




Medical Devices Used in Extreme Conditions in Pre-Hospital Emergency Medicine: Overview of the Issue, Use Case Regarding Mechanical Ventilation at Altitude and Advice

Carine Malle^{1,*}^a, Alban De Luca²^b and Thierry Chevallier^{3,4,5}^c

¹Direction of Training, Research and Innovation, French Defence Health Service,
1 Place Alphonse Laveran, 75005 Paris, France

²Archeon, 2 Chemin des Aiguillettes, 25000 Besançon, France

³Department of Biostatistics, Epidemiology, Public Health and Innovation in Methodology (BESPIM),
CHU Nîmes, Place du Pr. Robert Debré, 30029 Nîmes, France

⁴UMR 1302, Institute Desbrest of Epidemiology and Public Health, INSERM, Univ. Montpellier, Montpellier, France

⁵Tech4Health-FCRIN, France

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Abstract: Pre-hospital emergency medicine sometimes involves taking care of patients in environments far different from the hospital. Cold, heat, humidity, altitude, wind, etc. put human beings and equipment to a severe test. What are the extreme conditions to which pre-hospital emergency medicine professionals are exposed? What types of medical devices are particularly concerned? What are the regulations and standards in force? What are the impacts of exposure to extreme conditions on medical devices? To answer these questions, we rely on an analysis of the regulatory and normative context, on a scientific literature review and on a case study involving mechanical ventilation at altitude. Finally, we share some thoughts and advice intended for health facilities and users, in order to improve practices in terms of selection, use and monitoring of medical devices exposed to extreme conditions. This document is illustrated with examples concerning the French defence health service, but our approach can be applied to any entity concerned with pre-hospital emergency medicine.

1 INTRODUCTION

Pre-hospital emergency medicine focuses on caring for seriously ill or injured patients before they reach hospital. It calls upon various specialties: anaesthesiology, traumatology, toxicology, psychiatry, etc.


The increasing extension of the field of territories open to tourism and military operations lead medical personnel, both military and civilian, to intervene in environments that are qualified as extreme, either because of the climatic conditions (cold, heat, humidity, wind, etc.) or because of the characteristics of the point of care (aircraft, mountain, sea, etc.).


If the effects of extreme environments on human physiology have been the subject of numerous studies


for decades, this is not the case for their effects on drugs, and even less so on medical devices (MD).

After having made an inventory of the extreme conditions and their impact on the MD, we will illustrate our point with a concrete example regarding the use of mechanical ventilation at altitude in the context of aeromedical evacuations. Finally, we will try to share some thoughts and advice for health care institutions and users to improve practices in terms of selection, use and monitoring of MD exposed to extreme conditions.

The military medical personnel being very frequently confronted with extreme environments, we have chosen to illustrate our point with common military operational situations. However, we hope that this work will be of benefit to any health care

^a <https://orcid.org/0000-0002-6824-1383>

^b <https://orcid.org/0000-0002-0911-7311>

^c <https://orcid.org/0000-0002-5110-6273>

*carine.malle@gmail.com

facility or caregiver practicing pre-hospital emergency medicine.

2 EXTREME CONDITIONS IN PRE-HOSPITAL EMERGENCY MEDICINE

Military medical personnel routinely encounter extreme conditions, in particular in the context of medical care for soldiers injured in external military operations.

2.1 Extreme Climatic Conditions

Due to these activities, military medical personnel are occasionally faced with the practice of medicine in extreme climatic conditions, such as cold, heat, humidity or altitude.

In France, sub-zero temperatures are common in high mountain areas during the winter period. At altitude, the decrease in atmospheric pressure and the rarefaction of the air lead to a decrease in air temperature. The average thermal gradient is about 0.6°C every 100 m. Thus, when going from Chamonix valley (altitude: 1100 m) to the summit of Mont-Blanc (altitude: 4807 m), one loses about 20°C. Heat exposure is a constant in some theatres of operation, notably in the Sahel, where military professionals are faced with temperatures approaching 50°C. In equatorial areas, like French Guyana, the humidity rate is comprised between 70 and 90% all year long. It should be noted that these constraints are often combined with each other, humidity and heat, altitude and cold, and associated with other constraints (wind, difficult terrain, stress, etc.).

2.2 External Military Operations

In external military operations, medical care of the wounded soldiers is organized into four levels:

- Role 1 corresponds to the initial care of the wounded soldiers directly on the field. Role 1 must be mobile and responsive. Resuscitation procedures can be performed, and the health products available are of primary necessity. Nurses, physicians but also non-health professionals are involved.

- Role 2 includes mobile surgical units, rapidly deployable but with limited autonomy. They are capable of performing resuscitation and emergency surgical interventions, in particular haemostasis control.

- Role 3 corresponds to a heavier and more important surgical unit with reinforced medical, surgical and diagnostic means. At this level, the patient may be stabilized.

- Role 4 corresponds to hospitals located in mainland France. The patient is evacuated when his condition is critical or requires care that is not available on site.

Each level is provided with medical supplies, including specific MD. Role 1 receives mainly “rustic” MD, i.e., light, compact, solid and easy to use, such as portable pulse oximeters (class IIb), tactical tourniquets (class I), bandages (class I or IIa) or automatic bone injection guns (class IIb). In role 2, these same MD are added to all surgical equipment (e.g., stapler; class III). From role 3 onwards, caregivers have all the MD commonly used in conventional emergency medicine, such as external defibrillators (class III) and emergency ventilators (class IIb). Thus, each MD is associated with one (or more) level(s) of use, which will condition the constraints to which the MD must resist and the type of user.

2.3 Aeromedical Evacuations

A medical evacuation (MEDEVAC) is the transfer of a patient, carried out on a physician's prescription, in order to provide continuity of care and treatment. It can be performed with or without medical accompaniment. In times of conflict, the transfer of these patients is strongly influenced by various factors such as the operational environment, the climate, the length and quality of the evacuation routes and the availability of appropriate means of transport. In this sense, the air route is most often chosen.

Several types of aircraft can be used depending on the number of patients to be evacuated and the distance to be covered, all of which are equipped with at least one mechanical ventilator. Without adequate dynamic correction by the ventilator or by the physician, the decrease in barometric pressure during the ascent to altitude is accompanied by an increase in ventilator delivered gas volume. Depending on the level of cabin pressurization and on the instructions set for the ventilator (respiratory rate and fraction of inspired oxygen (FiO_2)), tidal volume can be increased by up to 30%, which exposes the patient to an increased risk of barotrauma (pneumothorax or alveolar trauma related to excess intrathoracic pressure) and ventilator-induced lung injury (VILI; alveolar trauma related to too much intra-alveolar volume sometimes responsible for secondary scar

fibrosis). A practical example of the impact of altitude on a mechanical ventilator is displayed in section 4.

2.4 What About CE Marking?

EU Regulation 2017/745 (Annex I. General safety and performance requirements) is not restrictive in terms of the environmental conditions to be met:

“7. Devices shall be designed, manufactured and packaged in such a way that their characteristics and performance during their intended use are not adversely affected during transport and storage, for example, through fluctuations of temperature and humidity, taking account of the instructions and information provided by the manufacturer.” (Chapter I, page 95)

“14.2. Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible: [...] (b) risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences;” (Chapter II, page 99).

Thus, the instructions for use remain the major source of information regarding “information that allows the user and/or patient to be informed of any warnings, precautions, contra- indications, measures to be taken and limitations of use regarding the device.” (Chapter III, page 106), although design may provide useful feedback to users

3 IMPACTS OF EXTREME CONDITIONS ON MD USED IN EMERGENCY MEDICINE

3.1 Literature Review

Kämäräinen et al. (2012) assessed the resistance of various single-use MD mainly composed of plastic materials, such as endotracheal tubes, suction catheters, and infusers, to a 15-minute exposure to a temperature of -21.5°C . Resistance was assessed via a manual stress test designed to mimic normal pre-hospital use. The authors observed a loss of flexibility that led in some cases to the rupture of tubes and catheters. A comparative study of several oxygen concentrators showed that storage for 24 hours at -35°C significantly impaired the ability of portable oxygen concentrators to maintain FiO_2 at set point (Blakeman et al. 2016).

In the early 1990s, as part of the development of heliborne medical evacuations in the United States, Bruckart and colleagues (1993) evaluated 34 MD, including defibrillators, ventilators, infusion pumps and vital signs monitoring devices under various environmental conditions (in accordance with the environmental tests described in the American military standard MIL-STD 810D): altitude (15,000 ft, or 4,572 m), heat, cold, humidity and vibrations. One third of the MD failed at least one environmental test, with the failure consisting of a “visible” device failure. A “visible” failure was defined as a MD that completely stops working, a display screen that goes out, a battery that discharges, an alarm that sounds without reason, etc. In the absence of a performance evaluation of MD, a dysfunction affecting the measurement by the sensors would probably not be identified by these tests. The compliance of two thirds of the devices evaluated with environmental standards does not guarantee the safety of patients treated with these devices in extreme conditions. Since then, more recent studies have compared various models of the same type of MD at altitude, either with the aim of determining the most “suitable” of them, or with the aim of understanding the cause of malfunction identified in current practice. For example, in a comparative study of 4 capnographs exposed to increasing altitude, one device failed as early as 3650 m and only one device was still functional at 5470 m (Pattinson et al. 2004). Few published studies have not stopped at listing failures but have actually assessed the performance of MD. For example, in 2019, a comparative study of 5 syringe pumps showed that miniature models, which are more easily transportable, were less accurate than standard-sized models in terms of infusion rate accuracy as early as 1700 m (Blancher et al. 2019). Regarding transport ventilators, several studies (e.g., Rodriguez et al., 2009; Blakeman et al, 2014; Boussen et al., 2014) have shown a decrease in the accuracy of volume delivered by some MD at altitude, even on MD with altitude-compensating features. Thus, Boussen's team compared 6 ventilators at moderate altitudes (1500 and 2500 m). If 4 of them proved to be efficient (average relative error of the delivered tidal volume $<10\%$), they showed however that the exposure to a moderate altitude led to an increase of 30% of the tidal volume (for a FiO_2 of 100%) on one of the recent models and whose use at altitude (up to 3500 m approximately) was not contraindicated by the manufacturer. It should be noted that some articles do not mention the use of measurement sensors independent of those of the MD, which suggests that the results are based on

the data displayed by the MD itself without verification of their accuracy.

Although these studies present relatively concerning results, we do not know whether they have had any real impact on the MD tested (e.g., changes to the design or the manual).

3.2 A Vital Risk for Patient

Due to the fragility of electronic components, active MD seem to be particularly at risk of malfunctioning under extreme conditions. Whether the failure results in an obvious malfunction (e.g., complete shutdown, display failure) or one that is more difficult to detect (e.g., measurement error), there is a vital risk for the patient.

The other types of MD are not spared: hardening, deformation (shrinking or swelling), rupture, oxidation, corrosion of materials, delamination of composite materials, condensation, air bubble formation, loss of seal, etc. (Janno & Degiovanni, 2018; Parent, 2017) are some of the potential consequences of exposure of any MD to extreme conditions. Continuous or repeated exposure to extreme conditions also participates in the accelerated aging of MD, which requires specific maintenance procedures. It therefore seems essential that MD intended to be used in extreme conditions be evaluated under these conditions during preclinical testing. Standards have been established to harmonize practices.

3.3 Main Applicable Standards Regarding Extreme Environments and Their Limits

Even if they are not mandatory, standards allow to meet certain requirements of the applicable regulations.

These standards are of 2 types: horizontal standards that concern development and manufacturing processes, risk analysis, clinical investigations and quality assurance systems, and vertical standards that concern specific MD. They are continually evolving because of the constant evolution of MD.

If the conformity of MD to these standards is important to take into account, one must however be aware of their limits. A first limitation is the existence of several standards depending on the country and the context (notably civil/military, air/land). A second limitation is the relative freedom left to manufacturers in the choice of tests performed to claim compliance with these standards. With regard to altitude, for

example, the military standards AECTP-230 and MIL-STD-810 indicate different exposure levels that can be investigated, but it is up to the manufacturer to choose which level to apply to test his MD. Thus, the manufacturer may claim compliance with a military aeronautical standard even though the MD has only been evaluated at moderate altitudes (e.g., 2500 m). A third limitation lies in the interpretation of test results. Most of these standards remain superficial as to the evidence of performance and safety that must be provided. For example, one can see that the standard for transport ventilators (ISO/IEC 10651-3:1997 “Lung ventilators for medical use - Part 3: Particular requirements for emergency and transport ventilators”) requires at a minimum that the ventilator “continue to function” under extreme conditions: “Extreme conditions [...] Note - The ventilator might continue to function but outside the specified tolerances.” (6.8.3.e, page 7).

Table 1: Main applicable standards relative to MD used in extreme conditions.

Publisher	Standard title	Scope of application
NATO	STANAG 4370 “Environmental testing”	MD used in the military field (in NATO countries)
Department of Defense, USA	MIL-STD-810E “Environment engineering considerations and laboratory tests”	MD used in the US army
Special Committee 135 (SC-135)	DO-160G “Environmental conditions and test procedures for airborne equipment”	On-board MD in aircraft
International standard	ISO/IEC 60601-1-2:2014	Active MD
International standard	ISO/IEC 60068-2-6	MD exposed to vibrations
International standard	ISO/IEC 60068-2-27	MD exposed to shocks
NATO: North Atlantic Treaty Organization STANAG: Standard Agreement		

4 CASE STUDY: MECHANICAL VENTILATION IN AEROMEDICAL EVACUATION

4.1 LTV® 1200

The LTV® 1200 (Care Fusion, San Diego, USA) is currently present in French MEDEVAC aircrafts. It is a turbine ventilator that can operate in both controlled and spontaneous mode with inspiratory support.

The LTV® 1200 ventilator is intended to provide continuous or intermittent ventilatory support for the care of persons requiring mechanical ventilation. The ventilator is a restricted MD intended for use by qualified and trained personnel under the direction of a physician. Specifically, the ventilator is applicable to adult and paediatric patients weighing at least 11 pounds (5 kg). The ventilator is suitable for use in institutions, at home or in transport.

The temperature must be between +5 and +40°C and the relative humidity between 15% and 95%. The device complies with the international standard IEC 68-2-27 for shock resistance, the international standards IEC 68-2-6 and IEC 68-2-34 for vibration resistance and the US military standard MIL-STD-810E for shock resistance in ground and helicopter transport. The device has also been approved by the FDA as a “transport ventilator” and the leaflet states that the LTV® 1200 is “suitable for use in institutional, home, or transport settings”. However, the manufacturer does not claim the standard for transport ventilators (ISO/IEC 10651-3:1997 “Lung ventilators for medical use - Part 3: Particular requirements for emergency and transport ventilators”). While the leaflet refers to the device's ability to automatically adapt tidal volume in response to increasing altitude, no indication is given regarding the altitude range at which the device should be used.

4.2 Performance Evaluation of the LTV® 1200 at Altitude

In 2012, the French defence health service conducted a study comparing the performance of 3 ventilators, including the LTV® 1200, at simulated altitude in a hypobaric chamber. The performance of the ventilators on an artificial lung was measured at ground level (FL0), at 2400 m (FL80) and at 3600 m (FL120).

This study showed that the tidal volume (V_T) delivered by the LTV® 1200 at FL80 and FL120 was significantly increased compared to the ground measurement. Whatever the altitude, the V_T delivered

never respected the V_T set point (450 or 700 ml). If the measurements were within the $\pm 20\%$ margin provided by the ISO/IEC 10651-3 standard at FL0 and FL80, this was no longer the case at FL120. For a set point of 450 ml (breathing rate = 12 breaths per minute; $FiO_2 = 50\%$), the ventilator delivered an average of 540 ml at FL120 (figure 1A). Furthermore, when the FiO_2 set point was increased from 50 to 100%, the V_T was even higher, increasing to an average of 585 ml (figure 1B). Similar results were observed with a tidal volume set point of 700 ml. This study concluded that the LTV® 1200 did not meet the stability criteria necessary for a transport ventilator (Forsans, 2012). However, the LTV® 1200 does still equip airborne MEDEVAC today. This study illustrates the unsuitability of certain medical MD for the environment in which they are used. As patient safety is at stake, we would like to share some thoughts and advice for health facilities and users.

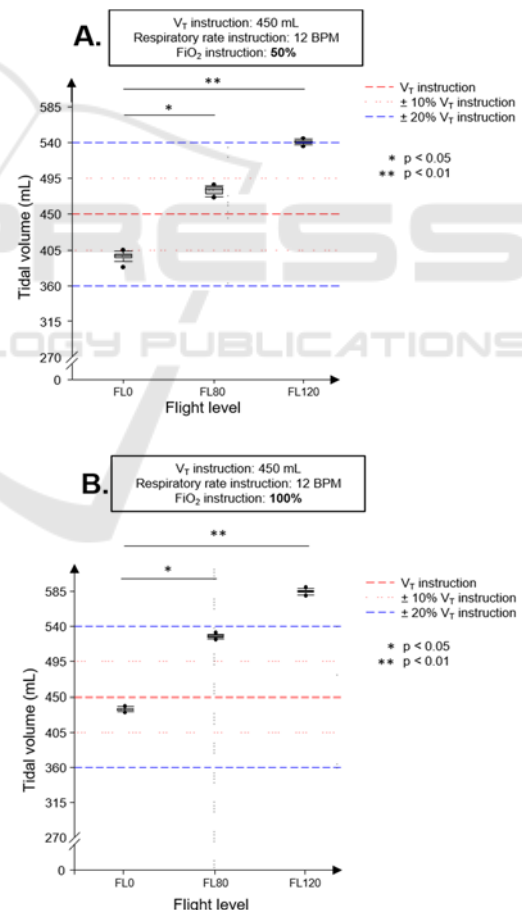


Figure 1: LTV® 1200 performance at altitude.

A and B parts display two different sets of instructions (framed text). BPM: breaths per minute; FiO_2 : fraction of inspired oxygen; V_T : tidal volume.

5 CONSIDERATIONS AND ADVICE FOR HEALTH FACILITIES AND USERS

Before purchase by the health facility, the analysis of requirements (by biomedical engineers) should be based on general recommendations (in particular the WHO technical series on MD: "Assessment of medical device requirements") and specific recommendations for each type of MD, and should include all the constraints to which the device is intended to be exposed. The choice of a MD over another should be based on reliable, verifiable information that is the responsibility of the manufacturer (instructions for use) and not on a sales pitch.

After purchase by the health facility, in the absence of specific recommendations from the manufacturer for the planned use, health facilities should ensure that the performance and safety of the device under extreme conditions are evaluated before use. This may involve different types of tests: pre-clinical tests, usability evaluations or even clinical investigations as defined in the EU Regulations 2017/745 and 2017/746. Monitoring should include traceability of conditions of use and the collection of safety information related to these (extreme) conditions of exposure/use. Finally, user training should include awareness of the impact of extreme conditions on the device (figure 2).

6 CONCLUSIONS

To conclude, we show that pre-hospital emergency medicine is inseparable from the notion of "extreme conditions", particularly in the French defence health service. The types of MD concerned are very diverse and of all classes. Only the instructions for use provide reliable information about the conditions supported by a given device. The claim of conformity to environmental standards must be analysed with care and is in no way a guarantee of the performance and/or safety of the MD. The scientific literature on the impact of extreme conditions on MD is relatively poor and official recommendations in terms of exposure to extreme conditions are almost non-existent. One interpretation of this finding could be the rarity of malfunctions, but we also suspect an under-reporting of incidents associated with a strong publication bias. Finally, the use case we described illustrates in a masterly way the gap that can exist between the needs of caregivers and the equipment

they actually have. It also highlights the lack of communication within a healthcare institution between the medical personnel who use MD and the department in charge of selecting and purchasing them.



Health facility

- Tip 1: Carefully read all the documentation provided by the manufacturer and the standards claimed (before purchase).
- Tip 2 : When needed, assess the MD under the intended conditions of use (before making it available to users).
- Tip 3 : Make users aware of the impact of extreme conditions on the device.
- Tip 4 : Implement a process for tracing conditions of exposure/use of the device and adapt maintenance to the collected data.
- Tip 5: Encourage the reporting of incidents related to extreme conditions in order to assess their frequency and severity.



User

- Tip 1: Carefully read all the documentation provided by the manufacturer and the standards claimed.
- Tip 2: Be aware of the technical limitations of the device.
- Tip 3: Be aware of the conditions under which the device is stored, transported and used.
- Tip 4: Report to the institution (but also to the manufacturer and to competent authorities) and any incident or risk of incident directly or indirectly related to extreme conditions.

Figure 2: Tips for health facilities and users.

This problematic raises ethical questions. How should the user behave when confronted with the emergency care of a patient with a medical device in unexpected extreme conditions? Use the medical device anyway and risk sanctions? Not to use it at the risk of letting the patient's condition deteriorate? How should he report the incident to his hierarchy? In our

view, in the same way that exceptions to the collection of patient's consent in emergency situations have been established, the unplanned use of a medical device in the emergency context should be the subject of reflection so as to result in rules of good practice ensuring protection of both patients and users. A major limitation of this article is that we have not found any tangible evidence (incident reports, product recalls, clinical investigation results, etc.) to prove that this problem is a clinical reality. However, we have collected several testimonies from French defence health service caregivers who have encountered difficulties in the use of MD in an operational context. This paradox raises questions. Our hypothesis is that incidents related to extreme conditions are under-reported by users, in particular because it is considered that the issue is not related to the device but is the responsibility of the user who has not followed the instructions for use. It seems crucial to encourage the reporting of these incidents, without implicating the manufacturer's responsibility, in order to measure their frequency and severity in real life.

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REFERENCES

- Blakeman, T., Britton, T., Rodriguez, D. Jr., & Branson, R. (2014). Performance of portable ventilators at altitude. *Journal of trauma and acute care surgery*, 77(3 Suppl 2):S151-5. <https://doi.org/10.1097/TA.0000000000000379>
- Blakeman, T. C., Rodriguez, D. Jr., Britton, T. J., Johannigman J. A., Petro, M. C., & Branson, R. D. (2016). Evaluation of Oxygen Concentrators and Chemical Oxygen Generators at Altitude and Temperature Extremes. *Military Medicine*, 181(5 Suppl):160-8. <https://doi.org/10.7205/MILMED-D-15-00130>
- Blancher, M., Repellin M., Maignan, M., Clapé, C., Perrin, A., Labarère, J., Debaty, G., & Viglino, D. (2019). Accuracy of low-weight versus standard syringe infusion pump devices depending on altitude. *Scandinavian Journal of Trauma Resuscitation and Emergency Medicine*, 11;27(1):65. <https://doi.org/10.1186/s13049-019-0643-1>
- Boussen, S., Coulangue M., Fournier M., Gainnier M., Michelet P., Micoli C., & Negrel L. (2014). Evaluation of transport ventilators at mild simulated altitude: a bench study in a hypobaric chamber. *Respiratory Care*, 59(8):1233-41. <https://doi.org/10.4187/respcare.02985>
- Forsans, E. (2012). Ventilation en altitude : Performances de trois ventilateurs [Thèse de médecine, Ecole du Val-de-Grâce].
- Jannot, Y., & Degiovanni, A. (2018). Mesure des propriétés thermiques des matériaux. Iste editions. ISBN 978-1-78405-423-6
- Kämäräinen, A., Virta, J., Yliherne, S., & Virkkunen, I. Evaluation of the effects of low temperature on performance of standard non-electric medical equipment at -21.5°C (-6.7°F) - a descriptive study on a real life challenge in the prehospital setting. (2012). *Resuscitation*, 83(12):1517-20. <https://doi.org/10.1016/j.resuscitation.2012.05.007>
- Parent, G. (2017). Evaluation de la durée de vie de composants électroniques de puissance commerciaux soumis à plusieurs tests de vieillissement et détermination des mécanismes de défaillance [Thèse de sciences, Université de Toulouse].
- Pattinson, K., Myers, S., & Gardner-Thorpe, C. (2004). Problems with capnography at high altitude. *Anaesthesia*, 59(1):69-72. <https://doi.org/10.1111/j.1365-2044.2004.03447.x>
- Rodriguez, D. Jr., Branson, R. D., Dorlac, W., Dorlac, G., Barnes, S. A., & Johannigman, J.A. (2009). Effects of simulated altitude on ventilator performance. *Journal of trauma and acute care surgery*, 66(4 Suppl):S172-7. <https://doi.org/10.1097/TA.0b013e31819cddb1>