[redacted]

RCloud Tasking Form – Part B: Statement of Requirement (SoR)

Title of Requirement	Diver Fluid Loss
Requisition No.	**RQ0000017025**
SoR Version	**1.0**

1.	**Statement of Requirements**
1.1	**Summary and Background Information**
	Mitigating fluid losses due to prolonged immersion in water. Immersion in water results in fluid losses to compensate for the movement of body fluids from the periphery to the torso. The volume of fluid lost is likely to impact on the performance of aerobic work on land. Military divers could be immersed for 4 hours or more and be expected to perform moderate to hard physical work on exiting the water. This project seeks to identify effective mitigations to minimise the impact of immersion induced fluid losses on the performance of military divers during the first few hours post-immersion. A secondary objective is to identify and mitigate any prolonged loss of body fluid, i.e. follow repeated daily immersions. Military divers are frequently required to spend long periods of time immersed in water, they may be carrying out repairs to ships, inspecting ship hulls or combat swimming. These dives are generally in shallow waters (<9 metres of seawater) and carry no staged decompression requirement. Prolonged immersion presents a number of physiological hazards to the diver: • Thermal stress • Immersion pulmonary oedema • Oxygen toxicity (if using closed/semi-closed circuit oxygen breathing apparatus) • Energy deficit • Immersion diuresis This requirement is focussed on mitigating the effects of immersion diuresis. Immersion diuresis results in water loss and reduction of plasma volume (Castagna et al. 2014 and Castagna et al. 2015). Combat swimmers, in particular, may be required to be physically active on exiting the water. The water loss associated with four hour or longer immersion is likely to impair

aerobic performance (Shirreffs 2005, Hess et al. 2018 and 2019) and there have been anecdotal reports of orthostatic hypotension when combat swimmers have left the water. Further, combat swimmers are typically highly physically trained (high volume, moderate intensity) and are likely to be more susceptible to orthostatic hypotension than sedentary people due to physical training induced alterations to cardiovascular reflexes (e.g. Ogoh et al. 2003).

During long dives, divers are likely to be exercising at moderate intensity but with the introduction of diver propulsion vehicles, exercise intensities during some dives are likely to decrease.

Drinking before or during a dive increases the volume of urine production. Hess et al (2018 and 2019) found consuming water after immersion made no improvement to aerobic exercise performance compared to no water. Due to delays with gastric emptying and absorption of water from the small intestine, it is plausible that the timing of drinking is important, i.e. fluid should be ingested shortly before exit from the water to allow some time for partial gastric empting.

[redacted] Drinking before, during or after a dive has been shown to have little effect on post dive plasma volume or performance (Castagna et al. 2014, Hess et al. 2018, 209). However, to Dstl's knowledge, the effects of drinking a rapidly absorbable fluid shortly before egress from the water has not been evaluated. It is plausible that timing drinking, such that gastric emptying is underway on exit from the water but vasopressin levels have not yet fallen sufficiently to decrease water absorption by the kidneys. Further, raising sympathetic activity with caffeine or a pharmaceutical may produce sufficient pressor response to enable moderate intensity exercise to be completed with minimum adverse effects.

Pharmaceutical interventions to reduce fluid loss are to be considered. Dstl is aware of only one study claiming the use of an anti-diuretic drug reduces fluid losses and maintains performance post dive (Taylor et al. 1997, Nyquist et al. 2005).

The overarching requirement is for a human participant trial to demonstrate the effectiveness of mitigations to improve post-dive plasma volume by reducing net fluid loss and promoting fluid absorption to minimise the subsequent impact of reduced plasma volume on cardiovascular function and physical performance on exit from the water.

The secondary objective is to identify and propose mitigations for any longer term effects of repeated daily dives, for example but not limited to: sodium losses, incomplete restoration of plasma volume. Any experimental verification and validation of the mitigations will be an option to follow this study.

References

CASTAGNA, O. and others. Alterations in Body Fluid Balance During Fin Swimming in 29 °C Water in a Population of Special Forces Divers. *International Journal of Sports Medicine*, 2015, 36(14), 1125-1133.

CASTAGNA, O. and others. Fluid balance during prolonged SCUBA diving: effect of hydration during immersion. *40th Annual Scientific Meeting of the European Undersea Biomedical Society* 2014.

HESS, H.W. and others. Effect of rehydration schedule after four-hour head-out water immersion on running performance and recovery. *Undersea and Hyperbaric Medicine*, 2018, 45(5), 495-503.

HESS, H.W. and others. Cold water submersion attenuates post-submersion aerobic performance and orthostatic tolerance irrespective of partial rehydration with water. *Undersea and Hyperbaric Medicine*, 2019, 46(1), 7-16.

NYQUIST, P.A. and others. *Desmopression Prevents Immersion Diuresis and Improves Physical Performance After Long Duration Dives*, Bethesda, NMRC Report 2005-001, 2005. (Available at https://apps.dtic.mil/sti/pdfs/ADA448907.pdf)

OGOH, S. and others. Carotid baroreflex responsiveness to head-up tilt-induced central hypovolaemia: effect of aerobic fitness. *The Journal of Physiology*, 2003, 551(2), 601-608.

SHIRREFFS, S.M. The importance of good hydration for work and exercise performance. *Nutrition Reviews*, 2005, 63(s1), S14-S21.

TAYLOR, W.F. and others. Effects of desmopressin on immersion diuresis and physical and cognitive performance after long dives. *Faseb Journal*, 1997, 11(3), 310-310. (Abstract only)

1.2	**Requirement**

Shall indicates a mandatory requirement to be included in the study. Should indicates that inclusion is negotiable within the study requirement.

The response to this SOR shall propose intervention(s) to mitigate the impact of immersion diuresis occurring after four or more hours immersed on human physical performance post dive. The proposal shall include the outline of a human participant research study to demonstrate the efficacy of the proposed intervention(s). The interventions can be pharmaceutical, dietary, e.g. liquid feeding, or novel. Intra-venous/arterial routes for restoration of plasma volume are deemed impractical.

The proposal in response to this invitation to tender shall:

- Provide a sufficient level of background information to demonstrate the supplying team are suitably qualified and experienced and have in-depth knowledge of the literature in this area and that they understand the research question. Multi-centre collaborations are welcomed;

- Explain the rationale for the interventions they propose. Methods to maintain plasma volume throughout the immersion should consider the risk of immersion pulmonary oedema;
- If a pharmaceutical intervention is proposed and a clinical trial is not to be conducted, the responses to the questions in 'Is it a clinical trial of a medicinal product' (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/949145/Algorithm_Clean__1_.pdf) shall be included in the proposal;
- If a clinical trial is to be conducted, the proposal shall outline how the principles of Good Clinical Practise will be complied with.
- Dietary interventions shall include an assessment of palatability.
- Demonstrate a clear, logical, efficient and robust scientific approach to study design, justification for the instrumentation to be used, sample size estimations, data collection and analysis providing evidence of previous relevant research work;
- Discuss how participants will be selected for human participant trials where as far as reasonably practicable fitness of those participants should be matched to that of RN divers ((https://www.royalnavy.mod.uk/-/media/files/cnr-pdfs/get-fit-to-apply-mine-clearance-diver.pdf?la=en-gb)).
- Provide a schedule of work which must be realistic and achievable within the budgetary and time constraints of the project;
- Provide a list of ethical issues, technical and programmatic risks and mitigations via a risk table/register as part of their proposal;
- Provide an outline of the mechanisms that they intend to employ internally to provide technical assurance for the scientific output;
- Identify any background Intellectual Property that is intended to be used during this project.
- Include a spend profile, broken down month by month.

The study shall undertake the following activities:

- Develop a MOD Research Ethics Committee protocol according to the process described in JSP 536 (https://www.gov.uk/government/publications/defence-research-involving-human-participants-jsp-536). On supplier's request Dstl shall provide the supplier with advice on preparing the MODREC Protocol. The supplier should allow for four to six months from submission to receipt of favourable opinion.
- Baseline cardiovascular function, body water and sodium status and human physical performance relevant to a military task, to be agreed with Dstl.

- Immerse participants in water under thermal neutral conditions. A wet suit or drysuit may be worn.
- Assess post-immersion cardiovascular function, body water and sodium status and human physical performance relevant to a military task.
- Compare an intervention with no-intervention.
- Assess time to return to baseline

The supplier is not limited to these activities and can suggest additional measures supported with suitable justification.

The Technical Assessment marking criteria for the proposal are given in section five below.

Additional information

Access to military divers can be challenging. The supplier shall assume military divers will not be available.

Dstl will provide a Technical Partner (TP) to support the work. The role of the TP is primarily technical assurance. Part of the technical assurance process is observation and audit of an early serial of any experiments involving humans. The supplier shall make provision for the TP to observe an early trial serial. The TP is also tasked to help the suppliers with communications with the military and to facilitate the preparation of MOD REC submission.

The work may need to comply with the Diving Operations at Work Regulations 1997 (https://www.hse.gov.uk/pubns/indg266.pdf). In this event, the proposal shall outline how compliance will be achieved. If the participants are not to be fully immersed, the proposal shall provide scientific justification of the approach, including discussion of any issues, which may arise with extending the findings to fully immersed divers using closed/semi-closed circuit breathing apparatus.

Prior to putting any information generated under this activity into the public domain, eg submission of a conference abstract, the supplier must seek permission to publish from Dstl. Typically, one month, from receipt by Dstl, should be allowed for this process.

1.3	**Options or follow on work**
	The response shall include an estimated cost for each of the two options below: 1. Option to provide support to the design and execution of a military trial and subsequent analysis of the data with the objective of demonstrating the effectiveness of the proposed mitigation in a military training setting. The location would likely be Portland Harbour. MOD and Dstl would lead the trial. 2. An experimental study to demonstrate the effectiveness of any proposed intervention to mitigate the effects of daily diving.
1.4	**Contract Management Activities**
	Regular progress reports as will be agreed at the Start-Up meeting.
1.5	**Health & Safety, Environmental, Social, Ethical, Regulatory or Legislative aspects of the requirement**
	Compliance with the provisions of the Diving Operations at Work Regulations 1997

[redacted]

1.6	Deliverables & Intellectual Property Rights (IPR)					
Ref.	**Title**	**Due by**	**Format**	**Expected classification**	**What information is required in the deliverable**	**IPR Condition**
D-1	Start-up meeting	T0 + 1 month	Presentation (.pptx) and meeting virtual or face to face	[redacted]	Supplier understanding of the project. Start-up is the opportunity to identify and clarify any uncertainties in the requirement.	As per R-Cloud Terms and Conditions
D-2	Quarterly Progress and Technical Review (QPTR 1)	D1+3 Months And quarterly thereafter	Presentation (.pptx) and meeting virtual or face to face	[redacted]	Presentation pack to include but not limited to: • Update on technical progress • Progress report against project schedule. • Review of risk management plan. • Commercial aspects. • Review of deliverables. • Risks/issues. • GFA and supplier performance	As per R-Cloud Terms and Conditions

D3	Submission of MODREC protocol to MODREC	T0+6 Months	Protocol in the format required by MODREC	[redacted]	Presentation pack to include but not limited to: • Update on technical progress • Progress report against project schedule. • Review of risk management plan. • Commercial aspects. • Review of deliverables. • Risks/issues. • GFA and supplier performance	As per R-Cloud Terms and Conditions
D4	Final technical report	D1 + 12 Months	Word and Adobe Acrobat format	[redacted]	Report on the experimental trials, which must include background, requirement, method, analysis, results, conclusions and recommendations. The report must be in the format specified in the “Defence Research Report Specification” document: DSTL/DOC099139 Clear information on the application of testing techniques and analysis. A full, detailed methodology should be provided with enough open access information to allow other	As per R-Cloud Terms and Conditions

					researchers / data analysts to replicate the testing / analysis.	
D5	Stakeholder presentation	D-4 + 6 weeks	Presentation (.pptx) and meeting virtual or face to face	[redacted]	Presentation to an informed but lay audience summarising the study design and findings	As per R-Cloud Terms and Conditions
D6	MODREC research study summary report	D1 +12 months	Word Document	[redacted]	Sent to MODREC secretariat as per JSP 536 and copied to Dstl	As per R-Cloud Terms and Conditions

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1.7	Deliverable Acceptance Criteria
	Additionally, any presentations or briefing material will be to be delivered to the TP two weeks prior to the presentation event. The TP is to agree the proposed content of any presentations with the Supplier ahead of the presentation event. Any external presentation of material will require Dstl authorisation for permission to publish.

2	Evaluation Criteria
2.1	Method Explanation
	Please submit two versions of your proposal. The Technical proposal should not contain any pricing information. The Commercial version should be a full response to the ITT including both Technical and pricing information. The Technical evaluation will be carried out by 3 assessors who will review the proposals independently. Their scores will then be brought to a moderation meeting with the Dstl Project Manager to discuss each Tenderer's response and allocate a moderated technical score to each of the technical criteria and calculate a final score. This requirement will be competed and awarded on the basis of the Value for Money Index (VFM Index), evaluating Technical Offering and Price using a lowest price per technical point scored. This will be ascertained by dividing each bidder's quoted price by their own final moderated technical score. DSTL reserves the right to fail a tender on the grounds of technical non-compliance.

Tender	Technical Score	Cost (£)	Price per technical point	Rank
A	90	90,000	£1000	1
B	45	67,500	£1500	3
C	60	66,000	£1100	2

The supplier with a fully commercially compliant proposal, with the lowest price per technical point (to 2 decimal places) will be the winning tenderer subject to available funding. Decisions shall be made at the sole discretion of the Authority.

	In the event of a tie between tenders having achieved exactly the same price per technical point, precedence shall be given to the tender that has achieved the highest overall technically weighted score. DSTL reserves the right to fail a tender on grounds of unaffordability. The limit of affordability remains unrevealed. Tenders will be technically evaluated using the criteria supplied in the following table. The scores for each criteria will be weighted as listed. The maximum technical score is 100, the minimum score is 0.
2.2	Technical Evaluation Criteria

The supplier's proposal will be technically acceptable if considered by Dstl Subject Matter Experts (SMEs) that the plan is credible and it provides sufficient confidence that it will achieve the requirements within the stated timescales.

Score	Definition
10	Excellent/ high confidence - Provides a very high level of detailed evidence that addresses all parts of the question/task. The evidence and information is very credible and gives a very high level of confidence.
9	
8	Very good/very confident- Bid addresses all parts of the question/tasks very well. The Supplier gives very good level of confidence about their ability to meet the requirement.
7	
6	Good/ confident - Bid addresses all parts of the question, evidence is credible and gives confidence that the Supplier has the ability to successfully meet the requirement
5	Fair/ minor concerns - Bid demonstrates some experience and provides some adequate supporting evidence but fails to address some parts of the question and/ or the evidence lacks some credibility.
4	Poor – The bid fails to address key parts of the question/tasks and/or lacks credibility. Inadequate supporting evidence.
3	Serious concerns - The bid fails to address most parts of the question and/or supporting evidence gives cause for concern on the Supplier's ability to meet the requirements.
2	Unacceptable- Evidence provided is misleading or evidence is not relevant to the question asked. Low confidence in the Supplier's competence.
1	
0	Unacceptable - No evidence or answer.

Criteria	Weighting of criteria
1. Provide evidence that the team are suitably qualified and experienced to conduct the proposed work. Appropriate evidence may include but is not limited to: application in a clinical setting, teaching practical methods, academic/ journal papers and other information generated from unpublished work. It is recognised a multi-disciplinary team will be required to delivery and collaboration is encouraged.	2
2. Provide information on the available facilities and specific instrumentation to be used within this project to include the rationale for their use.	2
3. Provide a description of your proposed experimental design and technical approach. This may include reference to academic/ journal papers and other information generated from previous unpublished work by the team. Evidence we are looking for will include the below items and approaches proposed should offer a rationale for selection based on the overall objectives of the study. a) Innovative solutions are encouraged b) The explanation of the likely effectiveness of proposed interventions is logical and supported by evidence. c) The proposed experimental design is logical and has sufficient power to discriminate a useful effect of any proposed intervention. d) The relative benefits and disadvantages of head out immersion versus full immersion are discussed. e) If the use of a pharmaceutical is planned, evidence is presented that this is not a clinical trial or how compliance with GCP will be achieved. If adequate evidence is not supplied the tender will be considered technically non-compliant and will be excluded from the competition f) A description of how palatability of orally administered interventions will be assessed.	4

4) Provide evidence of safe working practices and experience of ethical review processes applicable to work. a) If the trial is considered a clinical trial, evidence shall be presented on how compliance with Good Clinical Practice will be achieved. If adequate evidence is not supplied the tender will be considered technically non-compliant and will be excluded from the competition b) If the trial meets the definition of a diving operation under the Diving Operations at Work Regulations, evidence shall be presented of operating as a Diving Contractor. If adequate evidence is not supplied the tender will be considered technically non-compliant and will be excluded from the competition.	1
5. Provide an estimated cost plan for the option of an experimental study to demonstrate the effectiveness of any proposed intervention to mitigate the longer term effects of daily long immersions.	0.5
6. Provide an estimated costed plan for the design and execution of a military trial and subsequent analysis of the data with the objective of demonstrating the effectiveness of the proposed mitigation in a military training setting. The location would likely be Portland Harbour. MOD and Dstl would lead the trial. The proposal shall include a plan for working collaboratively with Dstl and MOD.	0.5

2.3 Commercial Evaluation Criteria

Commercial Proposals will be evaluated according to the following criteria:

Element	Requirement	Weighting
C1	Compliance with the Task specific terms and conditions as stated within the Statement of Requirement Part B and respective Call-Off Tasking Form Part C	Pass/Fail
C2	Please submit your full firm price breakdown for all costs to be incurred, including: • What rates are being used for what Grade • Quantity of manpower hours per Grade • Travel & Subsistence costs • Any Materials costs • Any Facility costs • Any Sub-Contractor costs • Any other costs	Pass/Fail

[redacted]

Commercial Scoring criteria:

Score	Definition
Pass	Fully meets the Authority's requirement. Provision and acceptance of the sub-criteria information in the format requested, which is clear, unambiguous and transparent.
Fail	Unacceptable/Nil Return. Tenderer did not respond to the question or the response wholly failed to demonstrate an ability to meet the sub-criteria requirement. **Any proposal marked as a Fail will be excluded from the competition**