

A modified device for continuous non-invasive blood pressure measurements in humans under hyperbaric and/or oxygen-enriched conditions

René van der Bel, Bart C Sliggers, Marc J van Houwelingen, Johannes J van Lieshout, John R Halliwill, Robert A van Hulst and C T Paul Krediet

Abstract

(van der Bel R, Sliggers BC, van Houwelingen MJ, van Lieshout JJ, Halliwill JR, van Hulst RA, Krediet CTP. *Diving and Hyperbaric Medicine*. 2016 March;46(1):38-42.)

Background: It would be desirable to safely and continuously measure blood pressure noninvasively under hyperbaric and/or hyperoxic conditions, in order to explore haemodynamic responses in humans under these conditions.

Methods: A systematic analysis according to 'failure mode and effects analysis' principles of a commercially available beat-by-beat non-invasive blood pressure monitoring device was performed using specifications provided by the manufacturer. Possible failure modes related to pressure resistance and fire hazard in hyperbaric and oxygen-enriched environments were identified and the device modified accordingly to mitigate these risks. The modified device was compared to an unaltered device in five healthy volunteers under normobaric conditions. Measurements were then performed under hyperbaric conditions (243 kPa) in five healthy subjects.

Results: Modifications required included: 1) replacement of the carbon brush motorized pump by pressurized air connected through a balanced pressure valve; 2) modification of the 12V power supply connection in the multiplace hyperbaric chamber, and 3) replacement of gas-filled electrolytic capacitors by solid equivalents. There was concurrence between measurements under normobaric conditions, with no significant differences in blood pressure. Measurements under pressure were achieved without problems and matched intermittent measurement of brachial arterial pressure.

Conclusion: The modified system provides safe, stable, continuous non-invasive blood pressure trends under both normobaric and hyperbaric conditions.

Key words

Patient monitoring; hyperbaric facilities; cardiovascular; physiology

Introduction

Arterial pressure is a highly controlled variable, and its responses to environmental stresses can provide insights into both normal physiological adaptations to these environments, and identify pathophysiological responses.¹⁻³ Thus, in basic and applied human research and in clinical settings there is a need for a safe, non-invasive, continuous blood pressure measurement system which can be used under hyperbaric and/or hyperoxic conditions including for haemodynamic monitoring in remote situations, where invasive measurements are unavailable (e.g., in the off-shore industry). Devices used under hyperbaric and/or hyperoxic conditions must meet strict safety requirements to avoid pressure failure and spark formation.^{4,5} At present, devices used to monitor critically-ill patients are not designed to withstand hyperbaric pressurization and are associated with an increased risk of fire in a pressure chamber.^{4,6,7}

Several blood pressure monitoring options are available for use in hyperbaric chambers.^{6,7} However, these are either invasive or measure only intermittently; there is no system available that enables continuous, non-invasive monitoring. Our aim was to perform a systematic analysis of a commercially available, beat-by-beat, non-invasive blood pressure monitor according to 'failure mode and effects

analysis' (FMEA) principles,⁸ and determine whether and how it could be modified to safely and accurately operate under hyperbaric and/or hyperoxic conditions.

Methods

The PortapresTM (Finapres Medical Systems, Amsterdam, The Netherlands) is a commercially available, ambulatory blood pressure monitoring system based on Peñáz-Wesseling finger arterial photo-volume plethysmography.⁹ The system has been validated for use under various conditions such as during exercise, high altitude, and in space, and is used in a variety of clinical settings.¹⁰⁻¹² The system records finger arterial blood pressure from which the waveform can be passed through pulse-wave analysis algorithms to estimate changes in stroke volume, cardiac output, and peripheral resistance.¹³ It is because of these unique characteristics that we considered the PortapresTM a suitable candidate for adaptation to the hyperbaric environment.

The PortapresTM system consists of a main unit weighing approximately 1.5 kg, which is typically worn on a waist belt that contains a 12-V battery pack. The front-end unit connecting the finger cuff with the main unit is worn on the wrist. The system records continuous finger arterial blood pressure at 100 Hz for up to 60 h. Recordings can

retrieved afterwards via a serial port. Also, an analogue output is available for real-time visualization of the pressure waveform. The system self-calibrates during a so-called 'physiocal'.

A 'physiocal' occurs over two consecutive beats (arterial pulse waves) during which the cuff pressure is fixed at mean pressure during the first of the two beats and a quarter of the pulse pressure lower during the second beat. Based on the plethysmograms of these two beats, the cuff pressure set point is determined.¹⁴ At the start of each measurement a physiocal is automatically performed every ten beats and when the set point deviations between consecutive physiocals are within the accepted range, then the physiocal interval is automatically increased by ten beats up to a maximum of 70 beats. Disturbances from external factors or internal errors (as relevant to our testing) that interfere with the plethysmogram will automatically reduce the physical interval. Attainment of the maximum physiocal interval of 70 beats is, therefore, an excellent indicator that the measurement of the arterial pulse wave signal is stable and reliable.

RISK ASSESSMENT

Based on the specifications provided by the manufacturer, the Portapres™ system (Model 1, Finapres Medical Systems, Amsterdam, The Netherlands) was systematically analysed according to FMEA principles.⁸ In the FMEA analysis, in case of a malfunction in the chamber, we identified the following potential failure modes related to pressure resistance and fire hazard in a hyperbaric and potentially oxygen-enriched environment:

- Spark formation: from various electric components, such as the carbon brush motorized pump and connections to the battery power supply;
- Overheating: due to increased power consumption at increasing gas densities;
- Hyperbaric implosion hazard of the gas-filled electrolytic capacitors.

A standard Portapres™ device was modified to mitigate these risks and then tested under normobaric and hyperbaric conditions.

RELIABILITY ASSESSMENT

After the necessary modifications (see Results) were made, the modified device was certified for electrical safety by our institutional Technical Safety Board and approved for research use in humans. The system was then applied in an on-going research protocol approved by the institution's Medical Ethics Committee (NL49531.018.14). All subjects gave written informed consent.

First, the modified device was exposed to a series of 15

hyperbaric challenges up to 283 kPa, while it was not connected to a human subject. Compression was achieved over fifteen minutes. The device was then kept at pressure for 90 minutes, before decompression over ten minutes. Thereafter, normal functioning of the device was verified by comparing the blood pressure readings to measurements with a standard non-portable version of the Portapres™ in five healthy volunteers (two male, three female, median age 27 (range 21–29) years) under normobaric conditions.

After correct functioning of the modified system was verified, hyperbaric measurements were performed in five subjects (four male, one female, median age 63 (range 61–68) years) and compared to intermittent brachial artery pressure using an Infinity Delta patient® monitor (Dräger AG, Germany). Measurements were considered stable and reliable when a physiocal interval of 70 beats was reached. Only after the maximal physical interval was reached, was brachial artery blood pressure measured.

STATISTICAL ANALYSIS

Data are presented as mean \pm SD. Agreement between the modified and unmodified systems was assessed by Bland-Altman analysis.

Results

TECHNICAL MODIFICATIONS

To prevent failures as identified in the risk-assessment, we applied the following modifications (Figure 1):

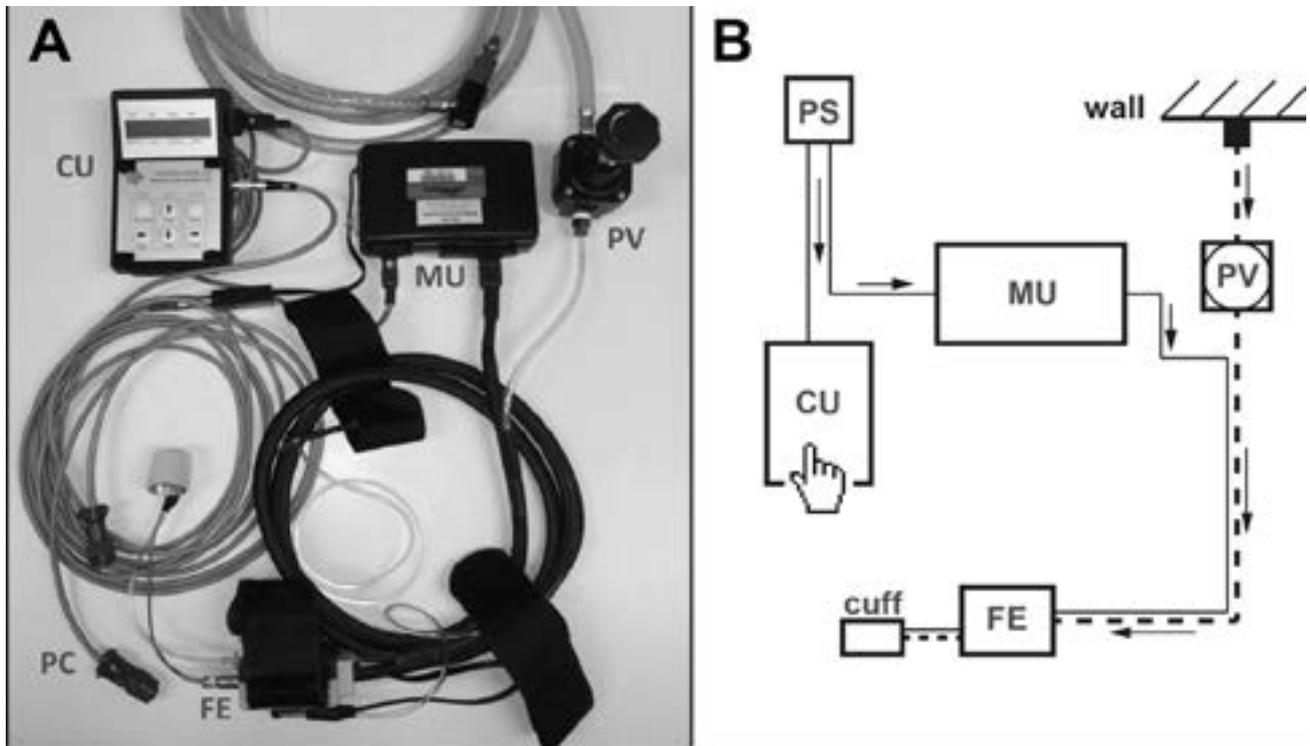
- *Spark formation*: 1) The carbon brush motorized pump was replaced by a connection to a pressurized air supply via a manually adjustable balanced pressure valve. The valve was set to 325 mbar, providing air at ≥ 60 L·min⁻¹, verified on a BP Pump 2 (Fluke Biomedical, Everett, USA) and sealed in that position. 2) The battery pack was replaced by 12-volt DC power adapters supplied by the manufacturer. These provided power through a chamber wall penetrator to a maximum rating of 2.74 A. Maximum power consumption by the device is 0.4 A.
- *Overheating*: Replacement with the air supply also eliminated this risk.
- *Hyperbaric implosion*: hazard of the gas-filled electrolytic capacitors: all gas-filled capacitors were replaced by solid-state equivalents.

Replacement of the motorized pump also reduced the power consumption of the device, meaning that power consumption would remain well below the listed 0.4 A.

Completion of these modifications by an experienced technician took approximately 15 man-hours. Applying them voided the manufacturer's warranty and CE certifications on the device; however, the modifications adhere to the EU

Figure 1

The Portapres™ system and modification; (A) modified Portapres™ system with main and control unit (MU, CU), front-end with cuff (FE), power cables (PC) for hyperbaric chamber power supply, and pressure valve (PV) connection to the air supply; (B) schematic overview with power supply (PS) and electrical current (solid lines) and air flow (dashed lines) indicated from wall to each subunit



guideline for medical devices 93/42/EEC, which allows the use of aftermarket-adapted devices to be used for research purposes. Clinical application can only be implemented after the CE certification of the device is extended to include its use under hyperbaric conditions.

DEVICE RELIABILITY

Under normobaric conditions, systolic/diastolic blood pressure was $116 \pm 9/64 \pm 10$ mmHg, measured by the modified device, compared to $117 \pm 8/69 \pm 7$ mmHg systolic/diastolic blood pressure using the unmodified control device, a mean difference of $1.0/4.9$ mmHg systolic/diastolic blood pressure (Figure 2).

At 243 kPa in five subjects, average systolic/diastolic blood pressure was $137 \pm 12/88 \pm 7$ mmHg compared to brachial artery measurements of $143 \pm 16/93 \pm 7$ mmHg systolic/diastolic blood pressure, a mean difference of $6.5/4.9$ mmHg systolic/diastolic pressure.

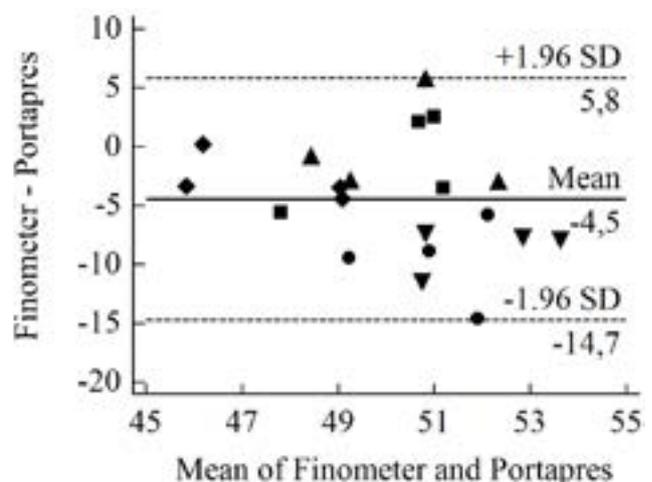
During all recordings the maximum physioal interval of 70 beats was reached. Data were successfully stored on the device and off-loaded after the subjects had left the hyperbaric chamber.

Discussion

Devices used under hyperbaric and/or hyperoxic conditions

Figure 2

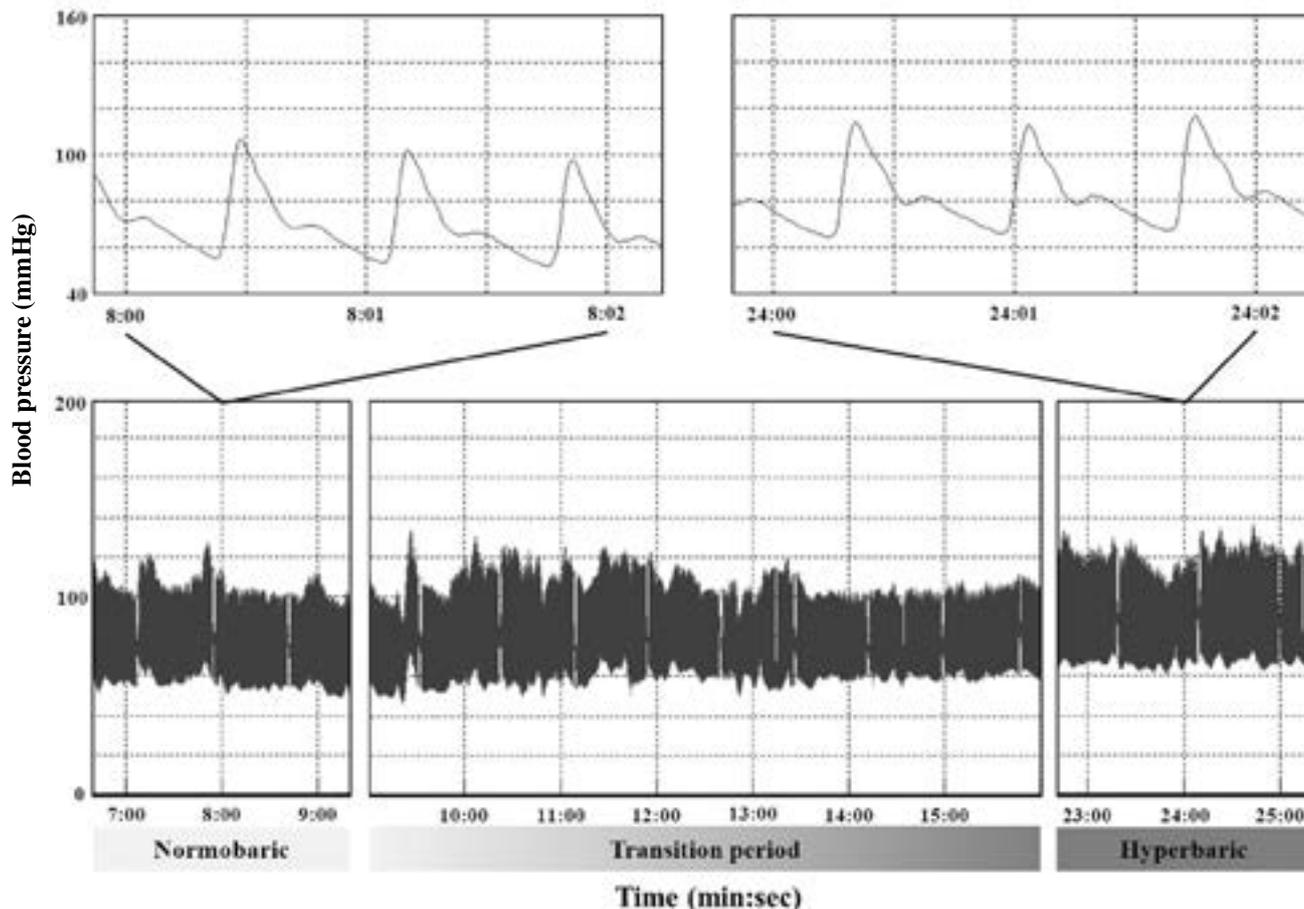
Bland-Altman analyses of repeated measures, comparing consecutive continuous blood pressure readings from the modified Portapres™ system and an unmodified Finometer™ in five healthy subjects; pulse pressure was determined in four evenly distributed 'physioal' intervals consisting of 70 beats in each recording; shapes indicate sets of repeated measurements per subject recording



must meet strict requirements to avoid pressure failure, spark formation and overheating.^{1,2} Previously continuous, non-invasive blood pressure monitoring has not been available under hyperbaric, hyperoxic conditions. A modified Portapres™ system can be used safely in a hyperbaric

Figure 3

Blood pressure recording under normo- and hyperbaric conditions; raw data from one continuous Portapres™ blood pressure recording during a normobaric (left upper and lower panels) and hyperbaric period (right upper and lower panels) in a healthy subject; included is the transitional phase during pressurization of the hyperbaric chamber from 101.3 kPa to 243 kPa in 6 minutes (middle lower panel); the upper panels depict detailed visualizations of the recorded pulse wave



chamber to provide continuous, non-invasive blood pressure monitoring. Tests in a small number of subjects demonstrate that the modified system functions normally and provides stable blood pressure readings under hyperbaric conditions at 243 kPa. Minor differences found all fall within the expected short-term physiologic variance in blood pressure as reported previously.¹⁵

Our aim was to perform a systematic analysis of a commercially available monitoring device according to FMEA principles to determine whether and how it could be modified to safely and accurately operate under hyperbaric and hyperoxic conditions. In all cases, once identified, components ‘at risk of failure’ were readily replaced with ‘low risk of failure’ alternatives that did not impact the overall function of the device. A FMEA approach could be applied to solve similar problems of adapting existing systems to the study of humans in technologically adverse environments. Because of the modifications, the Portapres™ device is no longer truly a portable system since both electrical power and pressurized air are no longer on board the device but, instead, are provide via chamber penetrators

(or in the case of the pressurized air supply, from a gas cylinder). We did not consider preservation of portability as an important redesign constraint as our goal was to enable measurements within a hyperbaric chamber.

Limitations of this study include the absence of validation against invasive arterial monitoring in the hyperbaric chamber. The reason for this is that few patients with an intra-arterial line undergo hyperbaric treatment in this centre.

Conclusion

We have modified and tested a beat-by-beat non-invasive blood pressure monitoring device (Portapres™) for safe use in hyperbaric and/or oxygen-enriched environments. This provides new opportunities for exploring cardiovascular and respiratory regulation and their possible interactions in health and disease associated with these environments. It may also allow patients who require more advanced monitoring to undergo hyperbaric oxygen therapy without the necessity for invasive arterial pressure monitoring.

References

- 1 Konda N, Shiraki K, Takeuchi H, Nakayama H, Hong SK. Seadragon VI: a 7-day dry saturation dive at 31 ATA. IV. Circadian analysis of body temperature and renal functions. *Undersea Biomedical Research*. 1987;14:413-23.
- 2 Ferrigno M, Ferretti G, Ellis A, Warkander D, Costa M, Cerretelli P, et al. Cardiovascular changes during deep breath-hold dives in a pressure chamber. *J Appl Physiol*. 1997;83:1282-90.
- 3 Shibata S, Iwasaki K, Ogawa Y, Kato J, Ogawa S. Cardiovascular neuroregulation during acute exposure to 40, 70, and 100% oxygen at sea level. *Aviat Space Environ Med*. 2005;76:1105-10.
- 4 Weaver LK. Hyperbaric oxygen in the critically ill. *Crit Care Med*. 2011;39:1784-91.
- 5 Sheffield PJ, Desautels DA. Hyperbaric and hypobaric chamber fires: a 73-year analysis. *Undersea Hyperb Med*. 1997;24:153-64.
- 6 Kot J. Medical equipment for multiplace hyperbaric chambers Part I: Devices for monitoring and cardiac support. *European Journal of Underwater and Hyperbaric Medicine*. 2005;6:115-20.
- 7 Kot J. Medical devices and procedures in the hyperbaric chamber. *Diving Hyperb Med*. 2014;44:223-7.
- 8 Willis G. Failure modes and effects analysis in clinical engineering. *J Clin Eng*. 1992;17:59-63.
- 9 Imholz BP, Wieling W, Van Montfrans GA, Wesseling KH. Fifteen years' experience with finger arterial pressure monitoring: assessment of the technology. *Cardiovasc Res*. 1998;38:605-16.
- 10 Sugawara J, Tanabe T, Miyachi M, Yamamoto K, Takahashi K, Iemitsu M, et al. Non-invasive assessment of cardiac output during exercise in healthy young humans: comparison between Modelflow method and Doppler echocardiography method. *Acta Physiol Scand*. 2003;179:361-6.
- 11 Claydon VE, Norcliffe LJ, Moore JP, Rivera M, Leon-Velarde F, Appenzeller O, et al. Cardiovascular responses to orthostatic stress in healthy altitude dwellers, and altitude residents with chronic mountain sickness. *Exp Physiol*. 2005;90:103-10.
- 12 Karemaker JM, Berecki-Gisolf J. 24-h blood pressure in Space: The dark side of being an astronaut. *Respir Physiol Neurobiol*. 2009;169Suppl 1:S55-8.
- 13 Sugawara J, Tanabe T, Miyachi M, Yamamoto K, Takahashi K, Iemitsu M, et al. Non-invasive assessment of cardiac output during exercise in healthy young humans: comparison between Modelflow method and Doppler echocardiography method. *Acta Physiol Scand*. 2003;179:361-6.
- 14 Wesseling KH, de Wit B, van der Hoeven GMA, van Goudoever J, Settels JJ. Physiological, calibrating finger vascular physiology for Finapres. *Homeostasis*. 1995;36:67-82.
- 15 Mancia G, Ferrari A, Gregorini L, Parati G, Pomidossi G, Bertinieri G, et al. Blood pressure and heart rate variabilities in normotensive and hypertensive human beings. *Circ Res*. 1983;53:96-104.

Acknowledgements and funding

This project was funded by the Dutch Kidney Foundation (Project KJPB 12.029 to CTPK). CTPK is supported by the Netherlands Organisation for Health Research (ZonMw, Clinical Fellowship 40007039712461). The Portapres™ was originally purchased by John M Karemaker, PhD, as part of project MG020 of the Space Research Organization Netherlands. This support is gratefully acknowledged.

Conflict of interest

MJvH is employed at Finapres Medical Systems.

Submitted: 08 June 2015; revised 16 December 2015 and 27 January 2016

Accepted: 28 January 2016

*René van der Bel*¹, *Bart C Sliggers*², *Marc J van Houwelingen*³, *Johannes J van Lieshout*^{1,4}, *John R Halliwill*⁵, *Robert A van Hulst*⁶, *C T Paul Krediet*¹

¹ Department of Internal Medicine, Academic Medical Center, University of Amsterdam, The Netherlands

² Department of Medical Technology, Academic Medical Center, University of Amsterdam, The Netherlands

³ Finapres Medical Systems, Amsterdam, The Netherlands

⁴ MRC/ARUK Centre of Musculoskeletal Ageing Research, School of Life Sciences, The Medical School, University of Nottingham, Queen's Medical Centre, Nottingham, UK

⁵ Department of Human Physiology, University of Oregon, USA

⁶ Hyperbaric Medicine, Academic Medical Center, University of Amsterdam, The Netherlands

Address for correspondence:

CTP Krediet

Department of Internal Medicine

Academic Medical Center at the University of Amsterdam

Meibergdreef 9, 1105AZ, Amsterdam

The Netherlands

Phone: +31-(0)20-566-5808

E-mail: <C.T.Krediet@amc.uva.nl>