info@biopac.com
support@biopac.com
www.biopac.com

NIBP100E AND NIBP100E-HD NONINVASIVE BLOOD PRESSURE MONITORING SYSTEM

NIBP100E module (right) shown with MP160 data acquisition system

- **Accurate noninvasive blood pressure values**
- **Comfortable for participants to wear**
- **Real-time, continuous, noninvasive blood pressure**
- **Easy to use**
- **Suitable for small children (~4–5 years) to large adults**

The NIBP100E and NIBP100E-HD noninvasive blood pressure systems provide a continuous, beat-to-beat, blood pressure signal recording from the fingers of a participant. The system outputs a continuous blood pressure waveform that is similar to a direct arterial pressure waveform.

The NIBP100E-HD license unlocks additional hemodynamic parameters. Key features of the NIBP100E-HD hemodynamics system include the following:

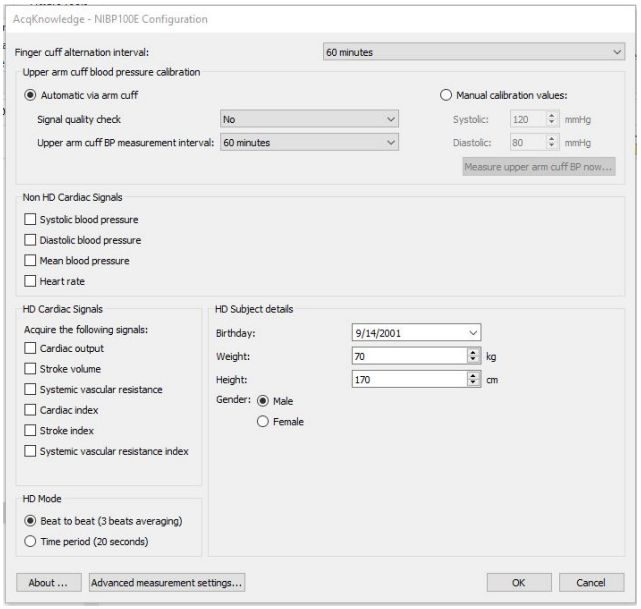
- Continuous arterial blood pressure waveform generation, allowing Acq*Knowledge* to compute systolic, diastolic, and mean arterial pressure (same as NIBP100E).
- CNSystems proprietary algorithms for calculating hemodynamic values (CO, CI, SV, SI, SVR, and SVRI), up to three of which can be included as analog signals during a single session.

The noninvasive blood pressure (NIBP) monitoring system uses a double-cuff finger sensor that is comfortable for the participant to wear and easy to place on the hand. Cuffs come in small, medium, and large to accommodate children through large adults. Three cuffs are included with the system (one of each size); additional cuffs can be added from the RXNIBPEFINGER series.

The NIBP100E and NIBP100E-HD noninvasive blood pressure systems are part of a complete research system, interfacing with the required MP160/MP150 data acquisition and analysis platform and Acq*Knowledge* software, allowing advanced research for multiple applications.

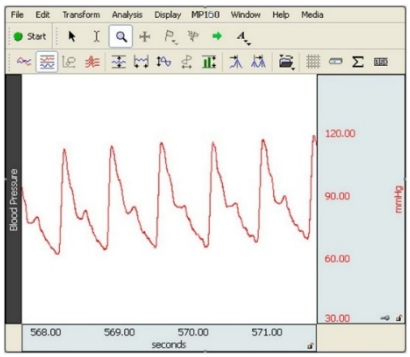
The NIBP100E amplifier with CNAP™ technology is controlled with BIOPAC's Acq*Knowledge* (5.0.7 or later) data acquisition and analysis software for MP160/150 Research Systems. Acq*Knowledge* displays the blood

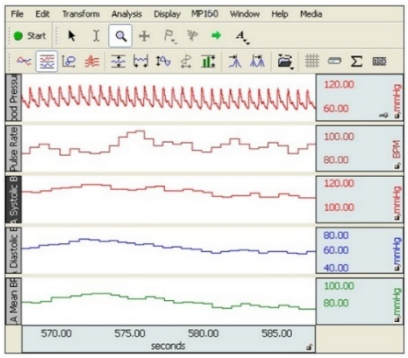
pressure signal plus systolic, diastolic, mean blood pressure, and heart rate for a detailed beat-to-beat analysis of the blood pressure signal.



The NIBP100E is calibrated using a standard blood pressure cuff that is placed around the participant's upper arm. The unit automatically takes a blood pressure measurement from the participant and uses the value for calibration purposes. Users can also manually enter systolic and diastolic pressure values (see AcqKnowledge Software Guide for additional details). During the calibration process, the system locates the pulse at the finger and performs a partial occlusion, switching from one finger to the next during recording to relieve the pressure from the occluded finger. The interval between finger rotations is user-selectable and can be up to 60 minutes. During the rotation, the system takes another calibration reading to ensure that values are accurate.

The system employs a vascular unloading technique to measure blood pressure at the fingers. A refined version of the Penáz' principle is used to deliver a continuous noninvasive blood pressure signal. The method is based on concentrically interlocking control loops for accurate long-term readings of finger blood pressure.





SIMPLE AND QUICK SETUP FEATURES

- Double-cuff finger sensor provides all parameters noninvasively without the need for a catheter or additional electrodes.
- Comfortable for participants in short or long-term studies.
- MP160/MP150 System: Attaches directly as an amplifier module.

The NIBP100E/NIBP100E-HD system is extremely user friendly. Initial setup and calibration takes less than three minutes, which includes placing the cuff around the upper arm and the sensor on the fingers. Equipping the finger sensor is as simple as sliding the participant's fingers through the two cuffs.

Note: Electric and magnetic fields may interfere with the functional reliability of the device, so avoid using the NIBP100E and NIBP100E-HD close to devices emitting powerful electromagnetic fields (e.g., x-ray equipment, diathermy applications, magnetic resonance tomographs).

RECORDING WITH IMMEDIATE FEEDBACK

- Real-time, continuous, noninvasive blood pressure displayed shortly after startup.
- Enables accurate & immediate feedback on BP and PR.
- Proven solution for consistent, repeatable results.

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MODULE QUICK SETUP INSTRUCTIONS:

1. Connect your MP160/150 device to a computer running Acq*Knowledge* version 5.0.7 or later per the device's operating instructions.
2. Attach the NIBP100E module to the MP160/150 data acquisition system.
3. Connect the NIBP100E USB cable to the USB connector on the back of the module and the computer's USB port.
4. Connect the AC150A power cord to the back of the module and plug it into a properly grounded AC Mains socket.
5. Select the correct double-cuff sensor size by using the sizing graph on the finger cuff controller. If a participant's finger size is between two cuff sizes, choose the larger cuff.
6. Assemble the finger cuff hardware by connecting the double-cuff finger sensor, the cuff controller, and finger sensor cable.
7. Connect the finger sensor cable to the outlet labeled "Finger Cuff" on the front of the NIBP100E module.
8. Select an upper arm blood pressure cuff that is the proper fit for the participant (i.e., Child, Small Adult, Adult, or Large Adult). The cuff part number indicates each cuff's circumference.
9. Connect the blood pressure arm cuff to the outlet labeled "BP Cuff" on the front of the NIBP100E.
10. Power on the MP160/150 device.
11. Power on the NIBP100E module by pressing the power button on the rear of the device. The power and USB lights should be illuminated when the device is ready.

PARTICIPANT SETUP

Applying Double-Cuff Finger Sensors

1. Equip the participant with the double-cuff finger sensor and cuff controller by placing the double-cuff finger sensor on the proximal joints of the index and middle fingers. Ensure that the cuff cables run along the outside of the participant's arm.
2. Place the cuff controller into the slide and fasten it to the participant's forearm with the Velcro strap. Make sure that no additional force (tension or pressure) is exerted on the double-cuff finger sensors via the cable connection.

Applying Arm Cuff

1. Use only BP arm cuffs authorized by BIOPAC.
2. Place the blood pressure cuff on the participant's upper arm, preferably contra-laterally, at heart level. The marker arrow on the NBP cuff should be directly above the brachial artery.

RECORDING BP DATA

See Acq*Knowledge* Software Guide for instructions on installing your NIBP100E or NIBP100E-HD license, setting up channels, and recording data.

HYPERBARIC/HYPOBARIC CHAMBER SETUP

1. Cuff controller and unit must be in the same chamber with the same "pressure" environment as both are equipped with sensors for surrounding pressure.
2. Pressure must be increased and/or decreased steadily rather than abruptly to avoid reading errors.
3. Hypobaric: take measures against overheating of the device as conventional cooling is limited.
4. Do not push, pull, or bend finger cuff during use.
5. Elevate hand to heart level and maintain a steady position.

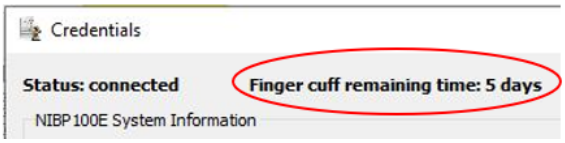
TWO-YEAR INSPECTION

Due to the mechanical nature of the device (e.g., pumps, seals, hoses) BIOPAC recommends that users return their NIBP100E/NIBP100E-HD module for service once every two years, regardless of frequency of use.

SPECIFICATIONS

Components

- **NIBP100E Module**
  - Dimensions 10 cm x 11 cm x 19 cm
  - Weight .89 Kg (1.97 lbs.) including components and accessories necessary for operability of device
  - USB connector (connects computer to module)
- **Hemodynamic Parameters—NIBP100E-HD only:** Acq*Knowledge* License for hemodynamic measures including CO, CI, SV, SI, SVR, and SVRI.
- **Double-Cuff Finger Sensors** – one each size
  - **L** 24–28 mm dark red, **M** 18–24 mm dark blue, **S** 10–18 mm light blue
  - Finger cuff sensors are consumable items and performance may degrade over time. Cuffs are programmatically encoded for **150 hours** of usage. Open the "About" window in Acq*Knowledge* with the NIBP100E module and finger cuffs installed to determine the time remaining for the finger cuff lifespan. See the Acq*Knowledge* Software Guide for more details.



- **Blood Pressure Cuffs** — one each size, latex-free
  - **Child** (12–19 cm), **Small Adult** (17–25 cm), **Adult** (23–33 cm), **Large Adult** (31–40 cm)

Electrical properties

- Nominal voltage: 12 VDC ± 10%
- Nominal current: 3 A

NIBP100E and NIBP100E-HD continuous noninvasive arterial pressure

- Parameter classification
  - Sys, Dia, Mean [mmHg]
  - Pulse [bpm]
- Measuring range
  - Sys: 40–250 mmHg (5.3–33.3 kPa)
  - Dia: 30–210 mmHg (4–28 kPa)
  - Mean: 35–230 mmHg (4–30.6 kPa)
  - Accuracy ±5 mmHg (0.6 kPa)
- Inflation pressure
  - Typ.: 120 mmHg (16 kPa)
  - Min.: 30 mmHg (4 kPa)
  - Max.: 300 ± 10 mmHg (41.3 kPa ± 1.3 kPa)
- Excess pressure limit
  - 300 ± 10 mmHg (40 kPa ± 1.3 kPa)
  - Response time: < 3 sec.
  - Deflation time: < 15 sec.
- Protection against electric shock: Type BF

Output

- Sensitivity: 5 µV/mmHg
- Delay of analog out signal: 50 msec (fixed)

External mains adapter

- AC150A (see linked product page for details and specs)

Compliance and Approvals

- Safety class II (IEC 60601)
- Class II b (93/42/EEC)
- Patent applied part type BF
- IEC 60601-1
- IEC 60601-1-2
- Defibrillation proof
- IEC 60601-1-6
- IEC 60601-1-8
- IEC 80601-2-30
- EN 1060-4 (NBP)
- ISO 81060-2 (NBP)

Intellectual Property

Patents

- US 6,669,648
- EP 1 179 991
- US 8,114,015
- EP 1 675 507
- US 8,343,062
- EU 2 493 370
- US 8,814,800 B2
- EP 2 493 373
- JP 4.414.767
- JP 20075508872
- CN 102647940
- An additional 66 patents

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