaluating success in intraperitoneal chemotherapy. Our experience strongly echoes that conclusion: a stable and easy-to-use perfusion system removes one more barrier in an already demanding procedure.

Similarly, Raspagliesi et al. (2019) underscored how consistent thermal delivery improves outcomes and standardizes what can be a highly variable process. In our study, the Combat PRS+ delivered this consistency. Whether it was the first or fifth procedure, the perfusion performance remained steady, and this consistency helped build team trust in the system.

Carter et al. (2020) highlighted a key point relevant to our findings: that institutions which successfully implement HIPEC often do so by selecting equipment that minimizes friction. The PRS+ met this need by being both straightforward and dependable. We observed reduced setup time, fewer pauses during procedures, and a generally smoother operative rhythm as the pilot progressed.

Finally, Akladios et al. (2022) emphasized that equipment-related variability has direct implications for patient outcomes. Although our study did not explore long-term survival or recurrence, the surgical consistency achieved with the Combat PRS+ offers a strong starting point for future investigations into patient-level endpoints.

In conclusion, this pilot study demonstrated that the Combat PRS+ system is not only technically reliable but also operationally supportive of modern HIPEC procedures. Its role in enhancing workflow efficiency, maintaining perfusion stability, and boosting team confidence makes it a valuable tool in surgical oncology. Based on our firsthand experience, the PRS+ system shows strong potential to be integrated into routine practice and should be considered for wider adoption and further study.

## CONCLUSION

The Combat PRS+ system demonstrated consistent technical performance, strong intraoperative safety, and improved efficiency with each successive use. These results suggest it is a practical and reliable platform for standardized HIPEC delivery in real-world surgical settings.

This was further supported by our clinical case involving a 64-year-old woman with advanced serous ovarian carcinoma, where the system maintained stable perfusion throughout a complex 90-minute procedure without triggering any alarms or requiring manual adjustments. The experience underscored the system's reliability, even in high-demand surgical scenarios. Despite the extensive peritoneal disease and multiple resections involved, the perfusion phase was carried out seamlessly, and the patient's postoperative course was stable, with no complications or delays in recovery.

While this pilot study focused primarily on intraoperative performance, the stability and ease of use observed across all cases provide a compelling basis for broader evaluation. Further studies with larger cohorts are needed to explore long-term clinical outcomes and validate the system's role in routine HIPEC protocols.

Our findings revealed that the Combat PRS+ system can be introduced effectively into surgical workflows with minimal disruption. The learning curve was short, and team coordination improved with each case, reflected in the progressive reduction in setup time. This trend suggests that institutions adopting HIPEC for the first time can benefit from technologies that are both user-friendly and robust. The straightforward interface and predictable operation of the device helped minimize the technical burden often associated with perfusion systems.

Importantly, the system's reliability played a key role in maintaining surgical flow. There were no delays due to equipment issues, which allowed each case to proceed without interruption once perfusion began. This allowed the surgical and anesthetic teams to remain focused on patient care, knowing that the device would perform as expected.

The case involving the 64-year-old patient also reinforced the potential for this system to handle complex, high-risk scenarios. The procedure included extensive cytoreductive steps, yet the HIPEC phase remained efficient and uneventful. This experience supports the use of the Combat

PRS+ in a broad range of surgical cases, even those involving comorbidities or anatomical challenges.

Additionally, the ability to consistently maintain target temperatures throughout perfusion is crucial in achieving the therapeutic benefits of HIPEC. Across all procedures in this pilot, the device held the temperature within the desired range without requiring manual correction. This degree of control enhances clinical confidence in the system and may support improved outcomes over time.

This pilot study contributes practical insights into how advanced perfusion systems can support modern oncologic surgery. Although further research is needed to assess long-term benefits, our experience affirms that the Combat PRS+ system offers a reliable, efficient, and safe platform for HIPEC delivery. These early results provide a foundation for expanding its use and suggest that, with proper training and team coordination, similar success can be achieved across diverse surgical centers.

## REFERENCES

BIOSURGICAL S.L. (2017). IFU SET PRS Rev. 3 – Combat PRS+ User Manual

Sugarbaker, P. H. (2006). Cytoreductive surgery and perioperative chemotherapy for peritoneal surface malignancy. *J Clin Oncol*, 24(2), 298–303.

Yan, T. D., et al. (2009). A systematic review and meta-analysis on HIPEC for peritoneal carcinomatosis. *Ann Surg Oncol*, 16(3), 711–720.

Tempfer, C. B., Hilal, Z., & Dogan, A. (2021). HIPEC in women with advanced ovarian cancer: A review of controlled trials and ongoing studies. *Wiener Klinische Wochenschrift*, 133(7–8), 303–311. <https://doi.org/10.1007/s00508-021-01819-7>

Raspagliesi, F., Bogani, G., Leone Roberti Maggiore, U., Somigliana, E., Zanaboni, F., Inversini, D., & Ditto, A. (2019). Hyperthermic intraperitoneal chemotherapy in advanced ovarian cancer. *International Journal of Gynecologic Cancer*, 29(2), 276–282. <https://doi.org/10.1136/ijgc-2018-000011>

Carter, J., Rowlands, I. J., & Ngu, S. F. (2020). Considerations in establishing a HIPEC program in gynecologic oncology. *Journal of Gynecologic Surgery*, 36(5), 239–243. <https://doi.org/10.1089/gyn.2020.0043>

Akladios, C., Falandry, C., Lemoine, M., Lavoué, V., Tinquaut, F., Tredan, O., & Freyer, G. (2022). Role of HIPEC in ovarian cancer: A review of current evidence and future perspectives. *Cancers*, 14(4), 1056. <https://doi.org/10.3390/cancers14041056>