## LifeFlow.

# Time Matters: Rapid Resuscitation in the Operational Environment

LifeFlow

## **Executive Summary**

Damage Control Resuscitation

(DCR) is a resuscitation strategy that identifies life-threatening injuries and seeks to improve clinical stability before arrival at surgical care. Remote Damage Control Resuscitation (RDCR) is the prehospital application of DCR strategies. Military research has demonstrated that blood and blood products are an essential RDCR capability. Materiel solutions to support rapid resuscitation, including rapid infusion, during RDCR and Prolonged Field Care (PFC) need to address the challenges of these environments directly. The LifeFlow PLUS Infuser is a commercial off-the-shelf (COTS) materiel solution that addresses the rapid resuscitation gaps in RDCR and PFC for blood or crystalloid infusions.

## **Current and Future Requirements**

Military research from past combat operations indicates that most potentially preventable deaths after trauma are related to hemorrhage and occur before arrival at the hospital (Eastridge et al., 2019). Damage Control Resuscitation (DCR) includes strategies to prevent or mitigate the development of tissue hypoxia, oxygen debt, and coagulopathy (Cap et al., 2018). To restore hemostasis and facilitate optimal hemostatic resuscitation, the Joint Trauma System (2018) recommends the fluids in Exhibit 1 for the management of DCR. Note, initiation of massive transfusion protocols (MTP) should be done if the patient has received, or is expected, to receive four units PRBC/4U FFP.

#### Exhibit 1:

- Whole Blood (Group O Low Titer preferred)
- Balance transfusion=RBCs plus plasma plus platelets=1:1:1 ratio
- RBCs plus plasma= 1:1 ratio
- Plasma with or without RBCs
- RBCs alone
- Walking Blood Banks (as necessary)
- Crystalloid or colloids (should be used sparingly in the prehospital setting and should be balanced against the risk of worsening coagulopathy)

The concepts of DCR have extended beyond the confines of the Role 2 and the Role 3. Remote Damage Control Resuscitation (RDCR) is the prehospital application of DCR strategies. RDCR identifies life-threatening injuries and seeks to improve clinical stability before arrival at surgical care (Jenkins et al., 2014). It starts at, or near, the point of injury (POI), the Role 1, and during medical evacuation (MEDEVAC) or casualty evacuation (CASEVAC). Research by Shackelford et al. (2017) validates the concept that timely administration of blood and blood products within minutes of injury was associated with greater 24-hour and 30-day survival than delayed transfusion or no transfusion. Blood and blood products are now an essential capability found in the RDCR operational setting.

With a shift in military strategy from Counterinsurgency (COIN) to Large Scale Combat Operations (LSCO) and Multi-Domain Operations (MDO), the ability to provide Prolonged Field Care (PFC) is a validated capability requirement. PFC is "field medical care, applied beyond doctrinal planning timelines to decrease patient mortality and morbidity, utilizing limited resources, and is sustained until the patient arrives at an appropriate level of care." (Keenan & Riesberg, 2017) It is anticipated that all resources, including medical, will be limited and strained. With limited ability for rapid evacuation, PFC will not only focus on timely lifesaving interventions (LSI) through RDCR techniques but also seeks to improve the ability to treat wounds, injuries, and sepsis associated with holding multiple patients for 5-7 days. Disease and Non-Battle Injuries (DNBI) requiring rapid resuscitation will remain prevalent in future operating environments (Shaw et al., 2022). This may include the treatment of cardiac arrest, septic shock, anaphylactic shock, severe dehydration, exertional heat stroke, hypothermia, and endemic diseases specific to a theater of operation.

## **Current and Future Capabilities Gaps**

DCR equipping efforts have primarily focused on the Role 2 and the Role 3. Equipment includes using a fluid warmer and rapid infuser that allows for timely and effective delivery of blood and blood products. When a patient arrives, blood is spiked using blood filter tubing and placed on a warmer and rapid infuser. The team quickly does this since every minute of shock and hypotension resuscitation delay increases the risk of organ injury and death (Figure 1) (Walsh et al., 2013).



The RDCR and PFC operational environment poses significant challenges (Fisher et al., 2015), including consideration of weight, cube, lack of power (or reliable power), very few personnel available to do a rapid resuscitation, and limited logistical support to include biomedical maintenance. Future military operations will only magnify these challenges.

Rapid infusers commonly found in the Role 2 and Role 3 medical equipment sets are heavy (approximately 28 pounds), bulky, require an IV pole mount to function correctly, a consistent power supply to operate or recharge the batteries, and biomedical maintenance support to remain serviceable. Larger rapid infusers often need one team member identified to manage and troubleshoot the device during resuscitation. None of these attributes are amenable to the RDCR and PFC environment. Additionally, rapid infusers are expensive (upwards of \$20,000 plus warranties and expensive consumables), making it cost-prohibitive for widescale deployability at the tactical level where RDCR and PFC are likely to occur.

The current workarounds to the prehospital rapid infusion problem include using inflatable pressure bags or hand-squeezing the blood bag. Research studies have demonstrated that a rapid infuser is superior to a pressure bag, gravity, hand-squeezing, or traditional IV pumps (Piehl & Park, 2021). Neither gravity nor pressure bags provide sufficient flow to rapidly transfuse patients in shock. Emerging evidence identifies that prehospital hypotension for hemorrhaging patients decreases the odds of survival, correcting it quickly in patients with traumatic brain injury is critical (Spaite et al., 2019). Infusion techniques that promote maximal optimization of interventions must be done when all resources, including blood, are severely limited.

While there have been concentrated efforts on enhancing RDCR and PFC capabilities through training and using blood and blood products, providing materiel solutions to support it has been slower. Materiel solutions found in the Role 2 and the Role 3 are not optimal for use in the prehospital environment (Martin et al., 2021). Current systems for prehospital blood and fluid infusion are often not compatible with each other. This forces a clinical decision to either warm or rapidly infuse the product. Rapid infusion solutions need to be compatible with blood and fluid warmers.

## **Solutions**

The LifeFlow PLUS Infuser is a commercial off-the-shelf (COTS) material solution that addresses the rapid resuscitation gaps in RDCR and PFC for blood or crystalloid solutions. It is a compact, lightweight (0.75 lbs), single-use, hand-operated rapid infuser. It does not require power, batteries, or an IV pole. Since it is disposable, no biomedical maintenance is needed. A unit of blood can be delivered 3x faster than with a pressure bag and 7x quicker than gravity (Figure 2). The controlled administration will facilitate the prevention of over-administration or under-administration of volume.



AirCheck reduces the risk of air embolism when compared to inflatable pressure bags. Administration can be done through high-resistance vascular access, such as smaller gauge peripheral IVs. Four units of blood can be infused before a new tubing set is needed.

The hand-operation allows for tactile feel so clinicians can control and monitor flow rate while doing other tasks, including care in low light conditions. Since it does not use power or batteries that produce light and noisy alarms, it is optimal when noise and light discipline must be maintained.

With a price point significantly lower than rapid infusers found in the Role 2 and Role 3, the LifeFlow PLUS Infuser allows for widespread adoption of rapid infusion at the tactical level.

Warming and rapidly infusing blood or crystalloid solution set the conditions for optimal resuscitation. The ability to rapidly warm blood products in the operational environment has improved dramatically over the last decade. Blood and fluid warmers, such as the QinFlow Warrior, were designed to support the prehospital setting.

## Summary

Materiel solutions for the rapid infuser capability gap must be lightweight, compact, portable, require no power, and decrease dependency on a biomedical logistics tail. The LifeFlow PLUS Infuser provides a commercial-off-the-shelf solution to optimizing resuscitation for the patient and the end-user in the RDCR and PFC environment.

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| GSA:  | 47QSWA19D0073  | LifeFlow. |
| DAPA: | SP020018H0066<br>via Red One Medical Devices - Cage Code: 71UG3                                    |           |
|       | Email: customerservice@redonemedical.com<br>Phone: 912-662-1443<br>Website: www.redonemedical.com/ |           |

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