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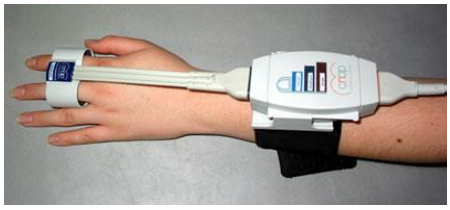
NIBP100D NONINVASIVE BLOOD PRESSURE MONITORING SYSTEM



The NIBP100D Noninvasive Blood Pressure Monitoring System is suitable for small children (~4-5 years) to large adults

- **Accurate noninvasive blood pressure values**
- **Comfortable for subjects to wear**
- **Real-time, continuous, noninvasive blood pressure**
- **Easy to use**

The NIBP100D noninvasive blood pressure system provides a continuous, beat-to-beat, blood pressure signal recorded from the fingers of a subject. The system outputs a continuous blood pressure waveform that is similar to a direct arterial pressure waveform. The monitor displays values for systolic, diastolic, mean blood pressure, and heart rate.

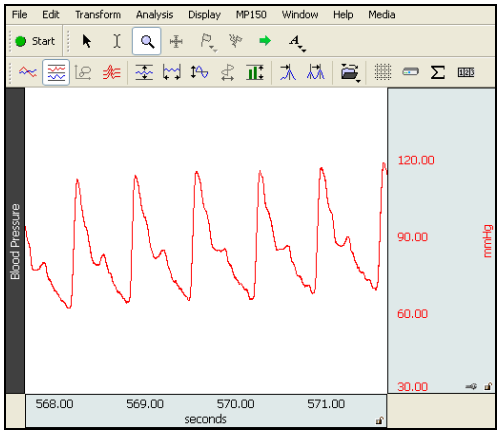
The noninvasive blood pressure (NIBP) monitoring system uses a double finger cuff that is comfortable for the subject to wear and easy to place on the hand. The cuffs (included with system) come in three sizes to accommodate children through large adults.

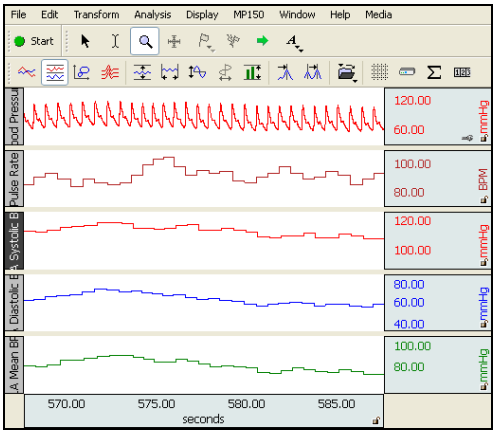
The NIBP100D interfaces with an MP160/150 Data Acquisition System (or third-party data acquisition system), via a DA100C and TCI105 Interface Connector. It is also compatible with the MP36/36R/35/45 Data Acquisition System via a BSL-TCI5 transducer and CBLHLT1 cable. The Acq*Knowledge* or BSL *PRO* software displays the blood pressure signal, plus systolic, diastolic, mean blood pressure and heart rate. It will also provide a detailed beat-to-beat analysis of the blood pressure signal.

The NIBP100D is calibrated using a standard blood pressure cuff that is placed around the subjectôs upper arm. The unit automatically takes a blood pressure measurement from the subject and uses the value for calibration purposes. During the calibration process the system locates the pulse at the finger and performs a partial occlusion. It will switch from one finger to the next during the course of the recording to relieve the pressure from the occluded finger. The interval between finger rotations is user-selectable and can be as long as 60 minutes. During the rotation, the system takes another calibration reading to ensure that values are accurate.

The system is very user friendly and the initial setup and calibration period takes less than three minutesð that time includes placing the cuff around the upper arm and the sensor on the fingers. Placing the finger sensor is as simple as sliding the subjectôs fingers through the two cuffs.

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.





Updated: 6.28.2017

HYPERBARIC/HYPOBARIC CHAMBER SETUP

1. Cuff controller and CNAP monitor must be in the same chamber with the same"pressure" environment as both are equipped with pressure sensor for surrounding pressure.
2. Pressure must be increased / decreased continuously rather than abruptly.
3. Hypobaric: take measures against overheating of the device as conventional cooling is limited (dim CNAP display low; do not restrict airflow through case).
4. No draught on cuff.
5. Hand on heart level in steady position.

SPECIFICATIONS

*For complete specifications, see the **NIBP100D User Manual** online under the product page "Support" tab.*

Components

- **Double-Cuff Finger Sensors** ï 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 a consumable item and typically last ~12 months based on 3-4 hours/week.
- **Blood Pressure Cuffs** ð one each size, latex-free
  - **Child** (12 ï 19 cm), **Small Adult** (17 ï 25 cm), **Adult** (23 ï 33 cm), **Large Adult** (31 ï 40 cm)
- **NIBP100D Monitor**
  - Dimensions 280 x 270 x 250 mm (11 x 10.6 x 9.8 in.)
  - Weight 7.5 Kg (16.6 lbs) including components and accessories necessary for operability of device
  - Battery Sealed lead gel, operating time = 2 hrs (fully charged battery, normal conditions)

Electrical properties

- Nominal voltage: 18 VDC ±10%
- Nominal current: 3 A
- Operability: No time-limit if powered by external mains adapter, at least 2 hrs if on battery-operation (fully charged battery)

NIBP100D continuous noninvasive arterial pressure

- Parameter classification
  - Sys, Dia, Mean [mmHg]
  - Pulse [bpm]
- Measuring range
  - Sys: 40 - 250 mmHg (5.3 ï 33.3 kPa)
  - Dia: 30 - 210 mmHg (4 - 28 kPa)
  - Mean: 35 - 230 mmHg (4 ï 30.6 kPa)
  - Heart rate indication range 20-200 bpm
  - Accuracy ±5 mmHg (0.6 kPa)
- Display resolution 1 mmHg (0.1 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

- Sensor bridge voltage: 2 ï 10 V (external monitor)
- Sensitivity: 5 µV/V/mmHg
- BP Wave Out: CNAPÊ transducer cable 0.3 m; connector RJ11 6P4C (e.g. Abbott IBP catheter)
- Delay of analog out signal: 50 msec (fixed)

Interface

- To DA100C via TCI105 (sold separately)

External mains adapter

- Nominal voltage: 100 ï 240 VAC
- Power frequency: ~50/60 Hz
- Power output: 18 V, 3.3 A
- Safety class: Class II with functional earth
- Earth leakage current: < 500 µA

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

Intellectual Property				
Patents	• US 6,669,648	• US 8,343,062	• JP 4.414.767	CE
	• EP 1 179 991	• EU 2 493 370	• JP 20075508872	
	• US 8,114,015	• US 8,814,800 B2	• CN 102647940	
	• EP 1 675 507	• EP 2 493 373	plus another 66 patents	

The NIBP100D CNAPÊ Monitor 500 is CE and FDA approved.

Note: Electric and magnetic fields may interfere with the functional reliability of the device, so avoid using the NIBP100D CNAPÊ Monitor 500 close to devices emitting powerful electromagnetic fields, e.g. x-ray equipment, diathermy applications or magnetic resonance tomographs.