

Boppli® platform

Boppli provides continuous, non-invasive blood pressure (cNIBP) monitoring for infants, including premature neonates, in critical care settings. Boppli reports systolic, diastolic and mean arterial blood pressure values comparable to an invasive arterial line (IAL).

The Boppli Band is a single-use, battery-powered blood pressure monitor that uses a thin, flexible sensor to continuously monitor blood pressure (BP) non-invasively. The Boppli Band wirelessly pairs with the Boppli Bedside tablet to enable live display of BP and pulse rate (PR), and review of recorded BP data over time.



Minimal contact,
no skin adhesive

INTENDED USE

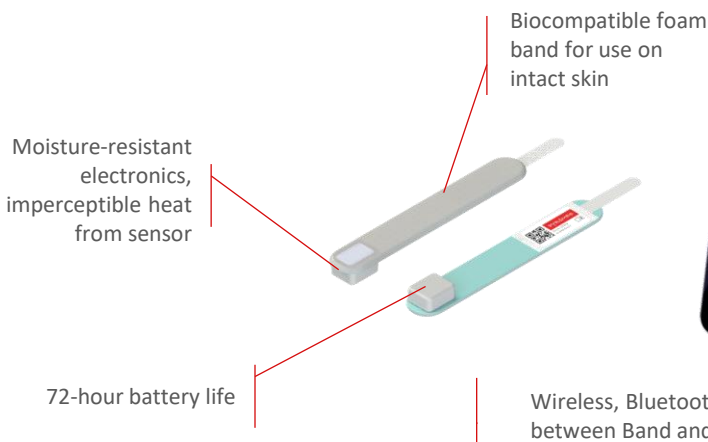
Boppli is intended for use by medically trained personnel in a clinical setting to continuously monitor and display diastolic, systolic, and mean arterial BP. Boppli is intended for use on neonates and infants with a palpable pulse and in conjunction with SpO2 monitoring.

FEATURES

- Patented, low-power sensor
- Lightweight electronics, splash-resistant electronic housing
- Easy to reposition
- Accuracy from robust statistical algorithms

BENEFITS

- Continuous, non-invasive monitoring for better health outcomes
- Lower risk than intraarterial BP monitoring
- Simple, cost-effective deployment
- Improved patient experience



Easy-to-use interface; clear presentation of BP and pulse rate values

Boppli® Band wearable sensor and tablet

Boppli platform

Indications for use	- Boppli is indicated for use by medically trained personnel in clinical settings, such as the NICU, PICU, CVICU, and emergency or operating room, to continuously monitor diastolic, systolic, and mean arterial blood pressures of neonates and infants, under 5 kilograms in weight, who have a palpable pulse. - Boppli reliability has not been established in patients where the pulse waveform shape may be affected, such as those treated with a left ventricular assist device (LVAD), balloon pump, or extracorporeal membrane oxygenation (ECMO).
Output values	- BP (mmHg): Systolic BP: 30 - 85; Diastolic BP: 15 - 50; Mean Arterial BP: 23 – 65 - PR (bpm): 80 to 250
Certifications and compliance	- FDA-cleared 510(k) Class II medical device - Compliant with ISO 10993-1:2018 for medium duration, intact skin contact - Compliant with IEC 60601-1 electromagnetic compatibility for medical devices
Operating specifications	- Environment: 20-40 C temperature, 20-95% rel. humidity (RH) non-condensing - Wireless Bluetooth Low Energy communication between Boppli Band and Bedside Device

Boppli Band

Features	- Single use, 72-hour maximum - Fits wrists or feet from 45mm to 150mm circumference - Soft, biocompatible foam band - Minimal skin compression; no adhesive; imperceptible heat from sensor - Effective on either radial or dorsalis pedis pulse point
Operating specifications	- Weight: 14g - Safe for use in oxygen-enriched environment

Boppli Bedside Kit

Operating specifications	- Application runs on exclusively-provisioned Android tablet - Installation Kit includes IV pole mounting bracket, wall transformer, power cable
User Interface attributes	- Clear presentation of blood pressure and pulse rate; trend view for data review - Configurable physiological alarms 4-channel adjustment screen to aid placement

Model #	Product	Description
51-0007-10	Sensor Band, Boppli, Box of 10	Boppli blood pressure monitoring bands
54-0002	Ship Kit, Boppli Bedside	Tablet device, power supply, pole mounting kit
53-0003	Bedside Device, Boppli	Tablet device

Boppli® Band wearable sensor and tablet

SHELF-LIFE AND STORAGE: Three years when stored between 5-50 C temperature, 20-95% non-condensing humidity, 700-1060hPa atmospheric pressure, out of direct sunlight, in original packaging.

DEFINITIONS: “PyrAmes” means PyrAmes Inc. “Seller” means a party selling or providing Products or Product samples to Purchaser. “Purchaser,” “Customer,” and/or “User” means the customer of Seller, jointly referred to as “Parties” or individually as “Party.” For the purpose of these Conditions, “Products” means goods, all parts, components and services sold, or provided as samples, by PyrAmes Inc. to Purchaser.

SAFETY: Customers/Users have full responsibility to determine the suitability of PyrAmes products for applications in their businesses, including clinical and safety.

LIMITED WARRANTY: PYRAMES is not engaged in rendering medical, clinical or other professional services; if medical or other expert assistance is required, the services of a competent professional person should be sought. Products shall conform to all operational features, to PyrAmes' current published specifications when delivered. Products are provided with the understanding that PURCHASER has independently determined the suitability of such Products for its purposes. PYRAMES warrants the Products to be free from defects in material and workmanship which affect Product performance. Should any failure to conform to this warranty appear within one year after the date of shipment, PYRAMES shall, upon notification thereof and substantiation that the Products have been stored and applied in accordance with PyrAmes' standards, correct such defects by suitable repair or replacement without charge; provided, however, if PYRAMES determines that repair or replacement is not commercially practical, PYRAMES shall issue a credit in favor of PURCHASER in an amount not to exceed the purchase price of the Products. THIS WARRANTY IS EXCLUSIVE AND IS IN LIEU OF ANY OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR USE OTHER THAN EXPRESSLY INDICATED, AS DESCRIBED, MATCH ANY SAMPLE SHOWN, USE OF REASONABLE CARE AND SKILL AND/OR NON-INFRINGEMENT. NO WAIVER, ALTERATION, ADDITIONAL OR MODIFICATION OF THE FOREGOING CONDITIONS SHALL BE VALID UNLESS MADE IN WRITING AND MANUALLY SIGNED BY AN OFFICER OF PYRAMES.

LIMITATION OF LIABILITY: In no event shall PYRAMES be liable for any incidental or consequential damages, including but not limited to, loss of profit, loss of use or production or loss of capital. The remedies of PURCHASER set forth herein are exclusive and the total liability of PYRAMES with respect to any contract, or anything done in connection therewith such as the performance or breach hereof, or from the manufacture, sale, delivery, resale, or use of any products whether arising out of contract, negligence, strict tort, or under any warranty, or otherwise shall not exceed the purchase price of the products upon which liability is based.

To learn more about how the value of Boppli® can help your NICU, PICU, and CVICU patients, contact us:
US: +1 408.216.0099

Boppli@PyrAmesHealth.com

www.Boppli.com