DanMedical Analysis System

D-MAS HyperSat 2540

Instructions for use

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DanMedical Ltd. assumes no responsibility for use of D-MAS not in accordance with this manual.

Before using a D-MAS please read this guide and become familiar with the contents.

The information in this user manual is subject to change without notice. Please check for latest revision.

For further information concerning this user manual please contact your supplier or sales representative. Alternatively, please contact:

DanMedical Ltd 12 Threshers Yard Kingham, Oxon OX7 6YF UK	sales@danmedical.com www.DanMedical.com

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General Information

The DanMedical Analysis System will be referred to as **D-MAS** throughout this manual.

Important! Read this manual before use.

About this manual

This user manual relates to the DanMedical Analysis System (D-MAS).

This manual explains how to set up and use D-MAS and includes important safety information.

All information in this manual is based on D-MAS and the standard factory default configuration.

Indications For Use Statement

Under the supervision of a qualified Healthcare Professional and for prescription use only, D-MAS can be used as a personal computer in hospitals, Healthcare Professional's offices, laboratories and occupational health testing or healthcare environments for an initial screening evaluation of a patient to:

- Display non invasive measurements of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, carboxyhemoglobin saturation, methemoglobin saturation and total hemoglobin concentration with a sensor.
- Display, record and analyze ECG signals for an initial evaluation of the electrical activity of the heart
- Measure and display systolic and diastolic blood pressures and pulse rate of an adult
- Measure and display the maximal volume and flow of air that can be moved in and out of a patient's lungs
- Measurement and display of images acquired using a digital examination camera.

This equipment is not designed to produce definitive interpretations for direct treatment or therapy.

Statements given with this interpretation program do not replace a detailed report by the Healthcare Professional and a clinical diagnosis is the responsibility of the Healthcare Professional.

Intended use

D-MAS HyperSat 2540 is intended for use in a HyperBaric or Diving Saturation chamber.

D-MAS is intended for use by medical clinicians on adult patients.

D-MAS is not intended for use in environments that are not supervised by a health care practitioner.

D-MAS is not intended for continuous monitoring.

D-MAS is designed with defibrillator protection, but it is recommended that the D-MAS ECG electrodes be removed from the patient before a defibrillator is used.

D-MAS is not intended for use on patients under critical care and the system is not intended for use within an intensive care environment.

D-MAS is not intended for use on neonatal patients.

D-MAS will provide Non Invasive Blood Pressure measurements when using the appropriate blood pressure cuff.

D-MAS is intended to provide an interpretation of a resting ECG in all situations.

D-MAS is not intended for use in conjunction with any high frequency generator, diathermy machine or exposure to other strong radio frequency interference. Under such circumstances, degradations in performance of D-MAS may be observed.

D-MAS is not intended for use in conjunction with pacemakers. Under such circumstances, degradations in performance of D-MAS may be observed.

D-MAS is not intended for use in the presence of flammable anaesthetics or other explosive atmosphere.

D-MAS will operate accurately over an ambient temperature range of 5 to 50 degrees Celsius.

Contraindications

The D-MAS is not designed to provide alarms and is not for arrhythmia detection. The device is not suitable for intra cardiac application.

Symbols

These symbols appear on D-MAS:

Symbols	Description
	The CE Mark and notified body registration number signify that the device meets all essential requirements of the European Medical Device Directive 93/42/EEC
	General warning sign. Defib. protection is within patient cable.
	Type CF Defibrillator proof
	Address of manufacture

These symbols appear in this user manual:

Symbols	Description
	Warning symbol
	Caution symbol

Warnings and cautions

	**WARNING!** Explosion hazard. Do not use D-MAS in the presence of flammable anaesthetics or other flammable environments.
	**WARNING!** D-MAS is designed for use by healthcare professionals who have completed user training.
	**WARNING!** During defibrillation, it is recommended that the D-MAS ECG electrodes are first removed from the patient.
	**WARNING!** Do not touch the patient, patient cable or D-MAS during defibrillation. Death or injury may occur from the electrical shock delivered by the defibrillator.
	**WARNING!** For the safety of patients and to ensure best product performance and accuracy, use only supplies and accessories recommended or supplied by DanMedical Ltd.
	**WARNING!** Do not place containers with liquids on or near D-MAS. Liquids spilled on D-MAS may cause it to perform inaccurately or fail.
	**WARNING!** The patient cables supplied with the D-MAS, or approved replacements, are an integral part of the D-MAS safety feature.
	**WARNING!** High intensity extreme lights (such as pulsating strobe lights) directed on the sensor, may not allow D-MAS to obtain vital sign readings.
	**WARNING!** D-MAS is NOT intended for use as an apnea monitor.
	**WARNING!** D-MAS should be considered an early warning device. As a trend towards patient hypoxemia is indicated, blood samples should be analyzed by laboratory instruments to completely understand the patient's condition.
	**WARNING!** Electric shock hazard. Do not open D-MAS. Only qualified personnel may perform maintenance procedures specifically described in this manual. Refer servicing to DanMedical for repair of this equipment.
	**WARNING!** The D-MAS Pulse CO-Oximeter function should not be used as a replacement or substitute for ECG based arrythmia analysis.
	**WARNING!** The use of ACCESSORIES, transducers and cables other than those specified, may result in increased EMISSIONS or decreased IMMUNITY of the D-MAS.
	**WARNING!** The D-MAS should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the D-MAS should be observed to verify normal operation in the configuration in which it will be used.
	**WARNING!** Always use the accessories with adherence to the manufacturer's instructions for use.
	**WARNING!** The use of multiple instruments connected to the same patient may pose a safety hazard due to the summation of leakage currents from each instrument. Any combination of instruments should be evaluated by local safety personnel before being put into service.
	**WARNING!** As with all medical equipment, carefully route NIBP hose and ECG cables to reduce the possibility of patient entanglement or strangulation.
	**WARNING!** Ensure that the Non Invasive Blood Pressure hose is routed carefully. Be sure that the hose cannot become trapped or kinked.
	**WARNING!** Do not place the D-MAS in any position that may cause it to fall on the patient. Do not lift D-MAS by the power cord or any other cable.
	**WARNING!** Do not block any ventilation slots of the D-MAS as this may cause failure of internal electronic devices.
	**WARNING!** Do not use the D-MAS or its accessories if it appears damaged. If dropped or damaged, it must be thoroughly tested by qualified service personnel before it is returned to service.

	**WARNING!** Do not subject the D-MAS to extreme moisture.
	**WARNING!** Do not use the D-MAS in an MRI environment.
	**WARNING!** D-MAS is not intended for use on patients under critical care.
	**WARNING!** To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth
	**WARNING!** For Adult use only. The D-MAS is not intended for use with neonates.
	**WARNING!** It is the user's responsibility to set alarm limits.
	**WARNING!** Be sure that the electrodes or lead wire tips do not come into contact with any other conductive materials, including earth grounded materials, especially when connecting or disconnecting electrodes to or from the patient.
	**WARNING!** Periodically check and replace all components of the D-MAS that appear damaged, worn or frayed.
	**WARNING!** The D-MAS contains no user serviceable parts other than the accessories.
	**WARNING!** Do not use the D-MAS on patients who are also connected to a heart or lung machine.
	**WARNING!** Do not use the D-MAS on patients who appear to be experiencing convulsions or tremors.
	**WARNING!** Protection against the effects of discharge of cardiac defibrillator is dependent upon the use of appropriate cables.
	**WARNING!** Do not modify D-MAS. No modification or unauthorized repair is allowed.
	**WARNING!** Patient Safety - If a sensor is damaged in any way, discontinue use immediately.
	**WARNING!** D-MAS can be used during defibrillation, but the readings may be inaccurate for up to 20 seconds.
	**WARNING!** Failure of Operation - If D-MAS fails any part of the setup procedures or leakage tests, remove D-MAS from operation until qualified service personnel have corrected the situation.
	**WARNING!** Refer servicing to authorized and qualified personnel. Important Notice All maintenance, repairs and other technical adjustments to be performed by DanMedical or authorised provider only. Warranties and any maintenance cover will lapse/end if unauthorised providers are used.

⚠	**CAUTION!** Interfering Substances: SpO2 is a functional calculation of arterial oxygen saturation. Carboxyhemoglobin and Methemoglobin may erroneously increase SpO2 readings. The level of increase is approximately equal to the amount of carboxyhemoglobin and/or methemoglobin that is present. Dyes, or any substance containing dyes, that change usual blood pigmentation may cause erroneous readings. If the accuracy of the D-MAS is in doubt, verify the measurement concerned by another method, and then have the D-MAS inspected by qualified service personnel.
⚠	**CAUTION!** Severe anemia may cause erroneous SpO2 readings.
⚠	**CAUTION!** Elevated levels of Methemoglobin (MetHb) will lead to inaccurate SpO2 and SpCO measurements.
⚠	**CAUTION!** Elevated levels of Carboxyhemoglobin (COHb) will lead to inaccurate SpO2 measurements.
⚠	**CAUTION!** Elevated levels of Total Bilirubin may lead to inaccurate Sp02, SpMet. SpCO, SpHb and SpOC
⚠	**CAUTION!** Very Low arterial Oxygen Saturation (Sp02) levels may cause inaccurate SpCO and SpMet measurements.
⚠	**CAUTION!** Hemoglobin synthesis disorders may cause erroneous SpHb readings
⚠	**CAUTION!** If the sensor is wrapped too tightly or supplementary tape is used, congestion/pulsations may occur causing erroneous readings.
⚠	**CAUTION!** Exercise caution when applying a sensor to a site with compromised skin integrity. Applying tape or pressure to such a site may reduce circulation and/or cause further skin deterioration.
⚠	**CAUTION!** With very low perfusion at the monitored site, the readings may read lower than core arterial oxygen saturation.
⚠	**CAUTION!** Misapplied sensors or sensors that become partially dislodged may cause either over or under reading of actual arterial oxygen.
⚠	**CAUTION!** Do not modify or alter the sensor in any way. Alterations or modification may affect performance accuracy.
⚠	**CAUTION!** Venous congestion may cause under reading of actual arterial oxygen saturation. Therefore assure proper venous outflow from monitored site. Sensor should be not below heart level (e.g. sensor on hand of patient in a bed with arm dangling to the floor).
⚠	**CAUTION!** Circulation distal to the sensor site should be checked routinely
⚠	**CAUTION!** To avoid cross contamination only use single use sensors on the same patient.
⚠	**CAUTION!** Sensors applied too tightly may cause erroneous readings. Inaccurate measurements or loss of signal may be caused by: • excessive patient movement • venous pulsations • placement of the Pulse CO-Oximeter sensor on an extremity with a blood pressure cuff, arterial catheter or intravascular line.
⚠	**CAUTION!** Loss of pulse signal can occur when: • the sensor is too tight • the patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia • there is arterial occlusion proximal to the sensor • the patient is in cardiac arrest or in shock
⚠	**CAUTION!** Read sensor directions for use prior to usage.
⚠	**CAUTION!** If using Pulse CO-Oximetry during full body irradiation, keep the sensor out of the irradiation field. If the sensor is exposed to the irradiation, the reading might be inaccurate or the unit might read zero for the duration of the active irradiation period.

⚠	**CAUTION!** For home use, ensure that the Pulse CO-Oximeter's alarm can be heard from other rooms in the house especially when noisy appliances such as vacuum cleaners, dishwashers, clothes dryers, televisions, or radios are operating.
⚠	**CAUTION!** Always remove the sensor from the patient and completely disconnect the patient from the Pulse CO-Oximeter before bathing the patient.
⚠	**CAUTION!** Do not place the Pulse CO-Oximeter where the controls can be changed by the patient.
⚠	**CAUTION!** Alarms are provided for indication only.
⚠	**CAUTION!** If the user saves inappropriate alarm limits, they will be retained, even when the unit is switched off.
⚠	**CAUTION.** The user should wait 30 seconds between NIBP measurements to allow venous return to the arm.
⚠	**CAUTION!** Ensure that D-MAS is placed on a secure, flat surface.
⚠	**CAUTION!** Do not use tape to secure the sensor to the site. This can restrict blood flow and cause inaccurate readings. Use of additional tape can cause skin damage or damage to the sensor.
⚠	**CAUTION!** Do not autoclave.
⚠	**CAUTION!** Keep all ventilation slots clear to enable free air flow.
⚠	**CAUTION!** Dispose of waste and equipment in accordance with local regulations, or contact DanMedical.
⚠	**CAUTION!** D-MAS accessories are not interchangeable. If operating/owning more than 1 D-MAS unit, don't interchange accessories between units.
⚠	**CAUTION!** A functional tester cannot be utilized to assess the accuracy of D-MAS or any sensors.
⚠	**CAUTION!** This equipment has been tested and found to comply with the limits for medical devices to the EN 60601-1-2: 2002, Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures: ■ Reorient or relocate the receiving device. ■ Increase the separation between the equipment. ■ Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
⚠	**CAUTION!** DO NOT UNDER ANY CIRCUMSTANCES REMOVE THE GROUNDING CONDUCTOR FROM THE POWER PLUG. THE POWER CORD AND PLUG MUST BE INTACT AND UNDAMAGED. IF THERE IS ANY DOUBT ABOUT THE INTEGRITY OF THE PROTECTIVE EARTH CONDUCTOR ARRANGEMENT, OPERATE THE OXIMETER ON INTERNAL BATTERY POWER UNTIL THE AC POWER SUPPLY PROTECTIVE CONDUCTOR IS FULLY FUNCTIONAL. DO NOT CONNECT TO AN ELECTRICAL OUTLET CONTROLLED BY A WALL SWITCH OR DIMMER. TO ENSURE PATIENT ELECTRICAL ISOLATION, CONNECT ONLY TO OTHER EQUIPMENT WITH ELECTRICALLY ISOLATED CIRCUITS.
⚠	**CAUTION!** To prevent damage, do not soak or immerse the sensor in any liquid solution. Do not attempt to sterilize by irradiation, steam, autoclave, or any method other than ethylene oxide as indicated.

⚠	**CAUTION!** Intravascular dyes or externally applied colouring (such as nail polish) may lead to inaccurate SpO2 measurements.
⚠	**CAUTION!** The pulsations from intra-aortic ballon support can be additive to the oximeter pulse rate. Verify patients pulse rate against the ECG heart rate.
⚠	**CAUTION!** Do not use damaged sensors or patient cables. Do not use a sensor or patient cable with exposed optical or electrical components.
⚠	**CAUTION!** Do not immerse the sensor or patient cable in water, solvents, or cleaning solutions (the sensor and connectors are not waterproof).
⚠	**CAUTION!** Do not attempt to reprocess, recondition, or recycle any D-MAS sensors or patient cables as these processes may damage the electrical components, potentially leading to harm.
⚠	**CAUTION!** Inaccurate measurements may be caused by incorrect application or use.
⚠	**CAUTION!** All D-MAS sensor and accessories listed are to be available for the device.

List of components

Quantity	Item
1	D-MAS HyperSat
1	Power supply unit
1	Power cord
4	Battery Blades
2	Battery Blade chargers
1	WiFi LAN Router (option)
1	SPO2 finger probe
1	SpO2, SpHb finger probe (option)
1	SpO2, SpCO, SpMet finger probe (option)
1	ECG patient cable
10	ECG electrode clips
1	BP cuff (Large adult , Standard adult & Small adult)
1	NIBP hose
1	USB Spirometer
1	General Examination Camera
1	Backpack (option)
	Protective case (option)
1	User manual (electronic)

Unpacking and inspection

Inspect packaging for signs of damage in transit. Contact DanMedical Ltd. immediately if any damage is discovered. If possible retain packaging for future use.

Product overview

D-MAS HyperSat has been designed for use in Hyperbaric and Diving Saturation chambers. It incorporates a personal computer with a Pulse CO-Oximeter, arterial oxygen saturation and pulse rate monitor, an electrocardiogram amplifier (10 Applied Parts), a blood pressure monitor, USB Spirometry, and digital image capture hardware and software.

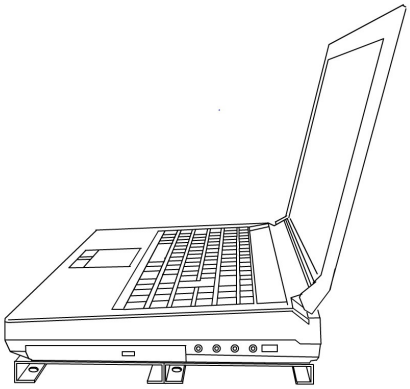
The unit is powered by Battery Blades. Battery Blades are intrinsically safe dedicated battery power packs designed for use in pressurized environments.

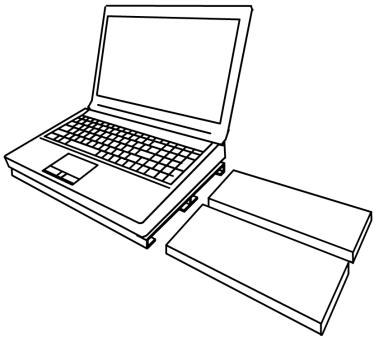
D-MAS has been designed to be used within the patient environment as detailed in EN 60601-1-1:2001 (Medical Electrical Equipment - General requirements for safety).

D-MAS will accurately measure and store:

- Pulse CO-Oximeter with continuous display of numeric values for SpO2, SpCO®*, SpMet™*,pulse rate, Perfusion Index (PI) and Pleth Variability Index (PVI)
- graphical displays for plethysmographic waveform and Signal Identification and Quality Indicator (Signal IQ®)
- 10 lead Resting ECG recordings with interpretation
- Non-invasive blood pressure with pulse rate for adult patients
- Spirometry (Lung function)
- Audiometry HSE & OSHA hearing thresholds
- USB scope and general examination digital camera images

Battery Blade General Description



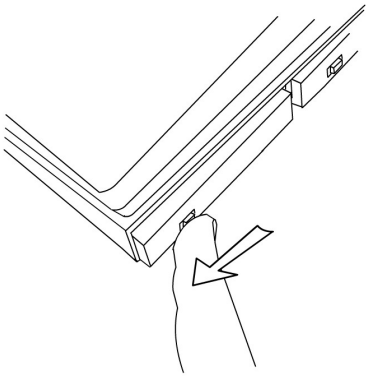


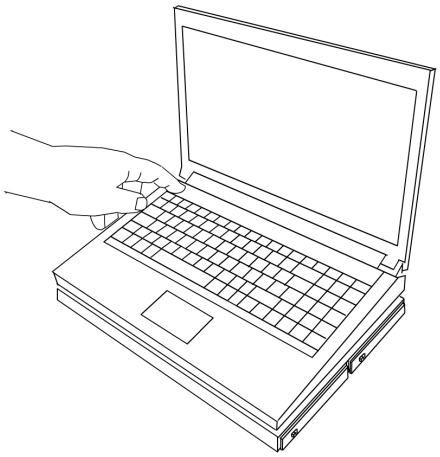
Twin Battery Blades are intended to provide DC supply to the D-MAS HyperSat device when it is used within a Hyperbaric or Diving Saturation chamber.

To fit a Battery Blade to a HyperSat, orientate the Battery Blade following the instruction labels and slide into the housing tray.

D-MAS HyperSat with twin Battery Blades

Ensure the battery locking button locates into tray when inserting the battery.
A positive click signals the Battery Blade is inserted correctly.



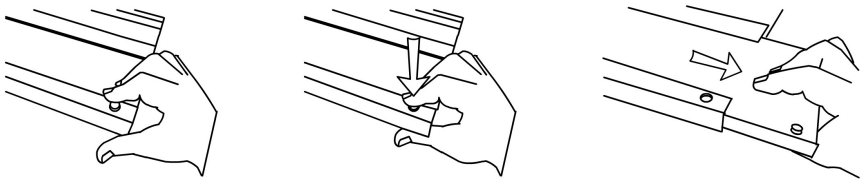


Battery Blade On/Off switch

Switch on the D-MAS HyperSat

Switch ON both Battery Blades using the ON/OFF switch on each Battery Blade then switch on the D-MAS HyperSat

Battery Blade removal

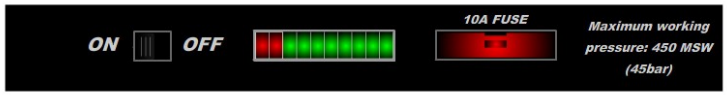


With the Battery Blade stud located in the tray, the battery cannot be removed.

To remove the Battery Blade from the HyperSat, push the battery locking button in and withdraw the battery.

Battery Blade Housing

The end panel has the On/Off switch, the battery capacity gauge and a 10 Amp fuse



Battery Blade end panel

With both fully charged twin battery blades inserted, turning each of the blades on with the on/off switch will result in power appearing at the jack connector and the output gauge on each blade will illuminate Green.

The twin battery blades will provide power to the HyperSat for approximately 3 hours, as the batteries becomes depleted the number of green segments on the capacity gauge will slowly reduce until the indicator will illuminate Red, an audible beep will occur every 10 seconds to provide a visual and audible indication that the battery is becoming flat, at this point the battery should be swapped out for a fully charged battery.

When new, each battery will last for approximately 15 minutes after the Low Battery alert first occurs.

Note
It is recommended that each battery is replaced with a fully charged battery once the low battery point is reached. The twin batteries should be replaced sequentially to prevent power loss from the D-MAS HyperSat.

Removing both batteries will result in complete power loss to the D-MAS HyperSat and it will require re-booting once fully charged batteries are inserted.

Charging the twin battery blades
A depleted battery will continue to indicate Lo.Batt after the battery output has turned off. The battery blade should then be switched off after its has been swapped out and then recharged.

The charger consists of two intelligent battery chargers, at power up, without batteries connected, the charger LED will initially illuminate Green and then Red for about 5 seconds, reverting to Green LED illumination.

Connect the Battery Blade to the charger, the Charger LED will turn RED to indicate charging is occurring, the charger LED will remain RED until the battery is fully charged at which point it illuminates Green (2 hours approx.)

The Battery Blade is provided with a 10Amp Auto fuse, it is a “when it blows it glows” type and will illuminate if blown.

FEATURES

Some D-MAS features may not be enabled depending on region or only available as optional extras.

Pulse CO-Oximetry

D-MAS is a fully featured Pulse CO-Oximeter. All pulse oximetry measurement information, as well as device status data is displayed on the screen. All user input is performed through the keyboard and touch pad. The sensor cable connector is located on the rear of the D-MAS instrument. These features are common to D-MAS:

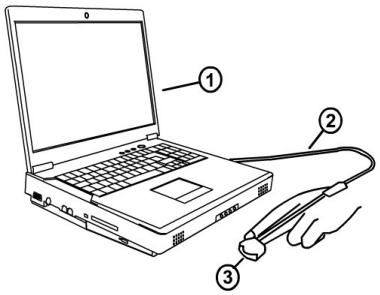
- Clinically proven to be the highest sensitivity and specificity pulse oximeter in the world.
- Rainbow technology uses 7+ wavelengths of light to continuously and noninvasively measure carboxyhemoglobin (*SpCO®) and methemoglobin (*SpMet™), as well as providing a more reliable probe-off detection.
- Perfusion Index (PI) with trending capability indicates arterial pulse signal strength and may be used as a diagnostic tool during low perfusion.
- Pleth Variability Index (PVI): captures vital thoracic pressure changes that may compromise normal cardiac function affecting systemic circulation.
- Accurate on cyanotic patients when used with an LNOP® Blue Sensor.
- Signal IQ® waveform provides signal identification and quality indication during excessive motion and low signal to noise situations.
- FastSat® tracks rapid changes in arterial O2 with high fidelity unlike any other pulse oximeter.
- Variable pitch provides tonal variance for every 1% change in saturation.
- 3D Alarm System Option:
- Desat Index Alarm™ enables clinicians to detect an increasing quantity of smaller desaturations that may precede declining respiratory status.
- PI Delta Alarm™ alerts clinicians to specified changes in perfusion, often a reliable indicator of illness severity.

Pulse CO-Oximetry General description

Pulse CO-Oximetry is a continuous and non-invasive method of measuring the level of arterial oxygen saturation in blood. The measurement is taken by placing a sensor on a patient, usually on the fingertip for adults and the hand or foot for neonates. The sensor is connected to the Pulse CO-Oximetry instrument with a patient cable. The sensor collects signal data from the patient and sends it to the instrument.

D-MAS displays the calculated data in three ways:

- As a percent value for arterial oxygen saturation (SpO2)
- As a pulse rate (BPM)
- As a plethysmographic waveform



1. Instrument
2. Cable
3. Sensor

SpCO GENERAL DESCRIPTION

Pulse CO-Oximetry is a continuous and non-invasive method of measuring the levels of carbon monoxide concentration (SpCO) in arterial blood. It relies on the same basic principles of pulse oximetry (spectrophotometry) to make its SpCO measurement. The measurement is obtained by placing a sensor on a patient, usually on the fingertip for adults and the hand or foot for infants. The sensor connects either directly to the Pulse CO-Oximetry instrument or through an instrument patient cable. The sensor collects signal data from the patient and sends it to the instrument. The instrument displays the calculated data as percentage value for the SpCO, which reflect blood levels of carbon monoxide bound to hemoglobin.

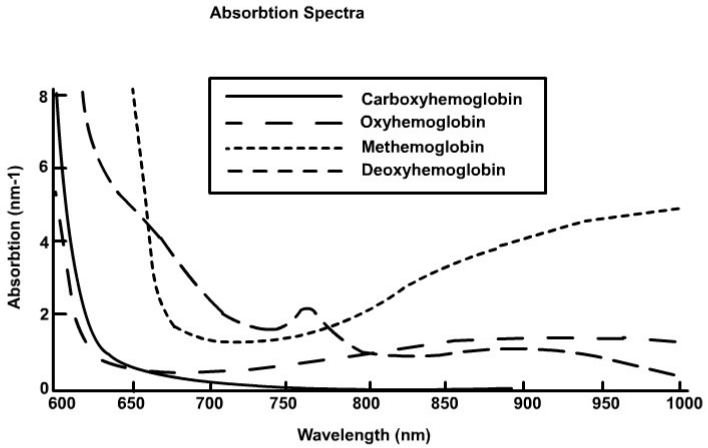
SpMet GENERAL DESCRIPTION

Pulse CO-Oximetry is a continuous and non-invasive method of measuring the levels of methemoglobin concentration (SpMet) in arterial blood. It relies on the same basic principles of pulse oximetry (spectrophotometry) to make its SpMet measurement. The measurement is obtained by placing a sensor on a patient, usually on the fingertip for adults and the hand or foot for infants. The sensor connects either directly to the Pulse CO-Oximetry instrument or through an instrument patient cable. The sensor collects signal data from the patient and sends it to the instrument. The instrument displays the calculated data as percentage value for the SpMet.

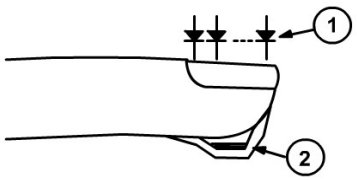
PRINCIPLE OF OPERATION

Pulse CO-Oximetry is governed by the following principles:

- Oxyhemoglobin (oxygenated blood), deoxyhemoglobin (non-oxygenated blood) carboxyhemoglobin (blood with carbon monoxide content) and methemoglobin species differ in their absorption of visible and infrared light (using spectrophotometry, see figure below).
- The amount of arterial blood in tissue changes with the pulse (photoplethysography). Therefore, the amount of light absorbed by the varying quantities of arterial blood also changes.



The D-MAS Pulse CO-Oximeter uses a multi-wavelength sensor to distinguish between oxygenated blood, deoxygenated blood, blood with carbon monoxide content and blood with oxidized hemoglobin. The D-MAS utilizes a sensor with various lightemitting diodes (LEDs) that pass light through the site to a photodiode (photodetector). Signal data is obtained by passing various visible and infrared lights (LED's, 500 to 1000nm) through a capillary bed (for example, a fingertip, a hand, a foot) and measuring changes in light absorption during the blood pulsatile cycle. The maximum radiant power of the strongest light is rated at 22mW. The photodetector receives the light which is converted into an electronic signal and is sent to D-MAS for calculation.



1. **Light Emitting Diodes (LEDs)**

   (7+ wavelengths)

2. **Recessed Photo Detector**

Once the D-MAS receives the signal from the sensor, it utilizes Rainbow SET signal extraction technology to calculate the patient's functional oxygen saturation, blood levels of carboxyhemoglobin (SpCO), methemoglobin (SpMet) and pulse rate. The SpCO and SpMet measurements rely on a multiwavelength calibration equation to quantify the percentage of carbon monoxide and methemoglobin in arterial blood. The maximum of the skin surface temperature is measured at an ambient temperature of less than 106º F (41º C). This is verified by sensor skin temperature test procedures

FUNCTIONAL SATURATION

The D-MAS is calibrated to measure and display functional saturation (SpO2): the amount of oxyhemoglobin expressed as a percentage of the hemoglobin that is available to transport oxygen. Note that carboxyhemoglobin and methemoglobin are not capable of transporting oxygen, but is recognized as oxygenated hemoglobin by conventional pulse oximetry.

MEASURED VS. CALCULATED SATURATION

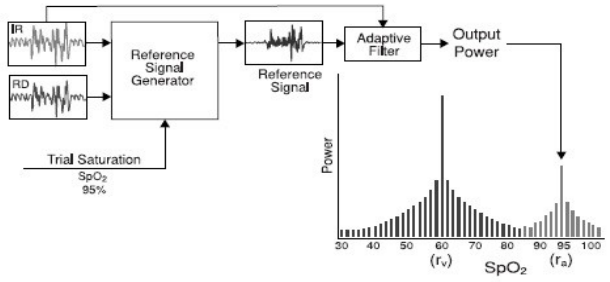
SpO2, SpMet and SpCO measurements that can be obtained from D-MAS are commonly compared to invasive measurements obtained from blood gas samples. When comparing invasive and noninvasive measurements and interpreting values, caution should be used, as the calculated values obtained from the blood gas sample may differ from the SpO2, SpMet and SpCO measurements of the Pulse CO-Oximeter. In the case of SpO2, different results are usually obtained from the arterial blood gas sample if the calculated measurement is not appropriately corrected for the effects of variables that shift the relationship between the partial pressure of oxygen (PO2) and saturation, such as: pH, temperature, the partial pressure of carbon dioxide (PCO2), 2,3-DPG, and fetal hemoglobin. In the case of SpMet and SpCO, in addition to the effects of temperature and pH, different results are also expected if concentration of methemoglobin in the blood gas sample are abnormal (less than 90% for arterial oxygen saturation, and greater than 2% for methemoglobin concentration). As blood gas samples are usually taken over a period of 20 seconds (the time it takes to draw the blood) a meaningful comparison can only be achieved if the oxygen saturation, carboxyhemoglobin and methemoglobin concentration of the patient are stable and not changing over the period of time that the blood gas sample is taken.

SIGNAL EXTRACTION TECHNOLOGY FOR SpO2 MEASUREMENTS

Signal Extraction Technology's signal processing differs from conventional pulse oximeters. Conventional pulse oximeters assume that arterial blood is the only blood moving (pulsating) in the measurement site. During patient motion, however, the non-arterial blood also moves, causing conventional pulse oximeters to read low values, because they cannot distinguish between the arterial and venous blood movement (sometimes referred to as noise). Pulse oximetry utilizes parallel engines and adaptive digital filtering. Adaptive filters are powerful because they are able to adapt to the varying physiologic signals and/or noise and separate them by looking at the whole signal and breaking it down to its fundamental components. The signal processing algorithm, Discrete Saturation Transform® (DST®) reliably identifies the noise, isolates it and, using adaptive filters, cancels it. It then reports the true arterial oxygen saturation for display on the monitor.

SpMet AND SpCO MEASUREMENTS DURING PATIENT MOTION

The D-MAS displays measurements of SpMet and SpCO during patient motion. However, because of the changes in the physiological parameters such as blood volume, arterial-venous coupling, etc. that occur during patient motion, the accuracy of such measurements may not be readable during excessive motion.



NUMERIC DISPLAY – SpO2
Stability of the SpO2 readings may be a good indicator of signal validity. Although stability is a relative term, experience will provide a good feeling for changes that are artifactual or physiological and the speed, timing, and behaviour of each. The stability of the readings over time is affected by the averaging mode being used. The longer the averaging time, the more stable the readings tend to become. This is due to a dampened response as the signal is averaged over a longer period of time than during shorter averaging times. However, longer averaging times delay the response of the oximeter and reduce the measured variations of SpO2 and pulse rate.

NUMERIC DISPLAY - PULSE RATE
The Pulse Rate display may differ slightly from the heart rate displayed on ECG monitors due to differences in averaging times. There may also be a discrepancy between cardiac electrical activity and peripheral arterial pulsation. Significant differences may indicate a problem with the signal quality due to physiological changes in the patient or one of the instruments or application of the sensor or patient cable. The pulsations from intra-aortic balloon support can cause the pulse rate displayed on the Pulse CO-Oximeter to be significantly different than the ECG heart rate.

NUMERIC DISPLAY – SpCO
A stable SpCO reading is associated with correct sensor placement, small physiological changes during the measurement and acceptable levels of arterial perfusion in the patient's fingertip (measurement site). Physiological changes at the measurement site are mainly caused by fluctuations in the oxygen saturation, blood concentration and perfusion.
Inaccurate measurements may be caused by:

- Significant levels of methemoglobin.
- Intravascular dyes such as indocyanine green or methylene blue.
- Abnormal hemoglobin levels.
- Abnormally low arterial perfusion.

NUMERIC DISPLAY – SpMet
A stable SpMet reading is associated with correct sensor placement, small physiological changes during the measurement and acceptable levels of arterial perfusion in the patient's fingertip (measurement site). Physiological changes at the measurement site are mainly caused by fluctuations in the oxygen saturation, blood concentration and perfusion.
Inaccurate measurements may be caused by:

- Intravascular dyes such as indocyanine green or methylene blue.
- Abnormal arterial perfusion

NUMERIC DISPLAY – PI
The Perfusion Index (PI) display provides a relative numeric indication of the pulse strength at the monitoring site. It is a calculated percentage between the pulsatile signal and nonpulsatile signal of arterial blood moving through the site. PI may be used to find the best perfused site and to monitor physiological changes in the patient. It displays an operating range of 0.02 to 20.00%. A percentage greater than 1.00% is desired. Extreme changes in the display number are due to changes in physiology and blood flow.

SIGNAL IQ
The D-MAS display provides a visual indicator of the plethysmogram signal quality and an alert when the displayed SpO2 values are not based on adequate signal quality. The signal quality indicator displayed is called the Signal IQ and can be used to identify the occurrence of a patient's pulse and the associated signal quality of the measurement. With motion, the plethysmographic waveform is often distorted and may be obscured by artifact. The Signal IQ, shown as a vertical line, coincides with the peak of an arterial pulsation.

Even with a plethysmographic waveform obscured by artifact, D-MAS locates the arterial pulsation. The pulse tone (when enabled) coincides with the vertical line of the Signal IQ.

The height of the vertical line of the Signal IQ indicates the quality of the measured signal. A high vertical bar indicates that the SpO2 measurement is based on a good quality signal. A small vertical bar indicates that the SpO2 measurement is based on data with low signal quality.

When the signal quality is very low the accuracy of the SpO2 measurement may be compromised, and a Low Signal IQ message is displayed.

When the Low Signal IQ message appears proceed with caution and do the following:

- Assess the patient
- Check the sensor and ensure proper sensor application. The sensor must be well secured to the site to maintain accurate readings. Also,misalignment of the sensor's emitter and detector can result in smaller signals
- Determine if an extreme change in the patient's physiology and blood flow at the monitoring site occurred, (e.g. an inflated blood pressure cuff, a squeezing motion, sampling of an arterial blood specimen from the hand containing the pulse oximetry sensor, severe hypotension, peripheral vasoconstriction in response to hypothermia, medications, or a spell of Raynaud's syndrome.)

LOW PERFUSION

D-MAS displays a "Low Perfusion" message when there are very low amplitude arterial pulsations. It has been suggested that at extremely low perfusion levels, pulse oximeters can measure peripheral saturation, which may differ from central arterial saturation[1].

This "localized hypoxemia" may result from the metabolic demands of other tissues extracting oxygen proximal to the monitoring site under conditions of sustained peripheral hypoperfusion. (This may occur even with a pulse rate that correlates with the ECG heart rate.)

CAUTION: IF THE LOW PERFUSION MESSAGE IS FREQUENTLY DISPLAYED, FIND A BETTER-PERFUSED MONITORING SITE. IN THE INTERIM, ASSESS THE PATIENT AND, IF INDICATED, VERIFY OXYGENATION STATUS THROUGH OTHER MEANS.

[1] Severinghaus JW, Spellman MJ. Pulse Oximeter Failure Thresholds in Hypotension and Vasoconstriction. Anesthesiology 1990; 73:532-537

ACTIONS TO BE TAKEN

If the SpO2 readings show significant differences, do the following:

- Make sure the emitter and photodetector are aligned directly opposite each other.
- Select a site where the distance between the emitter and photodetector is minimized.
- Wipe the sensor site with a 70% isopropyl alcohol pad or rubefacient cream (10- 30% methyl salicylate and 2-10% menthol) for 20-30 seconds to increase perfusion. However, strong vasodilator creams, such as nitroglycerin paste, are not recommended.
- If possible, remove electrical noise sources such as electrosurgical units or other electrical/electronic equipment. If these solutions are not possible, operate D-MAS on battery power, or try plugging D-MAS into a different electrical outlet.
- If artificial nails or excessive fingernail polish are present, select another site or remove the polish/artificial nails.
- If possible, ensure that the sensor is placed in a location with low ambient light. Although the D-MAS with integrated SET technology has significant immunity to ambient light, excessive ambient light may cause readings to be incorrect.

CAUTION: IF ANY MEASUREMENT SEEMS QUESTIONABLE, FIRST CHECK THE PATIENT'S VITAL SIGNS BY ALTERNATE MEANS AND THEN CHECK D-MAS FOR PROPER FUNCTIONING.

SENSITIVITY

D-MAS is equipped with 3 different sensitivity modes. Each mode allows the clinician to change the sensitivity settings of the device to meet the increased demands of the patient's physiological condition or enable it to work during periods of low perfusion and/or motion. They are as follows:

- Normal Sensitivity – This is the recommended mode for patients that are experiencing some compromise in blood flow or perfusion. It is advisable for care areas where patients are observed frequently.
- Adaptive Probe Off Detection (APOD) – This is the recommended start-up monitoring mode for most patients with acceptable perfusion or where a more robust sensor off detection is desired. It is the suggested mode for care areas where patients are not visually monitored continuously. This mode delivers enhanced protection against erroneous pulse rate and arterial oxygen saturation readings when a sensor becomes inadvertently detached from a patient.
- Maximum Sensitivity (MAX) - This mode is recommended for patients with low perfusion or when the low perfusion or low signal quality message is displayed on the screen in APOD or normal sensitivity mode. This mode is not recommended for care areas where patients are not monitored visually, such as general wards. It is designed to interpret and display data at the measuring site when the signal may be weak due to decreased perfusion. When a sensor becomes detached from a patient, it will have compromised protection against erroneous pulse rate and arterial saturation readings.

CAUTION: WHEN USING THE MAXIMUM SENSITIVITY SETTING, THE PERFORMANCE OF THE SENSOR OFF DETECTION MAY BE COMPROMISED. IF THE UNIT IS IN THIS SETTING AND THE SENSOR BECOMES DISLODGED FROM THE PATIENT, THE POTENTIAL FOR FALSE READINGS MAY OCCUR DUE TO ENVIRONMENTAL 'NOISE' SUCH AS LIGHT, VIBRATION AND EXCESSIVE AIR MOVEMENT.

Resting ECG general description

Electrocardiography (ECG or EKG from Greek: kardia, meaning heart) is a noninvasive transthoracic interpretation of the electrical activity of the heart over a period of time. D-MAS detects and records ECG signals with electrodes attached to the surface of the skin. The recording produced by this procedure is termed an electrocardiogram (also ECG or EKG).

The ECG is the most important test for interpretation of the cardiac rhythm, conduction system abnormalities, and for the detection of myocardial ischemia. The ECG is also of great value in the evaluation of other types of cardiac abnormalities including valvular heart disease, cardiomyopathy, pericarditis, and hypertensive disease. Finally, the ECG can be used to monitor drug treatment (specifically antiarrhythmic therapy) and to detect metabolic disturbances

Principle of operation

The basic principle of the ECG is that stimulation of a muscle alters the electrical potential of the muscle fibres. Cardiac cells, unlike other cells, have a property known as automaticity, which is the capacity to spontaneously initiate impulses. These are then transmitted from cell to cell by gap junctions that connect cardiac cells to each other.

Electrical impulses spread through the muscle cells because of changes in ions between intracellular and extracellular fluid. This is referred to as action potential. The primary ions involved are potassium, sodium and calcium. The action potential is the potential for action created by the balance between electrical charges (positive and negative) of ions on either side of the cell membrane.

When the cells are in a resting state, the insides are negatively charged compared to the outsides. Membrane pumps act to maintain this electrical polarity (negative charge) of the cardiac cells. Contraction of the heart muscle is triggered by depolarisation, which causes the internal negative charge to be lost transiently.

However, following depolarisation, the cardiac cells return again to their resting charge, known as repolarisation.

These waves of depolarisation and repolarisation represent an electrical current and can be detected by placing electrodes on the surface of the body. After the current has spread from the heart through the body, the changes are picked up by electrodes connected to D-MAS and the activity is recorded digitally. The D-MAS ECG is therefore a graphic representation of the electrical activity in the heart. The current is transmitted at the pre-defined points of contact of the electrode with the body.

The ECG comprises 12 leads: three standard leads (lead I, lead II and lead III); three augmented leads (AVR, AVL and AVF); and six chest leads (V1, V2, V3, V4, V5, V6).

A total of 10 electrodes (points of contact with the body) are used to perform the ECG.

It is called a 12 lead ECG because the heart is viewed and recorded from 12 different viewpoints.

Two electrodes are placed on the arms and two on the legs to provide the basis for the six limb leads (three standard and three augmented leads).

The four limb electrodes record six different views of electrical activity in the heart, while each of the chest electrodes records one lead each.

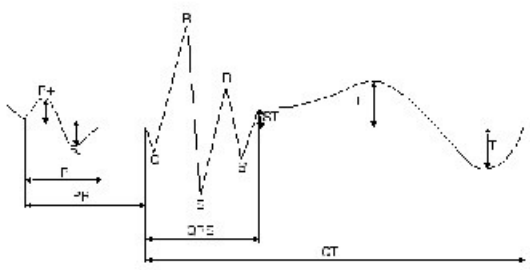
The ECG signals are acquired via electrodes attached to the ECG patient cable. The signals are digitized, displayed and stored electronically. The recorded signal is measured and an ECG interpretation algorithm is applied to the recording providing the user with displayed measurements and interpretation statements.

ECG Interpretation general description

Healthcare Professional's Responsibility

The interpretations provided by D-MAS are for the exclusive use of licensed physicians or personnel under their direct supervision. The suggested interpretation, including numerical and graphical results, should be examined with respect to the patient's overall clinical condition. It is the responsibility of the Healthcare Professional to ensure proper administration of the test, making a diagnosis, obtaining expert opinions on the results, and instituting the correct treatment.

Overall P onset, P offset, QRS onset, QRS offset and T termination are determined from all 12 leads. Individual lead wave amplitudes are then obtained.



P+, P-, Q, R, S, R', S', T+ and T- amplitudes are measured with respect to a horizontal line through the lead QRS onset.

Durations are measured between relevant points.
Areas are measured in units of millivolts x milliseconds (mV x ms). Units of measure are not specified when an area measurement appears in the criteria.
Isoelectric components between the overall QRS onset and an individual lead onset are not included in a Q or R duration.
The minimum wave acceptable has to have a duration >8 ms and an amplitude >20 ≒V.

Stability of the measurements in the presence of noise - IEC Measurement Accuracy - changes of measurements cause by NOISE on ECGs:

		Disclosed differences	
Global Measurement	Type of added NOISE	Mean (ms)	Standard deviation (ms)
P Duration	High frequency	0.600	2.503
P Duration	Line frequency (50Hz)	-0.400	1.265
P Duration	Line frequency (60Hz)	0.000	2.494
P Duration	Base-line	-0.400	1.265
QRS Duration	High frequency	0.600	3.534
QRS Duration	Line frequency (50Hz)	0.600	2.836
QRS Duration	Line frequency (60Hz)	-0.400	2.797
QRS Duration	Base-line	0.200	3.048
QT Interval	High frequency	-2.200	3.048
QT Interval	Line frequency (50Hz)	-0.200	0.632
QT Interval	Line frequency (60Hz)	-0.200	1.476
QT Interval	Base-line	-0.800	1.398

ECG Classification

A task force of the American College of Cardiology established a classification system for ECG abnormalities on the basis of the types of statements that could be made. These are as follows:

Type A: An ECG abnormality which can be confirmed by non electrocardiographic means, e.g ventricular hypertrophy that can be confirmed by echocardiography, or recent myocardial infarction confirmed by a rise in biomarkers;

Type B: An ECG abnormality basically detected by the ECG itself, e.g arrhythmias or conduction abnormalities such as bundle branch block;

Type C: An ECG abnormality that is essentially descriptive, e.g. axis deviation, moderate ST elevation etc.

Definitions

TRUE POSITIVE (TP) = A correct report of an abnormality being present

TRUE NEGATIVE (TN) = A correct report of an abnormality being absent

FALSE POSITIVE (FP) = An incorrect report of an abnormality being present

FALSE NEGATIVE (FN) = An incorrect report of an abnormality being absent

SENSITIVITY (SENS) = $\frac{TP}{(TP + FN)}$

SPECIFICITY (SPEC) = $\frac{TN}{(TN + FP)}$

POSITIVE PREDICTIVE VALUE (PPV) = $\frac{TP}{(TP + FP)}$

NEGATIVE PREDICTIVE VALUE (NPV) = $\frac{TN}{(TN + FN)}$

PREVALENCE = $\frac{\text{Number of occurrences of an abnormality}}{\text{Total number of cases in the data base}}$

TOTAL ACCURACY = $\frac{\text{Total number of cases correctly classified}}{1220}$

CSE Abbreviations

NL = Normal
LVH = Left ventricular hypertrophy
RVH = Right ventricular hypertrophy
BVH = Right and left ventricular hypertrophy
MI = Myocardial infarction
AMI = Anterior myocardial infarction
IMI = Inferior myocardial infarction
MIX = Anterior and inferior myocardial infarction
VH+MI = Ventricular hypertrophy and myocardial infarction
OTHER= Cardiologist defined abnormality excluding above definitions

Results

Results from an analysis of the CSE database in . In this case, the gold standard ("truth") was derived from the clinical data.

TYPE A STATEMENTS[1]

DIAGNOSTIC CATEGORY	SENSITIVITY	SPECIFICITY	PPV	NPV	PREVALENCE
Normal	97%	77% [2]	66% [2]	98%	382/1220
LVH	57%	98%	82%	93%	183/1220
RVH	44%	100%	92%	97%	55/1220
BVH	47%	99%	78%	98%	53/1220
AMI	72%	98%	88%	96%	170/1220
IMI	71%	99%	93%	92%	273/1220
MIX	63%	98%	69%	98%	73/1220

Total Accuracy: 73.7% Partially correct: 75.7% (both on 1220 cases)

[1] The CSE database does not allow a meaningful interpretation of statistics on statements involving "possible" and "probable" qualifiers. They are taken into account in determining the sensitivity etc of the various diagnoses as the statement with the highest likelihood, where definite > probable > possible, is given most weight in handling a specific interpretation.

[2] Specificity and positive predictive value for 'NORMAL' should be interpreted carefully. A report of 'NORMAL' in a case of 'MYOCARDIAL INFARCTION' or 'hypertrophy' contributes to decreased specificity for 'NORMAL' (even though the ECG may appear 'NORMAL'). In the CSE study, an ECG report stating only 'MYOCARDIAL ISCHEMIA' was mapped to 'NORMAL' even if the true answer was 'INFARCTION', thereby also contributing to decreased specificity for 'NORMAL'.

Results from an analysis of the CSE database in . In this case, the gold standard ("truth") was derived from the clinical data. In this table, there is a more detailed breakdown of the reports, e.g. 1.0% of ECGs from individuals regarded as normal were reported by the program as LVH. On the other hand, 29.5% of ECGs from patients with clinical evidence of LVH were reported as normal.

TYPE A STATEMENTS

PROG / TRUTH	NORM	LVH	RVH	BVH	AMI	IMI	MIX	VH +MI	OTHER	TOTAL	PREV
NORM	**97.1**	1.0	0.0	0.0	1.6	0.3	0.0	0.0	0.0	100%	382/1220
LVH	29.5	**56.8**	0.5	2.2	3.6	6.0	0.8	0.0	0.5	100%	183/1220
RVH	40.0	7.3	**43.6**	3.6	0.0	1.8	1.8	0.0	1.8	100%	55/1220
BVH	13.2	0.0	0.0	**46.7**	7.5	1.9	0.0	0.0	30.7	100%	53/1220
AMI	15.9	4.4	0.0	0.6	**71.8**	0.3	7.1	0.0	0.0	100%	170/1220
IMI	25.6	1.3	0.4	0.0	0.0	**70.5**	2.2	0.0	0.0	100%	273/1220
MIX	8.2	5.5	0.0	0.0	0.0	0.0	**63.4**	0.0	22.9	100%	73/1220
VH+MI	25.8	0.0	0.0	0.0	0.0	0.0	0.0	**46.8**	27.4	100%	31/1220

Total accuracy: 73.7 % Partially correct: 75.7 % (both on 1220)

Distributions of the CSE computer interpretations with respect to the consensus opinion of 8 cardiologists. Prevalence totals change compared to Tables 1 and 2 because the gold standard has changed.

TYPE A STATEMENTS

PROG REF	NORM	LVH	RVH	BVH	AMI	IMI	MIX	VH+ MI	OTHER	TOTAL	PREV
NL	**92.9**	2.2	0.7	0.5	1.0	1.2	0.1		1.4	100.0	503/1220
LVH	18.0	**72.0**		2.8	0.3	4.8	0.7		1.4	100.0	145/1220
RVH	28.3		**66.7**		1.7		3.3			100.0	30/1220
BVH	3.4	10.3	5.2	**70.7**	3.4				6.9	100.0	29/1220
AMI	9.4	2.5		1.3	**80.2**		6.6			100.0	159/1220
IMI	14.0	1.1	0.4	0.2		**82.9**	1.3			100.0	228/1220
MIX	11.8	0.7			2.8	4.9	**71.5**		8.3	100.0	72/1220
VH+MI	20.5	4.5				4.5		**61.4**	9.1	100.0	22/1220
OTHER	6.3	3.1		7.8	6.3		3.1	3.1	**70.3**	100.0	32/1220
TOTAL	46.3	10.4	2.1	2.6	11.4	17.0	5.6	1.2	3.4	**100.0**	**1220**

Total agreement 81.48%

Results on type B statements. Data were obtained from the Glasgow 1000 ECG database from which 73 children's ECGs were removed in order to provide results on adults only. In addition, 31 WPW examples were obtained from a group of 31 patients being investigated by electrophysiological testing. There were therefore 927+31 (958) ECGs available for assessment of type B statements in adults.

TYPE B STATEMENTS – CONDUCTION DEFECTS

CONDUCTION DEFECT	SENS	SPEC	PPV	NPV	PREVALENCE
RBBB	96%	99.9%	96%	99.9%	24/958
LBBB	100%	100%	100%	100%	16/958
RBBB with LAFB	100%	100%	100%	100%	9/958
Incomplete RBBB / rSr' V1	100%	99.9%	95.6%	100%	22/958
IVCD	100%	99.7%	82.4%	100%	14/958
WPW	88%	100%	100%	99.6%	33/958
(Possible) LAFB	100%	100%	100%	100%	15/958

RBBB = Right bundle branch block

LBBB = Left bundle branch block

LAFB = Left anterior fascicular block

IVCD = Intra ventricular conduction defect

WPW = Wolf Parkinson White

Results of rhythm interpretations. Several databases were used. The first was the Glasgow 1000 ECG database. A second database of 1498 ECGs from apparently healthy adults was also incorporated to increase the number of sinus and other common rhythms. These ECGs were supplemented by 72 cases of atrial fibrillation which were included to augment the number of cases of this arrhythmia.

TYPE B STATEMENTS – RHYTHM

DOMINANT RHYTHM STATEMENT	SENS	SPEC	PPV	NPV	PREV
Sinus rhythm	99.43	98.54	99.31	98.78	1746/2570
Sinus bradycardia	100.00	99.69	97.83	100.00	315/2570
Atrial fibrillation	93.66	99.84	97.08	99.63	142/2570
Sinus arrhythmia	93.14	100.00	100.00	99.72	102/2570
Sinus tachycardia	100.00	99.80	94.25	100.00	82/2570
Sinus bradycardia with sinus arrhythmia	84.44	100.00	100.00	99.72	45/2570
Atrial flutter	92.31	100.00	100.00	99.88	39/2570
Possible atrial flutter	100.00	99.96	97.37	100.00	37/2570
Possible ectopic atrial rhythm	96.15	99.92	92.59	99.96	26/2570
Possible ectopic atrial bradycardia	100.00	100.00	100.00	100.00	15/2570
A-V dissociation	50.00	100.00	100.00	99.92	4/2570
Probable atrial fibrillation	100.00	99.92	60.00	100.00	3/2570
Probable accelerated junctional rhythm	100.00	99.96	75.00	100.00	3/2570
Probable supraventricular tachycardia	100.00	100.00	100.00	100.00	3/2570
Probable sinus tachycardia	100.00	99.96	66.67	100.00	2/2570
Sinus tachycardia with sinus arrhythmia	100.00	100.00	100.00	100.00	1/2570
Irregular ectopic atrial bradycardia	100.00	100.00	100.00	100.00	1/2570
Probable atrial tachycardia	100.00	100.00	100.00	100.00	1/2570
Marked sinus bradycardia	100.00	100.00	100.00	100.00	1/2570
Possible junctional rhythm	100.00	99.96	50.00	100.00	1/2570
Regular supraventricular rhythm	100.00	99.88	25.00	100.00	1/2570

Results for supplementary statements using the same database. Results of rhythm interpretations. Several databases were used. The first was the Glasgow 1000 ECG database. A second database of 1498 ECGs from apparently healthy adults was also incorporated to increase the number of sinus and other common rhythms. These ECGs were supplemented by 72 cases of atrial fibrillation which were included to augment the number of cases of this arrhythmia.

SUPPLEMENTARY STATEMENT	SENS	SPEC	PPV	NPV	PREV
~ with rapid ventricular response	100.00	100.00	100.00	100.00	71/2570
~with PVCs	98.39	99.84	93.85	99.96	62/2570
~ with PACs	96.08	99.09	68.06	99.92	51/2570
~ with borderline 1st degree A-V block	97.87	99.76	88.46	99.96	47/2570
~ with 1st degree A-V block	94.59	99.92	94.59	99.92	37/2570
~ or aberrant ventricular conduction	100.00	99.96	95.00	100.00	19/2570
~ with slow ventricular response	100.00	99.96	92.86	100.00	13/2570
~ with 2:1 A-V block	80.00	100.00	100.00	99.92	10/2570
~with frequent multifocal PVCs	100.00	100.00	100.00	100.00	7/2570
~ with uncontrolled ventricular response	100.00	100.00	100.00	100.00	7/2570
~ with 4:1 A-V block	100.00	100.00	100.00	100.00	5/2570
~ with aberrantly conducted supraventricular complexes	60.00	99.84	42.86	99.92	5/2570
~ with frequent PVCs	100.00	99.92	60.00	100.00	3/2570
~ with frequent PACs	100.00	99.96	75.00	100.00	3/2570
~ with multifocal PVCs	100.00	100.00	100.00	100.00	2/2570
~ with undetermined irregularity	100.00	100.00	100.00	100.00	2/2570
~ with paroxysmal idioventricular rhythm	100.00	100.00	100.00	100.00	1/2570
-V block, Mobiltz I (Wenckeback)	0.00	99.96	0.00	99.96	1/2570
~ with 3:1 A-V block	100.00	100.00	100.00	100.00	1/2570
~ with complete A-V block	0.00	100.00	0.00	99.96	1/2570
~ with bigeminal PVCs	100.00	100.00	100.00	100.00	1/2570
~ with 2nd degree (Mobitz II) SA block	0.00	99.96	0.00	100.00	0/2570

Data derived from 47 cases of paced ECGs.

PACING STATEMENT	SENS	SPEC	PPV	NPV	PREV
Atrial Pacing	100%	97.3%	90.9%	100%	10/47
Demand Atrial Pacing	100%	100%	100%	100%	5/47
Ventricular pacing	90.9%	100%	100%	97.3%	11/47
A-V Sequential Pacemaker	90.9%	100%	100%	97.3%	11/47
Demand pacing	100%	97.3%	90.9%	100%	10/47

Type C statements in adults derived from the Glasgow 1000 ECG database less the 73 childrens' ECGs.

ECG FINDINGS	SENS	SPEC	PPV	NPV	PREV
LAD	100%	100%	100%	100%	65/927
Leftward axis	100%	100%	100%	100%	59/927
RAD	100%	100%	100%	100%	15/927
Severe RAD	100%	100%	100%	100%	1/927
Rightward axis	100%	100%	100%	100%	12/927
Non specific ST ± T changes	100%	99.8%	97.3%	100%	71/927
rSr' – probable normal variant	100%	99.9%	94.4%	100%	17/927
Poor R wave progression	92.8%	99.9%	96.3%	99.8%	26/927

LAD = Left axis deviation

RAD = Right axis deviation

ECGs for this table were taken from the Glasgow pediatric ECG database. (See description of this database for an explanation of prevalence's).

TYPE A STATEMENTS IN CHILDREN

ECG FINDINGS	SENS	SPEC	POSITIVE PRED. VALUE	NEGATIVE PRED. VALUE	PREV
Normal	97.5%	97.9%	97.8%	97.7%	405/840
RVH	53.5%	94.4%	53.5%	94.4%	71/664
LVH	44.4%	95.8%	28.9%	97.4%	27/664
BVH	100%	99.1%	73.9%	100%	17/840
Possible right atrial abnormality	100%	99.6%	96.7%	100%	89/840
Possible left atrial abnormality	100%	99.5%	73.3%	100%	11/840
Possible biatrial abnormality	100%	100%	100%	100%	6/840
Abnormal ventricular conduction pathways (Q waves)	92.8%	99.9%	96.3%	99.8%	26/840
Borderline high QRS voltage – probable normal variant	100%	100%	100%	100%	24/840

RVH = Right ventricular hypertrophy

LVH = Left ventricular hypertrophy

BVH = Biventricular hypertrophy

Results on Type B abnormalities in the Glasgow pediatric ECG database.

TYPE B ABNORMALITIES IN CHILDREN

ECG FINDINGS	SENS	SPEC	POSITIVE PRED. VALUE	NEGATIVE PRED. VALUE	PREV
RBBB	92.5%	99.8%	94.9%	99.6%	40/840
LBBB	100%	100%	100%	100%	1/840
IVCD	100%	99.5%	73.3%	100%	11/840
WPW pattern	50%	100%	50%	99.8%	4/840
Incomplete RBBB	100%	100%	100%	100%	6/840
rSr' (V1) – probable normal variant	100%	100%	100%	100%	14/840

RBBB = Right bundle branch block

LBBB = Left bundle branch block

LAFB = Left anterior fascicular block

IVCD = Intra ventricular conduction defect

WPW = Wolf Parkinson White

Results on Type C abnormalities in 840 ECGs in the Glasgow pediatric ECG database.

TYPE C ECG ABNORMALITIES IN CHILDREN

ECG FINDINGS	SENS	SPEC	POSITIVE PRED. VALUE	NEGATIVE PRED. VALUE	PREV
….ST ± T changes are non specific	100%	99.7%	98.1%	100%	107/840
….ST elevation……	100%	99.8%	97.2%	100%	35/840
Right axis deviation	100%	100%	100%	100%	43/840
Severe right axis deviation	100%	100%	100%	100%	8/840
QRS axis leftward for age	100%	99.7%	97.8%	100%	46/840
Left axis deviation	100%	100%	100%	100%	25/840
Indeterminate axis	100%	100%	100%	100%	3/840

Note:
Computer assisted interpretation is a valuable tool when used properly. However, no automated analysis system is completely reliable, therefore interpretations should be reviewed by a qualified Healthcare Professional before treatment, or non-treatment, of any patient.

Blood Pressure general description

General description

Blood pressure (BP), sometimes referred to as arterial blood pressure, is the pressure exerted by circulating blood upon the walls of blood vessels, and is one of the principal vital signs. When used without further specification, "blood pressure" usually refers to the arterial pressure of the systemic circulation and is a measure of the pressure in the brachial artery, the major artery in the upper arm.

During each heartbeat, blood pressure varies between a maximum (systolic) and a minimum (diastolic) pressure. The blood pressure in the circulation is principally due to the pumping action of the heart.

Differences in mean blood pressure are responsible for blood flow from one location to another in the circulation. The rate of mean blood flow depends on the resistance to flow presented by the blood vessels. Mean blood pressure decreases as the circulating blood moves away from the heart through arteries and capillaries due to viscous losses of energy. Mean blood pressure drops over the whole circulation, although most of the fall occurs along the small arteries and arterioles.

Gravity affects blood pressure via hydrostatic forces (e.g., during standing) and valves in veins, breathing, and pumping from contraction of skeletal muscles also influence blood pressure in veins.

For each heartbeat, blood pressure varies between systolic and diastolic pressures. Systolic pressure is the peak pressure in the arteries, which occurs near the end of the cardiac cycle when the ventricles are contracting. Diastolic pressure is minimum pressure in the arteries, which occurs near the beginning of the cardiac cycle when the ventricles are filled with blood. An example of normal measured values for a resting, healthy adult human is 120 mmHg systolic and 80 mmHg diastolic (written as 120/80 mmHg, and spoken as "one-twenty over eighty").

Systolic and diastolic arterial blood pressures are not static but undergo natural variations from one heartbeat to another and throughout the day (in a circadian rhythm). They also change in response to stress, nutritional factors, drugs, disease, exercise, and momentarily from standing up. Sometimes the variations are large. Hypertension refers to arterial pressure being abnormally high, as opposed to hypotension, when it is abnormally low.

Principle of operation

Arterial pressure is measured by D-MAS and reported in millimetres of mercury (mmHg), although D-MAS does not contain mercury.

D-MAS employs the noninvasive oscillometric technique and the measurement is simple and quicker than invasive measurements, requires less expertise, has virtually no complications, is less unpleasant and less painful for the patient. However, noninvasive methods may yield somewhat lower accuracy and small systematic differences in numerical results. Noninvasive measurement methods are more commonly used for routine examinations and monitoring.

The oscillometric method involves the observation of oscillations in the cuff pressure which are caused by the oscillations of blood flow, i.e., the pulse. D-MAS uses a sphygmomanometer cuff with an electronic pressure sensor (transducer) to observe cuff pressure oscillations, electronics to automatically interpret them, and automatic inflation and deflation of the cuff.

The pressure sensor should be calibrated annually to maintain accuracy.

The cuff is inflated to a pressure initially in excess of the systolic arterial pressure and then reduced to below diastolic pressure over a period of about 30 seconds.

When blood flow is nil (cuff pressure exceeding systolic pressure) or unimpeded (cuff pressure below diastolic pressure), cuff pressure will be essentially constant. It is important that the cuff size is correct: undersized cuffs may yield too high a pressure; oversized cuffs yield too low a pressure.

When blood flow is present, but restricted, the cuff pressure, which is monitored by the pressure sensor, will vary periodically in synchrony with the cyclic expansion and contraction of the brachial artery, i.e., it will oscillate.

Oscillometric monitors may produce inaccurate readings in patients with heart and circulation problems, which include arterial sclerosis, arrhythmia, preeclampsia, pulsus alternans, and pulsus paradoxus.

In practice the different methods do not give identical results.

The term NIBP, for non-invasive blood pressure, is often used to describe oscillometric monitoring equipment.

Stages of D-MAS NIBP measurement:

1. Cuff inflation: The D-MAS will inflate the NIBP cuff to the target pressure. When target pressure is achieved, the inflation pump will stop.

2. Pulse detection: The D-MAS will sense the pressure in the NIBP cuff and detect any pulsatile oscillations in pressure.

3. Cuff stepped deflation: The cuff will be deflated and oscillation detected until the patient blood pressure has been determined and displayed.

4. Rapid cuff deflation: The cuff pressure is rapidly deflated.

Spirometry general description

Spirometry (meaning the measuring of breath) is the most common of the pulmonary function tests (PFTs), measuring lung function, specifically the amount (volume) and/or speed (flow) of air that can be inhaled and exhaled.

Spirometry is an important tool used for generating pneumotachographs, which are helpful in assessing conditions such as asthma, pulmonary fibrosis, cystic fibrosis, and COPD.

Spirometry is indicated for the following reasons:

- to diagnose or manage asthma
- to detect respiratory disease in patients presenting with symptoms of breathlessness, and to distinguish respiratory from cardiac disease as the cause
- to measure bronchial responsiveness in patients suspected of having asthma
- to diagnose and differentiate between obstructive lung disease and restrictive lung disease
- to follow the natural history of disease in respiratory conditions
- to assess of impairment from occupational asthma
- to identify those at risk from pulmonary barotrauma while scuba diving
- to conduct pre-operative risk assessment before anaesthesia or cardiothoracic surgery
- to measure response to treatment of conditions which spirometry detects

Principle of operation

The spirometry test is performed using the D-MAS USB spirometer. D-MAS displays the following graphs, called spirograms:

- a volume-time curve, showing volume (liters) along the Y-axis and time (seconds) along the X-axis
- a flow-volume loop, which graphically depicts the rate of airflow on the Y-axis and the total volume inspired or expired on the X-axis

Generally, the patient is asked to take the deepest breath they can, and then exhale into the sensor as hard as possible, for as long as possible, preferably at least 6 seconds. It is sometimes directly followed by a rapid inhalation (inspiration), in particular when assessing possible upper airway obstruction.

Sometimes, the test will be preceded by a period of quiet breathing in and out from the sensor (tidal volume), or the rapid breath in (forced inspiratory part) will come before the forced exhalation.

During the test, soft nose clips may be used to prevent air escaping through the nose. Filter mouthpieces may be used to prevent the spread of micro organisms.

The manoeuvre is highly dependent on patient cooperation and effort, and is normally repeated at least three times to ensure reproducibility. Since results are dependent on patient cooperation, FVC can only be underestimated, never overestimated.

Due to the patient cooperation required, spirometry can only be used on children old enough to comprehend and follow the instructions given (6 years old or more), and only on patients who are able to understand and follow instructions — thus, this test is not suitable for patients who are unconscious, heavily sedated, or have limitations that would interfere with vigorous respiratory efforts.
Another major limitation is the fact that many intermittent or mild asthmatics have normal spirometry between acute exacerbation, limiting spirometry's usefulness as a diagnostic.

It is more useful as a monitoring tool: a sudden decrease in FEV1 or other spirometric measure in the same patient can signal worsening control, even if the raw value is still normal.

Patients should be encouraged to record their personal best measures.

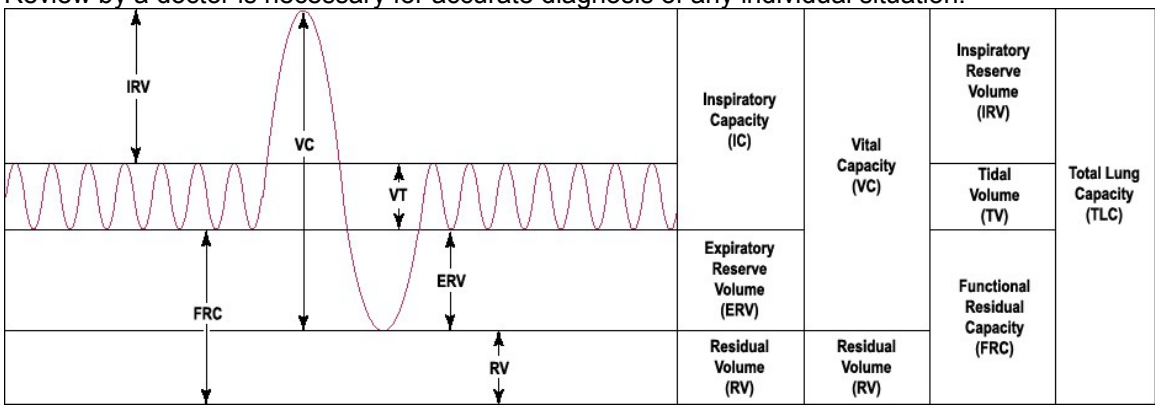
Spirometry can also be part of a bronchial challenge test, used to determine bronchial hyper responsiveness to either rigorous exercise, inhalation of cold/dry air, or with a pharmaceutical agent such as methacholine orhistamine.

Sometimes, to assess the reversibility of a particular condition, a bronchodilator is administered before performing another round of tests for comparison. This is commonly referred to as a reversibility test, or apost bronchodilator test (Post BD), and is an important part in diagnosing asthma versus COPD.

D-MAS can measure the most common parameters measured in spirometry They are Vital capacity (VC), Forced vital capacity (FVC), Forced expiratory volume (FEV) at timed intervals of 0.5, 1.0 (FEV1), 2.0, and 3.0 seconds, forced expiratory flow 25–75% (FEF 25–75) and maximal voluntary ventilation (MVV), also known as Maximum breathing capacity. Other tests may be performed in certain situations.

Results are given in both raw data (litres, litres per second) and percent predicted—the test result as a percent of the "predicted values" for the patients of similar characteristics (height, age, sex, and sometimes race and weight). Generally speaking, results nearest to 100% predicted are the most normal, and results over 80% are often considered normal.

Review by a doctor is necessary for accurate diagnosis of any individual situation.



Forced vital capacity (FVC) is the volume of air that can forcibly be blown out after full inspiration, measured in litres. FVC is the most basic manoeuvre in spirometry tests.

Forced expiratory volume in 1 second (FEV1) is the volume of air that can forcibly be blown out in one second, after full inspiration. Average values for FEV1 in healthy people depend mainly on sex and age. Values of between 80% and 120% of the average value are considered normal.

FEV1/FVC (FEV1%) is the ratio of FEV1 to FVC. In healthy adults this should be approximately 75–80%. In obstructive diseases (asthma, COPD, chronic bronchitis, emphysema) FEV1 is diminished because of increased airway resistance to expiratory flow; the FVC may be decreased as well, due to the premature closure of airway in expiration, just not in the same proportion as FEV1 (for instance, both FEV1 and FVC are reduced, but FEV1 is more affected because of the increased airway resistance). This generates a reduced value (<80%, often ~45%). In restrictive diseases (such as pulmonary fibrosis) the FEV1 and FVC are both reduced proportionally and the value may be normal or even increased as a result of decreased lung compliance.

Forced expiratory flow (FEF) is the flow (or speed) of air coming out of the lung during the middle portion of a forced expiration. It can be given at discrete times, generally defined by what fraction remains of the forced vital capacity (FVC). The usual intervals are 25%, 50% and 75% (FEF25, FEF50 and FEF75), or 25% and 50% of FVC. It can also be given as a mean of the flow during an interval, also generally delimited by when specific fractions remain of FVC, usually 25–75% (FEF25–75%). Average ranges in the healthy population depend mainly on sex and age.

MMEF or MEF stands for maximal (mid-)expiratory flow and is the peak of expiratory flow as taken from the flow-volume curve and measured in litres per second. It should theoretically be identical to peak expiratory flow(PEF), which is, however, generally measured by a peak flow meter and given in litres per minute.

Forced inspiratory flow 25–75% or 25–50% (FIF 25–75% or 25–50%) is similar to FEF 25–75% or 25–50% except the measurement is taken during inspiration.

Peak expiratory flow (PEF) is the maximal flow (or speed) achieved during the maximally forced expiration initiated at full inspiration, measured in litres per minute.

Tidal volume (TV) Tidal volume is the amount of air inhaled and exhaled normally at rest

Total lung capacity (TLC) is the maximum volume of air present in the lungs

Monitor mode General Description

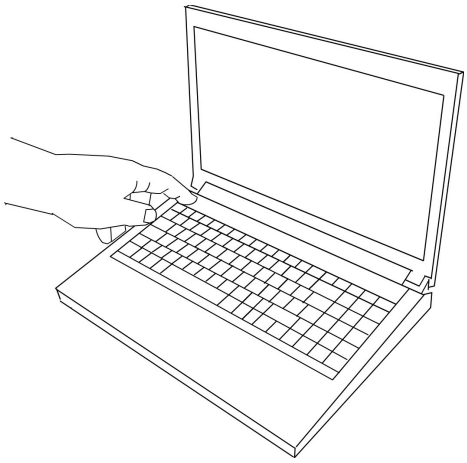
D-MAS can be used to perform continuous measurements of patient vital signs including Pulse CO-Oximetry, ECG and Blood Pressure.

Principle of operation
When Monitor mode is selected, D-MAS will present the user with a monitoring screen which continuously displays measurements of patient vital signs parameters.

D-MAS will activate alarms if any of the measured parameters fall outside of the user settable alarm limits.

Refer to the Pulse CO-Oximeter, ECG and Blood Pressure principles of operation for a detailed description of each parameter.

Set up



Remove the instrument from the shipping carton and examine it for signs of damage.
Before use, the D-MAS battery needs to be fully charged:

- Insert battery
- Connect the AC adapter to the D-MAS power connector.
- Connect the AC power adapter into an AC power source.
- Verify that the batteries are charging.

D-MAS battery charging LED indicators illuminated amber during charging and green when batteries are fully charged.

Shut down procedure

Click start/shut down. Alternatively, use the power on/off control.

Initial installation

Place D-MAS on a stable hard flat surface near the patient. Always place D-MAS on a dry surface and maintain a minimum of 3 cm (1 inch) free space around the unit. Make sure that the D-MAS loudspeaker is not covered to avoid a muffled alarm sound.

Configure the unit for your regional power line frequency (50 or 60 hz).

CAUTION: THE UNIT MUST BE CONFIGURED TO MATCH YOUR LOCAL POWER LINE FREQUENCY TO ALLOW FOR THE CANCELLATION OF NOISE INTRODUCED BY FLUORESCENT LIGHTS AND OTHER SOURCES.

Basic operation

WARNING! Defibrillation and Electrosurgery: Do not touch the patient, or table, or instruments, during defibrillation.

After defibrillation, the screen display recovers within 10 seconds if the correct electrodes are used and applied in accordance with the manufacturers instructions.
ECG cables can be damaged when connected to a patient during defibrillation. Check cables for functionality before using them again.

When using electrosurgical (ES) equipment, never place ECG electrodes near to the grounding plate of the ES device, as this can cause a lot of interference on the ECG signal.
When you are connecting the electrodes or the patient cable, make sure that the connectors never come into contact with other conductive parts, or with earth. In particular, make sure that all of the ECG electrodes are attached to the patient, to prevent them from contacting conductive parts or earth.

To operate D-MAS effectively, the device must be set up properly. The operator must know how D-MAS derives its readings, be familiar with its controls, components, operation and understand the status and alarm messages.

1. Inspect D-MAS for damage.
2. Connect a patient cable or a direct connect sensor to the Patient Cable Connector. Ensure a firm connection and that the cable is not twisted, sliced or frayed.
3. If using a patient cable, select a compatible sensor before connecting it to the patient cable. If using a single patient adhesive or disposable sensor, check that the emitter (red light) and the photodetector are properly aligned. Remove any substances that may interfere with the transmission of light between the sensor's light source and photodetector.
4. Refer to the Directions for Use of the sensor before attaching the sensor to the patient.
5. With a single patient adhesive or disposable sensor, connect the sensor to the patient cable with the logos lining up; make sure it is a firm connection.
6. Ensure the display is free of alarm and system failure messages.
7. Verify:
   • The high and low alarm limits for SpO2, SpMet*, SpCO* and pulse rate.
   • The readings for SpO2, SpMet*, SpCO*, pulse rate, perfusion index and PVI.

NOTE: "- - - " will remain lit on the numeric display until the SpO2, SpMet, SpCO*, pulse rate and PI readings have stabilized (less than 15 seconds for SpO2 and up to 25 seconds for SpMet* and SpCO* if* these parameters are installed in the unit)

8. Verify that the patient alarms are functional by setting the high and low SpO2, SpMet, SpCO and pulse rate alarm limits beyond the patient readings.
   - An alarm tone sounds.
   - The violated alarm limit and reading flash on the display.
9. Verify the sensor alarms are functional by removing the sensor from the sensor site.
   - SENSOR OFF appears in the message area of the graphic display.
   - The alarm tone sounds.
   - The alarm indicator flashes.
10. Disconnect the sensor from the patient cable or oximeter and confirm that SENSOR OFF appears in the message area of the graphic display.
11. Verify alarm silence operation.
    - Create an alarm condition by lowering the SpO2 or pulse rate high alarm limits beyond the patient readings.
    - Press the Alarm Silence button.
    - The alarm tone ceases for the displayed amount of time.
    - Perform the above steps for the SpMet and SpCO alarm limits.

To begin patient monitoring:

- Adjust the alarm limits
- Adjust the alarm volumes
- Adjust the pulse beep volume
- Place the sensor on a site that has sufficient perfusion and provides proper alignment of the LED's and photodetector
- Place the sensor on a site that has unrestricted blood flow
- Do not secure a sensor with tape
- Do not select a site near potential electrical interference (i.e. electrosurgical unit)
- Verify the sensor is on correctly and that the measured data is appropriate

After monitoring is complete, remove the sensor from the patient and store or dispose of the sensor according to governing rules.

SENSORS
Before use, carefully read the sensor Directions for Use.

Tissue damage can be caused by incorrect application or use of a sensor, for example by wrapping the sensor too tightly. Inspect the sensor site regularly to ensure skin integrity and correct positioning of the sensor.

Inaccurate results may be caused by incorrect application or use.

Software overview

Note: It must be assumed that the user of this device is capable and competent with a personal
computer and operating system.

D-MAS Software is subject to change. The latest software revision may differ from instructions provided.

D-MAS provides electronic recording of patient records. D-MAS can create a file for each patient which can contain but is not limited to Patient details and captured measurements.

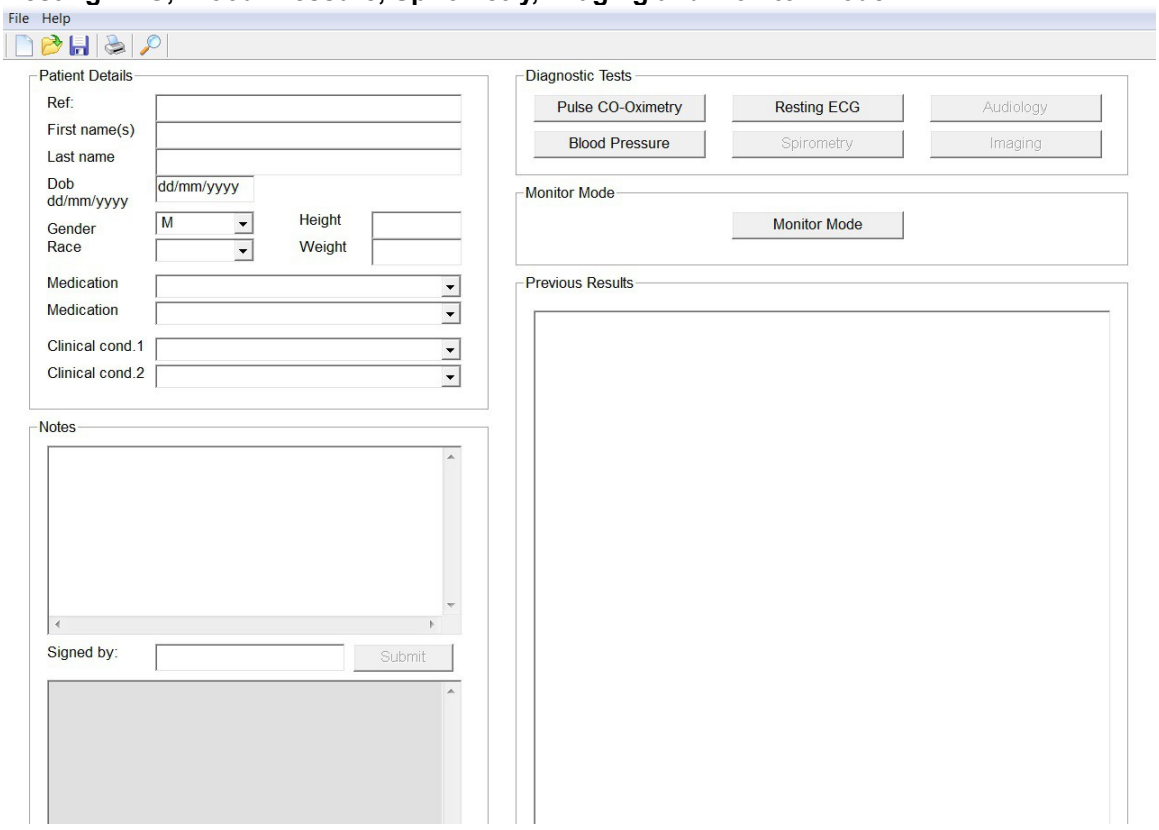
Depending on specification, the “Dan” file can be automatically encrypted.

The dan file can be opened by the D-MAS system or on any other computer with D-MAS encryption and decoding software installed.

Using the D-MAS System

Run the D-MAS software by double-clicking on the desktop icon.
Alternatively click Start, All Programs then select D-MAS Software.

At program launch the screen below is shown where patient details may be entered. Diagnostic test screen are accessed by clicking on the buttons for Pulse CO-Oximetry, Resting ECG, Blood Pressure, Spirometry, Imaging and Monitor mode.



Entering patient data is not required to record or perform any measurements or analysis.

However, specific patient data if entered beforehand will influence interpretation algorithms including:

- ECG interpretation: Age, gender, race, medication and clinical conditions.
- Spirometry predicted results: Age, gender, race, height and weight

To move from one data input field to the next, press TAB or click in the next field.

To enter patient data, perform the following steps:

1. Input the Patient reference
2. Enter the Patient Name
3. Enter the Patient Date of Birth

To return to a previous field, click in the previous field or press the keyboard shift & TAB.

Patient ID Fields:

Prompt	Comments	Entry	Characters
ID:	Input the Patient ID	Alphanumeric	16
Name:	Input the Patient Name	Alphanumeric	32
Age:	Input the Patient Age	Numeric	4
Gender:	Select Male or Female	Selection	-
Race:	Select ethnicity	Selection	-
Height:	Input the height (metres)	Numeric	4
Weight:	Input the weight (Kgs)	Numeric	3
Medication 1:	Select medication	Selection	-
Medication 2:	Select medication	Selection	-
Clinical condition 1:	Select Clinical condition	Selection	-
Clinical condition 2:	Select Clinical condition	Selection	-

Patient ID Fields:

Date and Time are saved with the recordings automatically. Check that the date and time is correct.

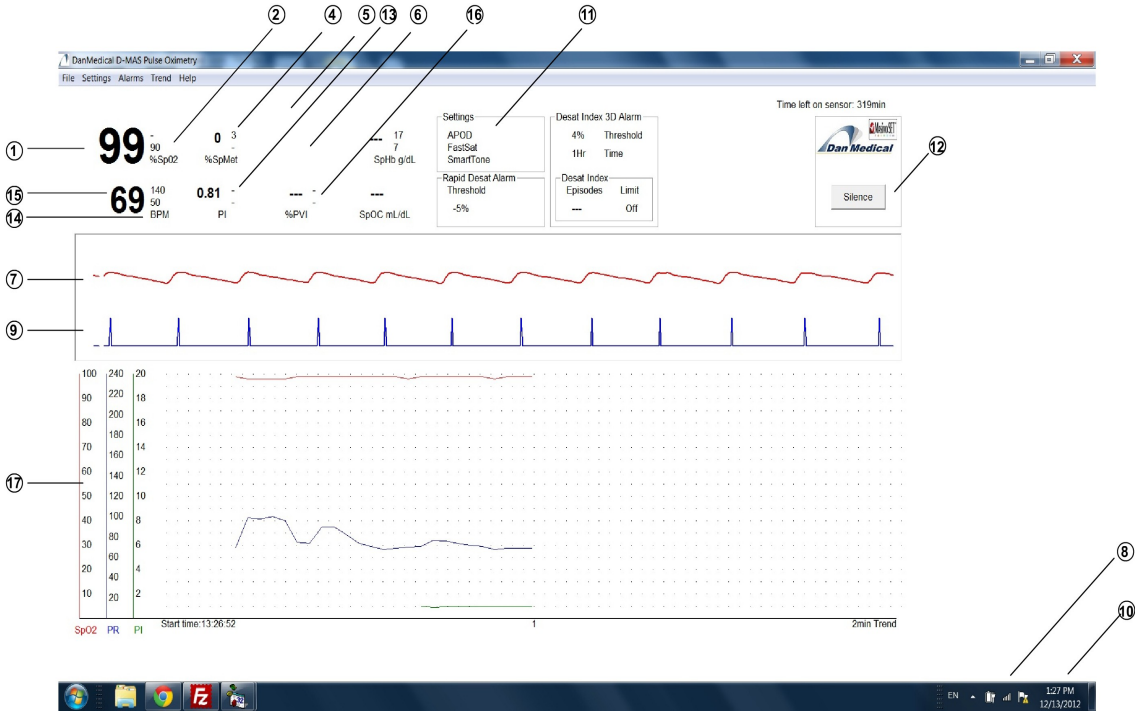
Calculating Body Mass Index (BMI)

D-MAS will automatically calculate BMI when the patient's height is entered into the height field in metres (m) and the patient's weight is entered into the weight field in kilograms (kg)

The BMI is calculated from the equation:

$$\text{BMI} = \frac{\text{Patient weight}}{(\text{Patient height}^2)} = \frac{\text{kg}}{\text{m}^2}$$

Pulse CO-Oximetry screen



1. SpO2 MEASUREMENT DISPLAY
The functional arterial hemoglobin oxygen saturation is displayed in units of percentage SpO2. The upper and lower SpO2 alarm limits are also displayed next to the SpO2 measurement. When a sensor is not connected to a patient and during pulse search, the display will show dashed lines and the message SENSOR OFF will appear at the top of the display screen. When the measured value is outside of the alarm limits, the SpO2 Measurement Display flashes and an alarm will sound. The oxygen saturation is calculated and the display is updated at a frequency of once per second.

2. SATURATION ALARM LIMITS DISPLAY
The Saturation Alarm Limits Display shows the upper and lower saturation alarm limits. When an alarm limit is exceeded, the SpO2 value and the violated limit flashes.

3. ALARM STATUS INDICATOR
The alarm status indicator can be shown with or without a slash. It flashes when an alarm condition is present. When the alarm is silenced using the Alarm Silence Button, an alarm status indicator with a slash and a timer is shown to indicate that the alarm is temporarily silenced. When the alarm is silenced through the All Mute menu selection (which is permanent until power is cycled or deselected using the menu) an alarm status indicator with a slash is shown to indicate that alarm has been silenced.

4. SpMet* MEASUREMENT DISPLAY
The measurement of methemoglobin concentration levels is displayed in units of percentage SpMet. The upper and lower SpMet alarm limits are also displayed next to the SpMet measurement. When a sensor is not connected to a patient and during pulse search, the display will show dashed lines and the message SENSOR OFF will appear at the top of the display screen. When the measured value is outside of the alarm limits, the SpMet measurement display flashes and an alarm will sound. The methemoglobin is calculated and the display is updated once per second.

5. Low Signal IQ SYSTEM MESSAGE AREA
The system messages generated by the instrument are displayed in the System Message Area. See Section 5, System Messages.

6. SpCO* MEASUREMENT DISPLAY
The measurement of carbon monoxide concentration levels is displayed in units of percentage SpCO. The upper and lower SpCO alarm limits are also displayed next to the SpCO measurement. When a sensor is not connected to a patient and during pulse search, the display will show dashed lines and the message SENSOR OFF will appear at the top of the display screen. When the measured value is outside of the alarm limits, the SpCO measurement display flashes and an alarm will sound. The carboxyhemoglobin is calculated and the display is updated at a frequency of once per second.

7. PULSE WAVEFORM DISPLAY
The Pulse Waveform Display shows the acquired plethysmograph waveform. The pleth waveform is scaled with signal strength. Signal strength is defined as the relation of arterial pulsatile signal to the non-pulsatile signal component.

8. BATTERY STATUS INDICATORS
The Battery Status Indicators show the capacity of the D-MAS batteries. The battery management notifies the user when less than 15 minutes of battery life is left and the battery needs to be recharged. The indicator is not shown when the D-MAS is powered by the AC Adapter.

9. SIGNAL IQ
The Signal IQ shows the acquired signal quality and the timing of the pulse. A tall vertical line indicates a high quality signal, while a small vertical line indicates a low quality signal.

10. TIME AND DATE INDICATOR
The Time and Date Indicator displays the current time and date. The time is displayed in 12 or 24 hour format. The date is displayed in dd/mm/yy or mm/dd/yy format. Select the date and time display formats in the Clock menu.

11. The MAX or APOD™
Sensitivity icon is shown on the D-MAS display to indicate if the D-MAS is set to operate in Normal sensitivity, Maximum sensitivity or Adaptive Probe Off Detection mode. When in Normal mode, this area will appear blank.

FastSat FASTSAT The FastSat® label is shown on the D-MAS display whenever the D-MAS is set to operate in the FastSat mode.

12. ALARM SILENCE BUTTON
Click the Alarm Silence Button to temporarily silence patient alarms. Press the Alarm Silence Button when the SENSOR OFF message is flashing (i.e. the sensor is removed from the patient) to acknowledge the end of monitoring. In this state, all further alarms are suspended until the Pulse CO-Oximeter starts measuring SpO2, SpMet, SpCO, PI and pulse rate again.

NOTE: System failure alarms can be silenced by clicking the Alarm Silence Button.

13. PI PERFUSION INDEX
The Perfusion Index indicates numerically the percentage of pulsatile signal to non-pulsatile signal (pulse strength)

14. PULSE RATE ALARM LIMITS DISPLAY
The Pulse Rate Alarm Limits Display shows the upper and lower pulse rate alarm limits. When an alarm limit is reached or exceeded, the pulse rate value and the violated limit flashes.

15. PULSE RATE

The Pulse Rate Measurement Display shows the patient's pulse rate in beats per minute. The upper and lower pulse rate alarm limits are also displayed next to the pulse rate measurement. The pulse rate is calculated and the display is updated at a frequency of once per second.

16. PLETH VARIABILITY INDEX

The Pleth Variability Index indicates numerically the percentage of variation in the pleth waveform as a result of a inhalation and exhalation cycle.

* For instruments that include SpMet and SpCO parameters: the SpMet and SpCO parameters will be disabled in the display screen if a non-Rainbow sensor is being used.

NOTE: The Pulse CO-Oximeter display view will be different without the SpMet and SpCO options.

17. MAIN SCREEN TREND GRAPH DISPLAY

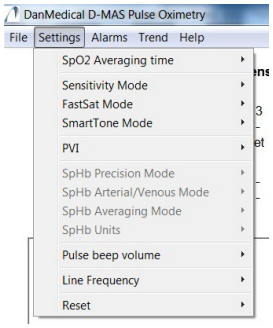
The D-MAS Pulse CO-Oximeter provides a Trend Graph display function which allows the user to quickly check the trend of each parameter by selecting the desired parameter. This is done on the Trend menu. Once the parameter is selected, the parameter is displayed in the trend graph.

The bottom line of the trend graph display shows the selected parameter followed by the time scale of the trend graph.

Menu Navigation

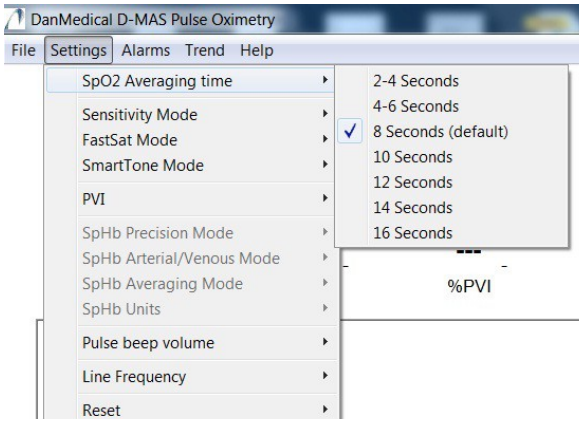
Each of the 'Settings' menu items are accessed by mouse over and further options relating to the menu item will be displayed.

When 'Settings' is clicked, the settings menu drops down. Depending on the type of sensor attached, some of the menu selections may be disabled or unavailable for selection.



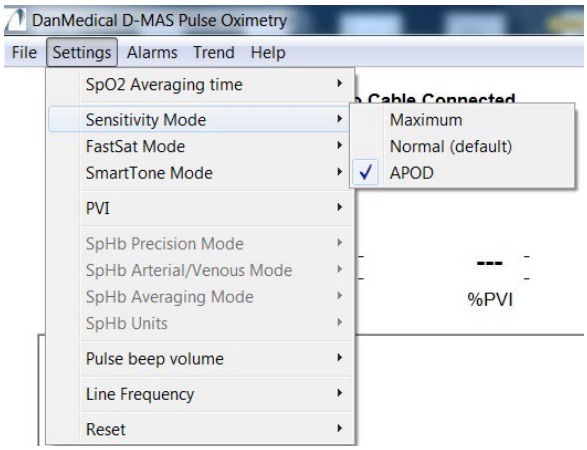
Sp02 Averaging Time.

Click 'Settings' and mouse over Sp02 Averaging time will show the available Sp02 averaging times, mouse over the required averaging time and click to make the selection.



Sensitivity Mode

Click the Settings menu to select the Normal, APOD and Maximum Sensitivity modes. Use the Normal Sensitivity setting for typical monitoring purposes. Use the APOD setting where there is a high probability of the sensor becoming detached. Use the Maximum Sensitivity setting for patients with low perfusion or when the low perfusion message is displayed on the screen in APOD or normal sensitivity mode. The default is Normal.

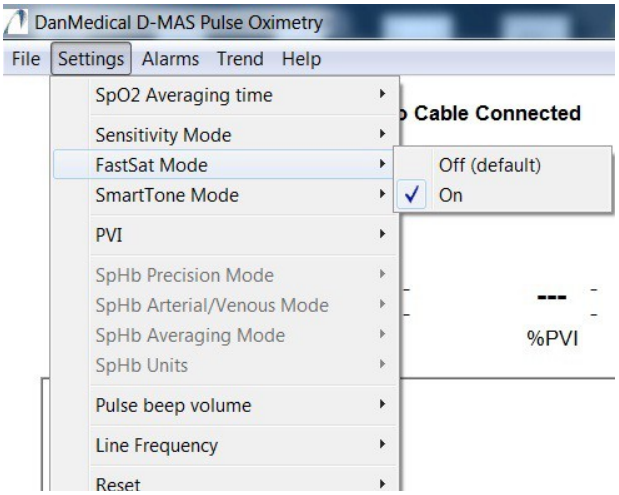


CAUTION: WHEN USING THE MAXIMUM SENSITIVITY SETTING, THE PERFORMANCE OF THE SENSOR OFF DETECTION MAY BE COMPROMISED.

NOTE: In "Custom" mode the unit will remain in Normal or APOD setting after a power cycle. Maximum Sensitivity will automatically reset to Normal Sensitivity after a power cycle.

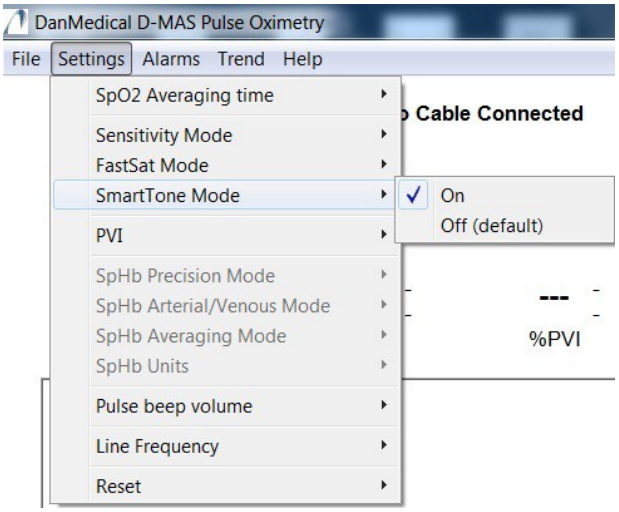
FastSat Mode

Turn FastSat On or Off by Clicking on 'Settings' and mouse over FastSat Mode to see the On/Off selections, click to enable the required FastSat Mode.



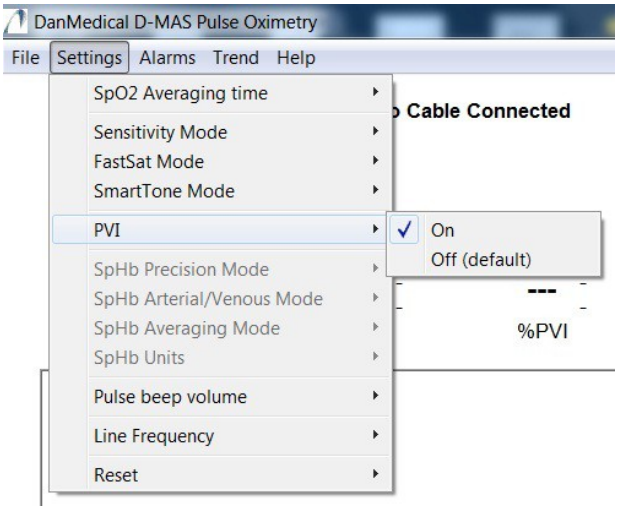
SmartTone Mode

Turn SmartTone On and Off by Clicking 'Settings' and mouse over SmartTone Mode to make the On/ Off selection.



PVI Mode

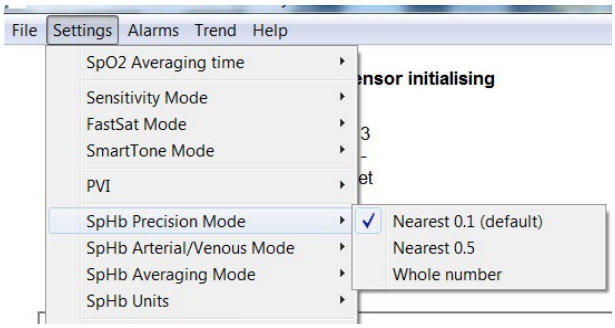
Turn PVI mode On and Off by Clicking 'Settings' and mouse over PVI to make the On/ Off selection.



SpHb settings

When a SpHb sensor is in use, the SpHb adjustments Settings become active.

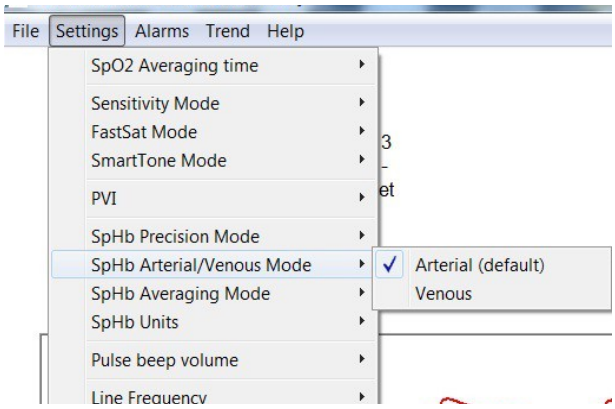
The Precision Mode is set to 'Nearest 0.1' by default, but this may be changed to 'Nearest 0.5' or 'Whole number'.



SpHb Arterial/Venous mode

With a suitable sensor attached, select whether Arterial or Venous Mode is used.

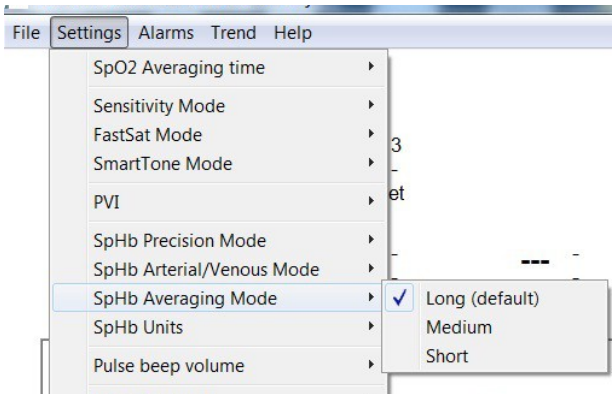
Click on 'Settings' and mouse over 'SpHb Arterial/Venous Mode' to access the Arterial/Venous mode selection.



SpHb Averaging Mode

SpHb Averaging Mode may be selected as Long (Default), Medium or Short.

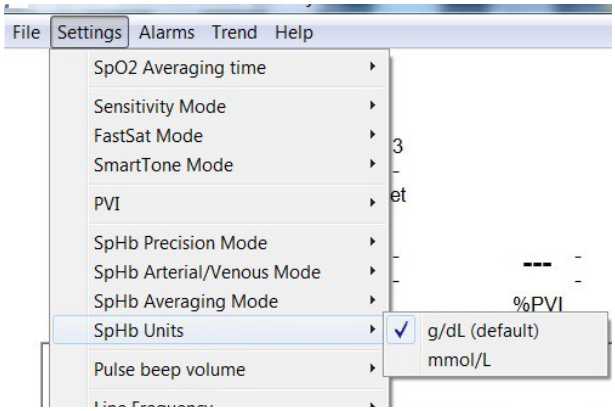
Click on 'Settings' and mouse over 'SpHb Averaging Mode' to access the Averaging mode selections, click to select the required setting.



SpHb Units

SpHb Units may be displayed as g/dL (default) or as mmol/L depending on regional preference.

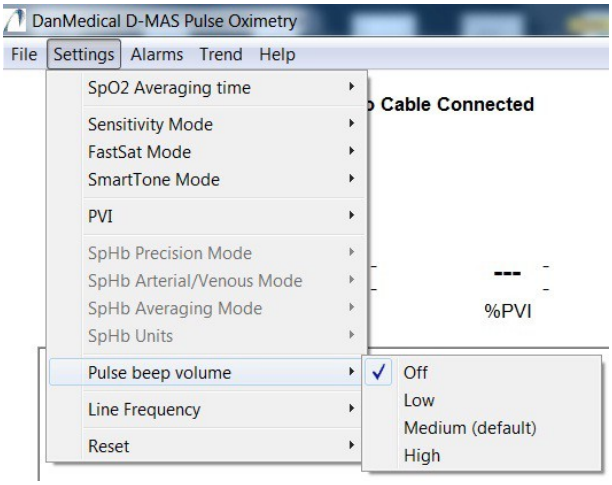
Click on 'Settings' and mouse over 'SpHb Units' to access the SpHb Units selection.



Increase/Decrease Pulse Beep Volume

Click the Settings menu and mouse over Pulse beep volume, click the High loudness option to increase the volume of the pulse beep.

Four levels of volume are available:
Off, Low, Medium (default) and High.

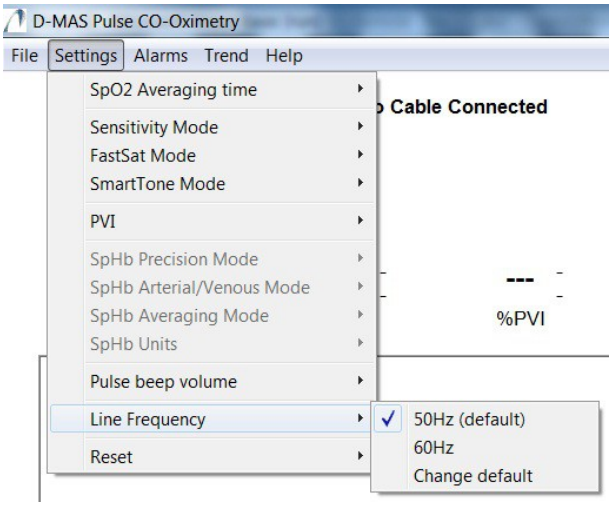


Line Frequency

Select the required Line Frequency by clicking 'Settings' and mouse over Line Frequency.

Select 50 Hz or 60 Hz. The user can change the default setting depending on location by selecting Change Default.

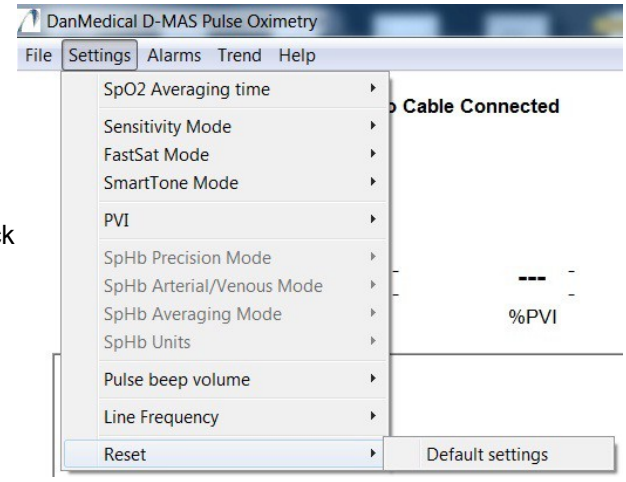
Select the required default setting and enter the password “2222” then click OK to confirm the change.



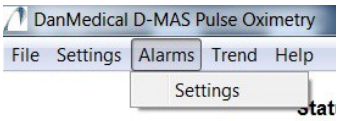
Reset

Restore default settings by clicking 'Settings' and selecting 'Reset' to enable the Default settings selection.

This action will reset all previous settings back to factory default.



Alarms

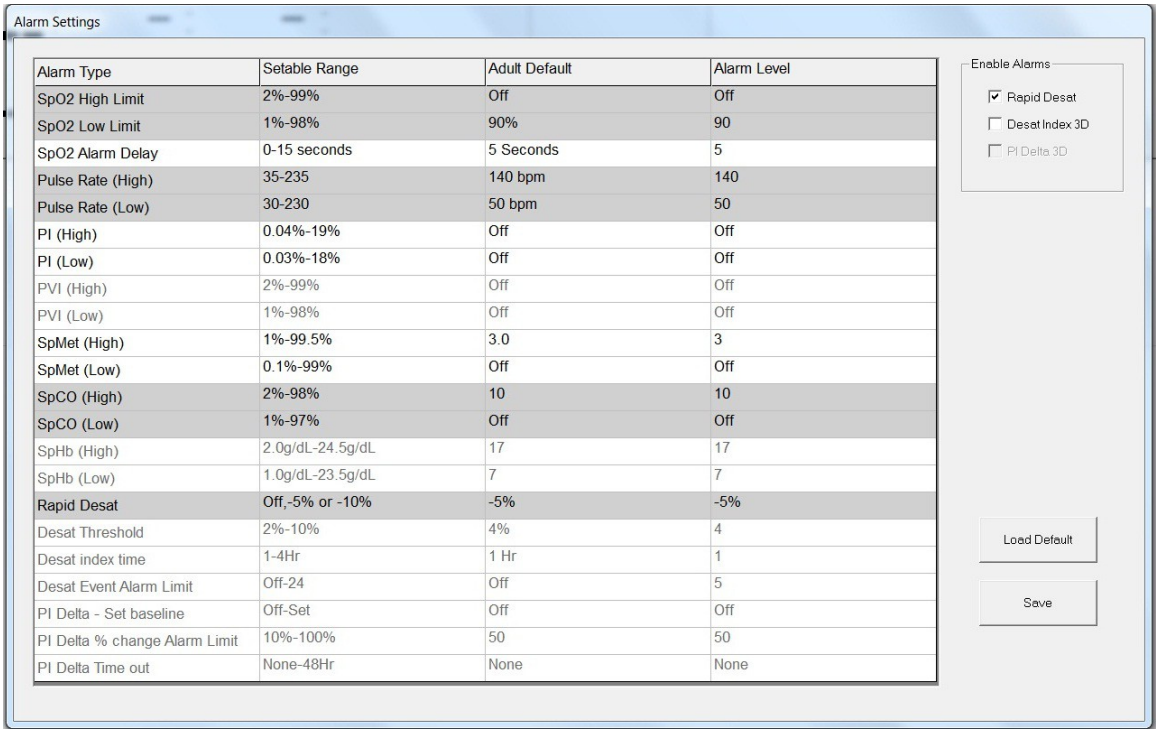


Click on 'Alarms' to access the 'Settings' menu.

When the alarm form is accessed the monitor remains functional and the saturation and pulse rate numbers will continue to be displayed.

The Alarms Setting menu allows the adjustment of alarm limits and turning on and off of Rapid Desat and the 3D alarms. Adjustment of the alarm limits is made by clicking the desired Alarm Level label

A selection drop down box allows easy adjustment of the selected alarm level.

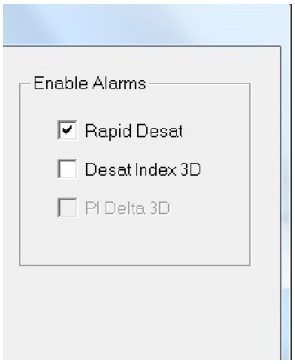


Alarm Type	Setable Range	Adult Default	Alarm Level
SpO2 High Limit	2%-99%	Off	Off
SpO2 Low Limit	1%-98%	90%	90
SpO2 Alarm Delay	0-15 seconds	5 Seconds	5
Pulse Rate (High)	35-235	140 bpm	140
Pulse Rate (Low)	30-230	50 bpm	50
PI (High)	0.04%-19%	Off	Off
PI (Low)	0.03%-18%	Off	Off
PVI (High)	2%-99%	Off	Off
PVI (Low)	1%-98%	Off	Off
SpMet (High)	1%-99.5%	3.0	3
SpMet (Low)	0.1%-99%	Off	Off
SpCO (High)	2%-98%	10	10
SpCO (Low)	1%-97%	Off	Off
SpHb (High)	2.0g/dL-24.5g/dL	17	17
SpHb (Low)	1.0g/dL-23.5g/dL	7	7
Rapid Desat	Off,-5% or -10%	-5%	-5%
Desat Threshold	2%-10%	4%	4
Desat index time	1-4Hr	1 Hr	1
Desat Event Alarm Limit	Off-24	Off	5
PI Delta - Set baseline	Off-Set	Off	Off
PI Delta % change Alarm Limit	10%-100%	50	50
PI Delta Time out	None-48Hr	None	None

Rapid Desat, Desat Index 3D and PI Delta 3D alarms are located at the top right-hand side of the Alarms page.

Tick the boxes to turn each alarm on.

PI Delta 3D is Off by default. Turn on the PI Delta 3D in the Alarm Level column.



Check alarm limits each time D-MAS is used to ensure that they are appropriate. An audible alarm and a flashing alarm icon will occur when an alarm limit is exceeded. The operator should be within a minimum of 2metres/10 feet from the unit.

MENU ITEMS	**DESCRIPTION**
SpO2 HIGH LIMIT	The SpO2 high alarm limit can be set anywhere between 2% and 99%, with a 1% step size. In the "----" (off) setting, the alarm can be turned off completely.
SpO2 LOW LIMIT	The SpO2 low alarm limit can be set anywhere between 1% and 99%, with a 1% step size. ***NOTE:*** *The low alarm limit always has to be set below the high alarm setting. When the high alarm limit is set below the low alarm limit, the low alarm limit will automatically adjust to the next setting below the newly entered high alarm limit setting.*
PULSE RATE HIGH LIMIT (BPM)	The pulse rate high alarm limit can be set anywhere between 30 BPM and 240 BPM, with a 5 BPM step size.
PULSE RATE LOW LIMIT (BPM)	The pulse rate low alarm limit can be set anywhere between 25 BPM and 235 BPM, with a 5 BPM step size. ***NOTE:*** *The low alarm limit always has to be set below the high alarm setting. When the high alarm limit is set below the low alarm limit, the low alarm limit will automatically adjust to the next setting below the newly entered high alarm limit setting.*
SpMet HIGH LIMIT	The SpMet high alarm limit can be set anywhere between 1% to 100%. Between 1% and 2%, the step increment is 0.1%. Between 2% and 100%, the step increment is 0.5%.
SpMet LOW LIMIT	The SpMet low alarm limit can be set anywhere between 0.1% to 99.5%. Between 0.1% and 2%, the step increment is 0.1%. Between 2% and 99.5%, the step increment is 0.5%. In the "----" (off) setting, the alarm can be turned off completely. ***NOTE:*** *The low alarm limit must always be below the high alarm limit. If the high alarm limit is set below the low alarm limit, the low alarm limit will automatically adjust to the next setting below the newly entered high alarm limit.*
SpCO HIGH LIMIT	The SpCO high alarm limit can be set anywhere between 1% and 100%, with a 1% step size.
SpCO LOW LIMIT	The SpCO low alarm limit can be set anywhere between 1% and 99%, with a 1% step size. In the "----" (off) setting, the alarm can be turned off completely. ***NOTE:*** *The low alarm limit must always be below the high alarm limit. If the high alarm limit is set below the low alarm limit, the low alarm limit will automatically adjust to the next setting below the newly entered high alarm limit*
SILENCE	This menu allows the user to set the alarm silence period. An alarm is silenced by clicking the Alarm Silence button on screen. The alarm silence can be set for these durations: **30, 60, 90,120 SECONDS**. As an indicator that the alarm system is silenced, the Alarm Status Indicator is shown as a bell with a slash through it. A timer is shown next to the bell indicating the remaining alarm silence duration. ***NOTE:*** *The alarm silence period is reset to 120 seconds upon power cycle.*

MENU ITEMS	DESCRIPTION
VOLUME	This menu allows the user to set the alarm volume. Three levels are available: level LOW being the softest and level HIGH being the loudest. The device retains the Alarm Volume setting upon a power cycle. ***NOTE:*** *For home use, set the alarm level to HIGH.*
DELAY	This menu allows the users to set an audible saturation delay. The delay can be set to either 0, 5, 10 or 15 seconds. The delay setting only affects saturation alarm indications. ***NOTE:*** *The unit will retain the Alarm Delay setting after a power cycle.*
AVERAGING TIME	The signal averaging time of this device can be set to: 2-4, 4-6, 8, 10, 12, 14 and 16 seconds*. *With FastSat the averaging time is dependent on the input signal. For the 2 and 4 second settings, the averaging times may range from 2 to 4 and 4 to 6 seconds, respectively.
FASTSAT	Select to activate the FastSat algorithm. In the 2 and 4 seconds averaging mode, the FastSat algorithm is automatically enabled.
SMART TONE	Select to activate the SmartTone function. This will allow the audible pulse to continue to beep when the pleth graph shows signs of motion. Deselect to turn off SmartTone.
PVI	Select to display the PVI parameter. The PVI will display numerically on the main screen and also will allow the user to change the maximum and minimum PVI settings in the Alarm Setup menu. Deselect to turn off the PVI parameter.
FREQUENCY	Set to match regional power line frequency (50 or 60 Hz) to allow for cancellation of noise introduced by fluorescent lights and other sources. Default is 60 Hz (standard for the United States)
RAPID DESAT LIMIT	The Rapid Desat Limit will ignore the Alarm Delay setting if desaturation falls below the Low SpO2 alarm threshold to a user-defined percentage. Audible tones are generated immediately, along with all visual indicators. The Rapid Desat Limit can be set to the following: **OFF:** The Alarm Delay setting will delay audible alarm tones regardless of how deep the desaturation is below the alarm threshold. **-5:** The Alarm Delay setting is ignored if the desaturation is 5% (meaning 5 saturation units) below the Low SpO2 alarm threshold. **-10:** The Alarm Delay setting is ignored if the desaturation is 10% (meaning 10 saturation units) below the Low SpO2 alarm threshold.

3D Alarm System Option

This section applies only if you have purchased the optional 3D Alarm System. Contact DanMedical to purchase this option.

D-MAS includes user-selectable High and Low alarm limits for SpO2 and pulse rate. This provides specific, audible and visual levels of these vital signs that the clinician has determined merits their attention as described in this manual. The 3D Alarm System enables clinicians to be alerted to changes in multiple interacting factors to provide an additional level of vigilance and flexibility to manage their patients.

The following is a summary of each of the 3D Alarm System features:

DESAT INDEX ALARM (***NOTE:*** *The alarms in this option are considered to be Medium priority.)* The Desat Index Alarm is a user-selectable feature which allows a clinician to request an audible and visual alarm if a patient experiences a specified number of desaturations over a specific period of time.

Traditional high and low SpO2 alarm limits alert clinicians to saturation levels that exceed user-selected thresholds and these thresholds are typically established at a considerable change from the patients' baseline saturation level. However, in select patient populations, substantial desaturation events that exceed a typical low alarm limit threshold may be preceded by a cycle of transient desaturations over a limited timeframe. The ability to alert clinicians to a cycle of these smaller desaturations may provide an earlier indication of a potential significant decline in the patient's status and the need for more focused monitoring and/or a change in treatment.

To address patient populations at risk for cyclic and moderate desaturations, the 3D Alarm System option includes a user-selectable Desat Index Alarm. This allows the clinician to request an audible and visual alarm in the event the patient experiences a specified number of desaturations beyond a defined level from the patient's baseline saturation over a specific window of time. The desaturation variables are selectable by the user within the ranges established below:

Desat Index Threshold:	Range of 2% to 10% in 1% increments, default of 4%
Desat Index Timeframe:	Range of 1 to 4 hrs in 1-hr increments, default of 1 hr
Desat Index Alarm/Quantity:	Range of 1 to 25 desaturations, default is OFF

To translate the above Desat Index variables and ranges into perspective, consider a patient at risk of respiratory compromise with the definition for respiratory compromise of 5 or more transient moderate desaturations (associated with a 4% drop in SpO2) per hour. To request a Desat Index alarm for this situation, the clinician would set the Desat Index variables as follows:

Desat Index Threshold:	4.00%
Desat Index Timeframe:	1 hour
Desat Index Alarm	5 (desaturations)

Post-operative patients receiving pain medication may be predisposed to respiratory depression. If the patient has an underlying respiratory condition, pain medication may cause the patient to spiral into a cascade of cyclic desaturations, which initially are mild but may worsen quickly. The Desat Index Alarm may give an early warning of this type of respiratory disturbance that can lead to respiratory depression and even arrest.

CAUTION: THE DESAT INDEX ALARM IS INTENDED AS AN ADJUNCT RATHER THAN IN PLACE OF THE LOW SATURATION ALARM

USER INTERACTION TO IMPLEMENT DESAT INDEX ALARM

The Desat Index Alarm function is enabled in the D-MAS by the following method:

1. Select the ALARMS menu from the main menu page.
2. Select Desat Index check box.
3. The Desat Index Alarm menu will be enabled and the user can select from the following entries:

Desat Index Threshold:	Range of 2% to 10% in 1% increments, default of 4%
Desat Index Time:	Range of 1 hr to 4 hrs in 1-hr increments, default of 1 hr
Desat Index Alarm:	Range of 1 to 25 desaturations, default is OFF

If the measured Desat Index parameter is greater than the configured Desat Index Alarm level selected, the D-MAS will make a MEDIUM priority alarm tone and post an alarm message as follows:

DESAT INDEX = ##

where ## is equal to the current Desat Index and updates real time. If the Alarm Suspend key is pressed during the Desat Index alarm, the tone is silenced and will not return when the Alarm Suspend time expires unless the condition is removed and then returns. The message will remain on the screen until the Alarm condition is removed.

PERFUSION INDEX (PI) DELTA ALARM
(***NOTE:*** *The alarms in this option are considered to be Medium priority.)*

The PI Delta Alarm is a user-selectable feature which allows a clinician to request an audible and visual alarm if perfusion at the monitored site decreases by a specified level (delta) over a specific period of time.

Perfusion Index gives an indication of the level of perfusion at the monitored site. D-MAS measures perfusion at the SpO2 site by comparing the pulsatile signal to the nonpulsatile signal, and expressing that ratio as a percentage. PI has been clinically proven to be useful as a predictor of the level of illness in neonates and adults and that PI may change dramatically in response to sympathetic changes caused by inhalational agents and pain stimulation[2]. If PI decreases over time, there may be underlying physiological reasons that may need to be addressed.

[2] De Felice C, Latini G, Vacca P, Kopotic RJ. The pulse oximeter perfusion index as a predictor for high illness severity in neonates. Eur J Pediatr. 2002;161:561-562.

The 3D Alarm System provides an audible and visual alert to important changes in perfusion compared to the patient's baseline PI rate. The baseline is set by the D-MAS once the user has enabled the alarm. The baseline is 30 seconds of currently averaged PI. The 3D Alarm System option includes a user-selectable PI Delta Alarm. This allows the clinician to request an audible and visual alarm if perfusion at the monitored site decreases by a specified level (delta) over a specified window of time. Three of the variables are selectable by the user within established ranges as noted below:

Set Baseline:	**Select OFF or SET. Default is OFF.**
PI Delta % Change:	Range of 10% to 100%. Default is 50%.
PI Delta Timeout	Range of 1 min, 5 min, 30 min, 1 hr, 4 hr, 8 hr, 12 hr, 24 hr, 36 hr, 48 hr and NONE. Default is NONE.
PI Delta Baseline	Displays OFF, the current PI baseline or TIMEOUT. If the baseline is activated and then turned off, TIMEOUT will display. ***NOTE:*** *This is a Read Only display and not user interactive.*

USER INTERACTION TO IMPLEMENT PI DELTA ALARM
The PI Delta Alarm function is enabled in D-MAS by the following method:

1. Select the ALARMS menu from the main menu page.
2. Select PI Delta check box.
3. The PI Delta Alarm menu will be displayed and the user can select from the following entries:

If the PI Delta parameter is greater (more negative) than the configured PI Delta Alarm, then the D-MAS will make a MEDIUM priority alarm tone, and post an alarm message as follows:

PI DELTA = ##% where ## is equal to the current PI Delta percentage and updates real time.

The PI trend graph will also display.

If the Alarm Suspend key is pressed during this alarm, the tone shall be silenced and not returned when the Alarm Suspend time expires unless the condition is removed and then returns. The message will remain on the screen until the Alarm condition is removed.

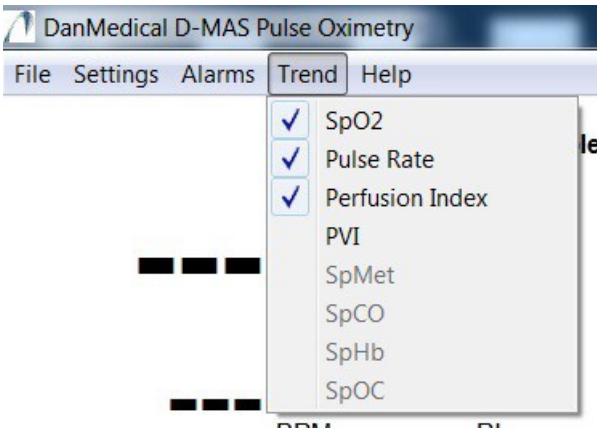
Alarm settings

PARAMETER	MENU ITEM	DESCRIPTION
DESAT INDEX ALARM	**DESAT THRESHOLD**	The Desat Threshold can be set in the range of 2%to 10% in 1% increments. Default is 4%
	DESAT INDEX TIME	The Desat Index Time can be set in the range of 1hr to 4 hrs in 1-hr increments. Default is 1 hr.
	DESAT INDEX ALARM	The Desat Index Alarm can be set in the range of1 to 25 desaturations. Default is OFF.
PI DELTA ALARM	**SET BASELINE**	The Set Baseline can be turned on by selectingSET. Selecting OFF disables the alarm. Default is OFF.
	PI DELTA % CHANGE	The PI Delta % Change can be set in the range of 10% to 100%. Default is 50%.
	PI DELTA TIMEOUT	The PI Delta Timeout can be set in the range of the following increments: 1 min, 5 min, 30 min, 1 hr. 4 hr, 8 hr, 12 hr, 24 hr, 36 hr, 48 hr and NONE. Default is NONE.
	PI DELTA BASELINE	The PI Delta Baseline displays OFF, the current PI baseline or TIMEOUT. ***NOTE:*** *This is a Read Only display and not user interactive*

TREND GRAPH

Click the Trend menu to show the trend data to display.

Tick the parameters required to be displayed in the trend graphics, each trend parameter is colour coded, also the scale is shown in the corresponding colours.



Trend Display

Once the Trend Display menu is selected, the trend data is displayed on the main screen. D-MAS stores the data set of SpO2, pulse rate, SpMet, SpCO, PI, and PVI in a dedicated memory area. D-MAS can store 72 hours of continuous trend data. D-MAS only stores data in the trend memory while the device is turned on.

The Trend Display can be configured to display any or all of the six available trend parameters (SpO2, SpMet, SpCO, pulse rate, PI or PVI) that are enabled and selected by the user.

The 'y axis' of the trend display shows the time scale of the trend graph, including the starting date, starting time and end time of the data set that is displayed on the screen.

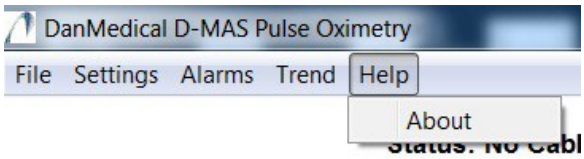
The 'x axis' scale shows the range of SpO2, BPM, PI, SpMet and SpCO.

A broken line in the trans display indicates a period of time for which the sensor is off the patient or the Low Signal IQ indicator was active, indicating the signal quality was very low and the accuracy of the measurement may have been compromised.

Trend Data is acquired every 2 seconds and all parameters are stored in the memory. At the end of monitoring, upon exit of the D-MAS software, the user is prompted to save the stored Trend Data. Select a location for storage and to name the file. The stored trend data file may be used for further analysis and printing.

Help

Click 'Help' followed with 'About' to see the software version.



System Messages

The following chart lists all system messages displayed on the LCD screen, the cause of the message and the action(s) to be taken. The operator should become thoroughly familiar with this information before using the oximeter for patient monitoring.

Message	Possible Cause(s)	Recommendation
AMBIENT LIGHT	• Too much light on patient (sensor). • Inadequate tissue covering sensor detector.	• Remove or reduce lighting. • Cover sensor from light. • Reposition sensor.
DEFECTIVE CABLE	• Oximeter cannot identify the connected cable or the cable has failed.	• Inoperative or faulty cable • Replace cable. • Refer to the Directions for Use of the cable being used.
INCOMPATIBLE SENSOR	• Not a proper Masimo sensor.	• Replace with a proper Masimo sensor.
INVALID SENSOR	• Oximeter cannot identify the connected sensor.	• Broken sensor cable wire or inoperative LEDs or faulty detector. • The sensor has failed. • Replace sensor. • Refer to the instructions for the sensor being used.
LOW BATTERY	• Battery charge is low.	• Charge battery by powering the unit with the AC line power adapter. • Replace battery if necessary.
LOW PERFUSION	• Signal too small.	• Move sensor to better perfused site. • Refer to Chapter 3, Low Perfusion.
LOW SIGNAL IQ	• Low signal quality.	• Ensure proper sensor application. • Move sensor to a better perfused site. • Refer to Chapter 3, Signal IQ.

MESSAGE	POSSIBLE CAUSE(S)	RECOMMENDATION
LOW SpCO CONF	• SpCO measurement reading is obscured.	• Ensure proper sensor application. • Check sensor to see if it is working properly. • If not, replace the sensor.
LOW SpMet CONF	• SpMet measurement reading is obscured.	• Ensure proper sensor application. Check sensor to see if it is working properly. • If not, replace the sensor
NO SENSOR	• Sensor not fully inserted into the connector.	• Maybe an incorrect sensor, or a defective sensor or cable. • Insert sensor into connector. • Disconnect and reconnect sensor. • Refer to the instructions for the sensor being used.
NO CABLE	• Cable not attached or not fully inserted into the connector.	• Disconnect and reconnect cable into connector
	• Unit is searching for patient's pulse.	• Disconnect and reconnect the sensor into the Patient Cable Connector.
PULSE SEARCH	• Unit is searching for patient's pulse.	• If values are not displayed within 30 seconds, disconnect and reconnect sensor. • If pulse search continues, remove sensor and replace on a better perfused site.
SENSOR CALIBRATING	• Unit is checking the sensor for proper functioning and performance.	• If values are not displayed within 30 seconds, disconnect and reconnect sensor. • If values are still not displayed, replace with a new sensor.
SENSOR OFF	• Sensor off patient.	• Disconnect and reconnect sensor. • Reattach sensor.
SERVICE REQUIRED*	• Internal Failure	• Unit requires service.
UNRECOGNIZED CABLE	• Not a proper cable.	• Replace with a proper cable. Refer to Section 8.

*The SERVICE REQUIRED message is a numeric error code.
Contact DanMedical for service.

Sensors & patient cables

Introduction
This section covers the use and cleaning of sensors and patient cables.

Before use of any sensor, carefully read the sensor's Directions for Use. Use only Masimo oximetry sensors and cables for SpO2, SpMet and SpCO measurements. Other oxygen transducers or sensors may cause improper D-MAS performance.

Tissue damage can be caused by incorrect application or use of a sensor, for example by wrapping the sensor too tightly. Inspect the sensor site as directed in the sensor Directions for Use to ensure skin integrity, correct positioning and adhesion of the sensor.

CAUTIONS:

- **DO NOT USE DAMAGED SENSORS OR PATIENT CABLES. DO NOT USE A SENSOR OR PATIENT CABLE WITH EXPOSED OPTICAL OR ELECTRICAL COMPONENTS.**
- **DO NOT IMMERSE THE SENSOR OR PATIENT CABLE IN WATER, SOLVENTS, OR CLEANING SOLUTIONS (THE SENSORS AND CONNECTORS ARE NOT WATERPROOF).**
- **UNLESS OTHERWISE SPECIFIED, DO NOT STERILIZE SENSORS OR PATIENT CABLES BY IRRADIATION, STEAM, AUTOCLAVE OR ETHYLENE OXIDE. SEE THE CLEANING INSTRUCTIONS IN THE DIRECTIONS FOR USE FOR REUSABLE SENSORS.**
- **DO NOT ATTEMPT TO REPROCESS, RECONDITION OR RECYCLE ANY SENSORS OR PATIENT CABLES AS THESE PROCESSES MAY DAMAGE THE ELECTRICAL COMPONENTS, POTENTIALLY LEADING TO PATIENT HARM.**
- **ALL SENSORS AND CABLES ARE DESIGNED FOR USE WITH SPECIFIC MONITORS. VERIFY THE COMPATIBILIY OF THE MONITOR, CABLE AND SENSOR BEFORE USE, OTHERWISE PATIENT INJURY CAN RESULT.**

SELECTING A SENSOR

When selecting a sensor, consider, the patient's weight, the adequacy of perfusion, the available sensor sites, and the duration of monitoring. For more information refer to the following table or contact your Sales Representative. Use only sensors and sensor cables. Select an appropriate sensor, apply it as directed, and observe all warnings and cautions presented in the Directions for Use accompanying the sensor.

High intensity extreme lights (such as pulsating strobe lights) directed on the sensor, may not allow the sensor to obtain vital sign readings. High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of the sensor. To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with opaque material, if required. Failure to take this precaution in high ambient light conditions may result in inaccurate measurements.

SENSOR APPLICATION INSTRUCTIONS

Unless indicated otherwise in the directions for use, reposition reusable sensors at least every 4 hours and for adhesive sensors inspect the site at least every 8 hours or sooner. If indicated by circulatory condition or skin integrity, reapply to a different monitoring site.

Sensors

Sensors must be used with the D-MAS CO-Oximeter to enable measurement of Carboxyhemoglobin (SpCO) and Methemoglobin (SpMet). Sensors will only function with instruments containing SET Technology or licensed to use Rainbow compatible sensors. Rainbow sensors connect to the device directly or with a patient cable.

RAINBOW REUSABLE SENSORS

SpO2, SpCO, SpMet and pulse rate accuracy for the Rainbow sensors is specified in the following table.

SENSOR	**Weight Range**	**Saturation Accuracy**		**Pulse Rate Accuracy**		**Low Perfusion Accuracy**		**SpCO Accuracy**	**SpMet Accuracy**
		No Motion	**Motion**	**No Motion**	**Motion**	**Saturation**	**Pulse Rate**	**No Motion**	**No Motion**
DCI	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 3%	± 1%
DCIP	10 - 50 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 3%	± 1%

RAINBOW ADHESIVE SENSORS

SpO2, SpCO, SpMet and pulse rate accuracy for the Rainbow sensors is specified in the following table.

SENSOR	Weight Range	Saturation Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy		SpCO Accuracy	SpMet Accuracy
		No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate	No Motion	No Motion
R25	> 30 kg	60 - 80% ± 3% 70 - 100% ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 3.5%	± 1%
R25-L	> 30 kg	60 - 80% ± 3% 70 - 100% ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 3.5%	± 1%
R20	3 - 10 kg	60 - 80% ± 3% 70 - 100% ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 3.5%	± 1%
R20-L	3 - 10 kg	60 - 80% ± 3% 70 - 100% ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 3.5%	± 1%
	10 – 30 kg	60 - 80% ± 3% 70 - 100% ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 3.5%	± 1%

SpO2 Sensors

D-MAS may use standard Masimo LNOP, LNOPv and LNCS SpO2 sensors, when used with Red PC, Red LNC or Rainbow Patient Cables respectively.

Select the appropriate patient cable to attach the LNOP or LNCS sensor to the device.

RED REUSABLE SENSORS

Red sensors can be used with D-MAS to enable measurement of SpO2 only. Red sensors will only function with oximeter devices equipped with Masimo Rainbow SET technology.

SENSOR	Weight Range	Saturation Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy	
		No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate
DCI	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
DCIP	10 - 50 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm

LNOP® REUSABLE SENSORS
(LNOP sensors must be used in conjunction with Red PC cables)

SENSOR	Weight Range	Saturation Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy	
		No Motion	Motion	No Motion	Motion	Saturation	Pulse
LNOP DCI	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOP DCIP	10 - 50 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOP YI	> 1 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	N/A	N/A
LNOP TC-I	> 30 kg	± 3.5%	N/A	± 3 bpm	N/A	± 3.5%	± 3 bpm
LNOP DC-195	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOP TF-I	> 30 kg	± 2%	N/A	± 3 bpm	N/A	± 2%	± 3 bpm

NOTE: *The LNOP TF-I and TC-I sensors were not validated under motion condition*

LNOP® ADHESIVE SENSORS
(LNOP sensors must be used in conjunction with Red PC cables)

SENSOR	Weight Range	Saturation Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy	
		No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate
LNOP Adt	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOP Adtx	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOP Pdt	10 - 50 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOP Pdtx	10 - 50 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOP Neo	< 10 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
LNOP NeoPt	< 1 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
LNOP Neo-L	< 3 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
	> 40 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOP NeoPt-L	< 1 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
LNOP Inf-L	3 - 20 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm

LNOPvTM ADHESIVE SENSORS
(LNOPv sensors must be used in conjunction with Red PC cables)

SENSOR	Weight Range	Saturation Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy	
		No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate
LNOPv In	3 - 20 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOPv Ne	< 3 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
LNOPv Ad	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm

LNOP® SPECIALTY SENSORS
(LNOP sensors must be used in conjunction with Red PC cables)

SENSOR	Weight Range	Saturation Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy	
		No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate
LNOP Newborn Infant	3 - 10 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
	10 - 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOP Newborn Neonatal	< 3 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm

SENSOR	Weight Range	Saturation Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy	
		No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate
LNOP Blue	2.5 - 30 kg	60 - 80% ± 4%	N/A	± 3 bpm	N/A	± 3%	± 3 bpm
		70 - 100% ± 3.3%	N/A	± 3 bpm	N/A	± 3%	± 3 bpm
		80 - 100% ± 3%	N/A	± 3 bpm	N/A	± 3%	± 3 bpm

LNCSTM REUSABLE SENSORS
(LNCS sensors must be used in conjunction with Red LNC or Rainbow patient cables)

SENSOR	Weight Range	Saturation Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy	
		No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate
LNCS DC-I	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNCS DC-IP	10 - 50 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNCS TC-I	> 30 kg	± 3.5%	N/A	± 3 bpm	N/A	± 3.5%	± 3 bpm
LNCS TF-I	> 30 kg	± 2%	N/A	± 3 bpm	N/A	± 2%	± 3 bpm

NOTE: *The LNCS TF-I and TC-I sensors were not validated under motion conditions.*

LNCS™ ADHESIVE SENSORS
(LNCS sensors must be used in conjunction with Red LNC or Rainbow patient cables)

SENSOR	Weight Range	Saturation Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy	
		No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate
LNCS Adtx	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNCS Pdtx	10 - 50 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNCS Inf-L	3 - 20 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNCS Neo-L	< 3 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
	> 40 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNCS NeoPt-L	< 1 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm

SENSOR ACCURACY

Refer to Section 7, *Specifications* for SpO2, SpMet, SpCO and pulse rate accuracy. Unless otherwise specified in the previous tables:

The sensor accuracy specified is when used with Masimo Rainbow SET technology Pulse CO-Oximetry monitors or with licensed Masimo SET pulse oximetry modules during no motion. Accuracy range variation equals ± 1 standard deviation. Plus or minus one standard deviation represents 68% of the population. SpO2 accuracy represents from 70% to 100%, pulse rate accuracy represents from 25 to 240 bpm, SpCO accuracy represents from 1% to 40% and SpMet accuracy represents from 1% to 15%.

CLEANING AND REUSE OF REUSABLE SENSORS AND CABLES

Reusable sensors and patient cables can be cleaned using the following procedure:

1. Remove the sensor from the patient.
2. Disconnect the sensor from the patient cable.
3. Disconnect the patient cable from the monitor.
4. Wipe the entire sensor and/or patient cable clean with a 70% isopropyl alcohol pad.
5. Allow to air dry thoroughly before returning it to operation.

CAUTION: CAREFULLY ROUTE PATIENT CABLES TO REDUCE THE POSSIBILITY OF PATIENT ENTANGLEMENT OR STRANGULATION.

REATTACHMENT OF SINGLE USE ADHESIVE SENSORS

■ Single use sensors may be reapplied to the same patient if the emitter and detector windows are clear and the adhesive still adheres to the skin.

NOTE: *If the sensor fails to track the pulse consistently, the sensors may be incorrectly positioned. Reposition the sensor or choose a different monitoring site.*

CAUTION: DO NOT ATTEMPT TO REPROCESS, RECONDITION OR RECYCLE ANY SENSORS OR PATIENT CABLES AS THESE PROCESSES MAY DAMAGE THE ELECTRICAL COMPONENTS, POTENTIALLY LEADING TO PATIENT HARM.

WARNING: ELECTRICAL SHOCK AND FLAMMABILITY HAZARD – BEFORE CLEANING THE OXIMETER, ALWAYS TURN IT OFF AND DISCONNECT THE POWER CORD FROM THE AC POWER SUPPLY.

Cleaning
To clean the display panel, use a cotton swab moistened with 70% isopropyl alcohol and gently wipe the panel.

To clean the outer surface of the oximeter, use a soft cloth dampened with a mild soap and water. Do not allow liquids to enter the interior of the instrument.

CAUTIONS:

- **DO NOT AUTOCLAVE, PRESSURE STERILIZE, OR GAS STERILIZE D-MAS.**
- **DO NOT SOAK OR IMMERSE D-MAS IN ANY LIQUID.**
- **USE THE CLEANING SOLUTION SPARINGLY. EXCESSIVE SOLUTION CAN FLOW INTO D-MAS AND CAUSE DAMAGE TO INTERNAL COMPONENTS.**
- **DO NOT TOUCH, PRESS, OR RUB THE DISPLAY PANELS WITH ABRASIVE CLEANING COMPOUNDS, INSTRUMENTS, BRUSHES, ROUGH-SURFACE MATERIALS, OR BRING THEM INTO CONTACT WITH ANYTHING THAT COULD SCRATCH THE PANEL.**
- ***DO NOT USE PETROLEUM-BASED OR ACETONE SOLUTIONS, OR OTHER HARSH SOLVENTS, TO CLEAN D-MAS. THESE SUBSTANCES ATTACK THE DEVICE'S MATERIALS AND DEVICE FAILURE CAN RESULT.***

Resting ECG Screen

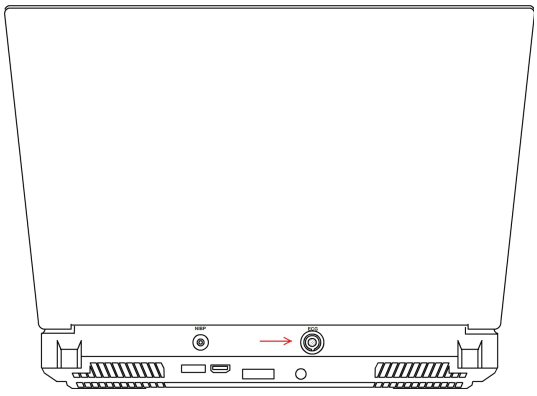
	**WARNING!** Defibrillation and Electrosurgery: Do not touch the patient, or table, or instruments, during defibrillation. After defibrillation, the screen display recovers within 10 seconds if the correct electrodes are used and applied in accordance with the manufacturers instructions. ECG cables can be damaged when connected to a patient during defibrillation. Check cables for functionality before using them again. When using electrosurgical (ES) equipment, never place ECG electrodes near to the grounding plate of the ES device, as this can cause a lot of interference on the ECG signal. When you are connecting the electrodes or the patient cable, make sure that the connectors never come into contact with other conductive parts, or with earth. In particular, make sure that all of the ECG electrodes are attached to the patient, to prevent them from contacting conductive parts or earth.

Preparing the Patient

Proper patient preparation and correct electrode placement is important.

Perform the following steps to prepare the patient.

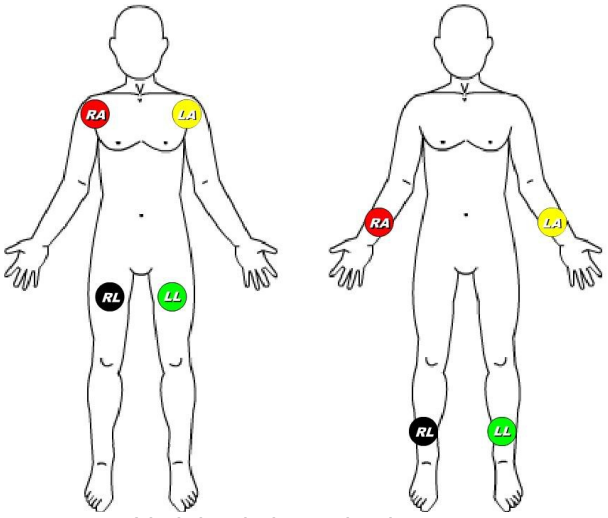
- Relax the patient
- Remove hair at electrode site
- Gently abrade the skin
- Place the electrodes on the patient
- Attach each patient lead wire to the correct electrode



D-MAS Remote ECG Socket

12 Lead ECG electrode placement

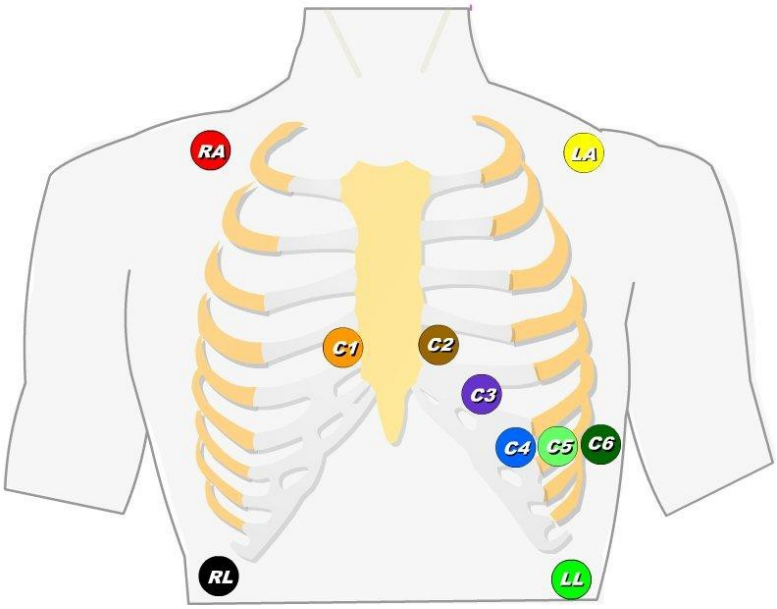
- Place 10 skin electrodes on the patient.
- Connect the electrode clips to the patient skin electrodes
- Connect the 12 lead ECG cable to the D-MAS ECG socket.
- Launch D-MAS software to view ECG.



Limb lead electrode placement.

Locating the C1 position (fourth intercostals space) is critically important because it is a reference point for locating the placement of the remaining C leads.

- To locate the C1 position, place your finger at the notch in the top of the sternum.
- Move your finger slowly downwards about 3 cms (1.5 inches) until you feel a slight horizontal ridge or elevation.
- Locate the second intercostals space on the patient's right hand side
- Move your finger down two more intercostal spaces to the fourth intercostal space, which is the C1 position.



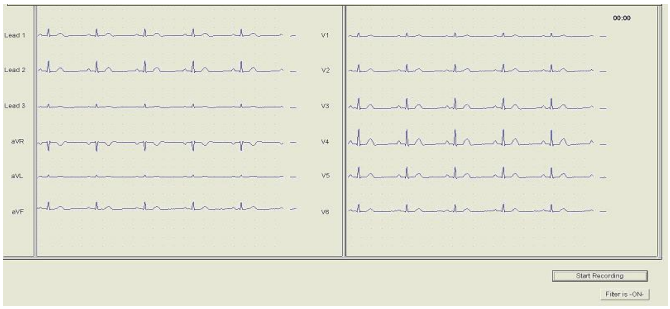
Chest lead electrode placement.

The six pericardial (chest) leads are placed as follows

C1	Fourth intercostals space to the right of the sternum.
C2	Fourth intercostals space to the left of the sternum.
C3	Directly between leads C2 and C4
C4	Fifth intercostals space at midclavicular line
C5	Level with C4 at left anterior auxiliary line
C6	Level with C5 at left midaxillary line

Note: When placing electrodes on female patients, always place leads C3-C6 under the breast rather than on the breast.

1. Prepare the patient and attach electrodes.
2. Ensure that the ECG cable is connected to the patient electrodes and the ECG socket.
3. Click on the Resting ECG button.
4. Monitoring is displayed:
5. Start the recording by clicking “Start recording”.
6. Remove the electrodes from the patient.

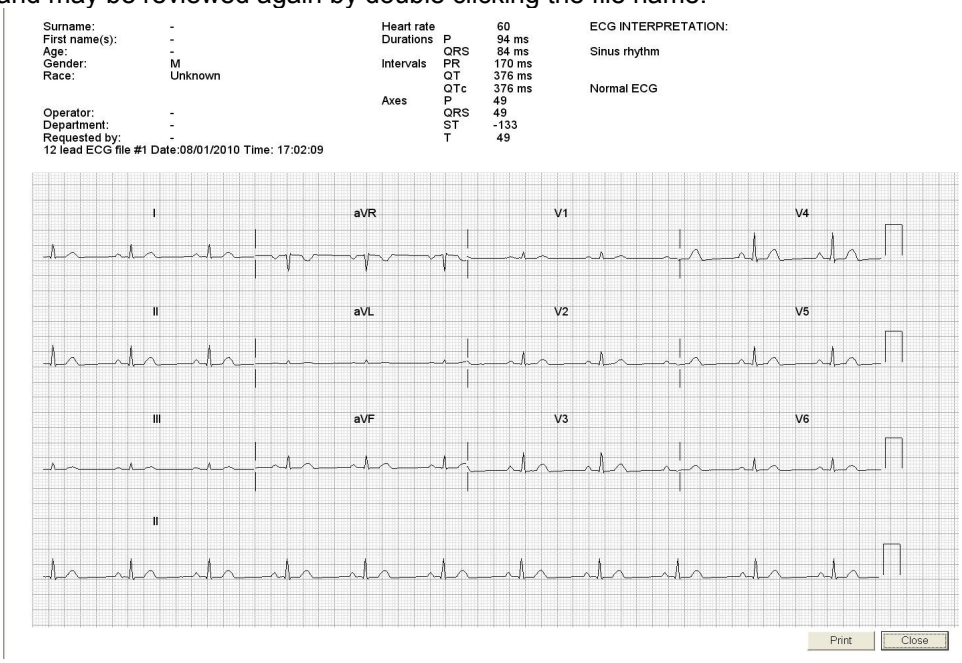


ECG monitor

Resting ECG report

The resting ECG report with patient details, measurements and interpretation is then shown. The report may be printed to make a paper copy or saved as a Pdf.

If the Resting ECG report has been saved, it will appear in the results list box on the Welcome Screen and may be reviewed again by double clicking the file name.



Resting ECG report

Note:

ECG sensitivity settings are 5mm/mV, 10mm/mV and 20mm/mV.
DanMedical recommends testing the sensitivity regularly with a calibrated ECG simulator.

A filter is provided as the ECG may sometimes be affected by line interference.

The ECG signals are sampled at 500 samples/s per channel during data acquisition. The skew between channels being used for determination of angles <100 µs. Amplitude quantisation is 0.945 µV/LSB referred to input.

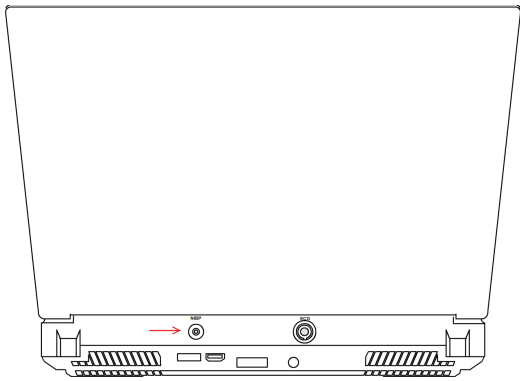
BATTERY POWER- The minimum length of time that the equipment will conform to the requirements of EN 60601-2-51 is a minimum of 30 minutes with a new fully charged battery.

Blood Pressure measurement

Note: It is recommended that the patient should sit comfortably and relaxed with no conversation for 5 minutes before Blood Pressure measurements commence. Do not place the cuff too tightly and avoid restricting circulation.

Measurement accessory connection - NIBP

1. To perform NIBP measurement, select and place the appropriately sized NIBP measurement cuff around the patient's arm
2. Connect the NIBP hose to the cuff and then to the D-MAS NIBP hose connector

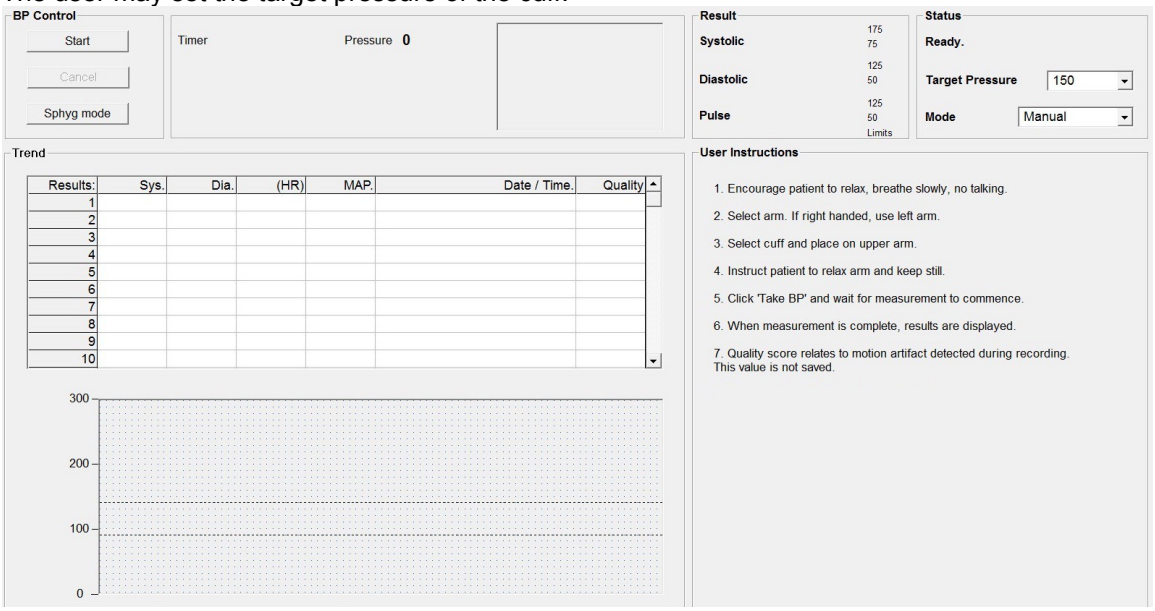


D-MAS Remote NIBP hose connector

Blood Pressure screen

To view the Blood Pressure screen, click on the “Blood Pressure” button.

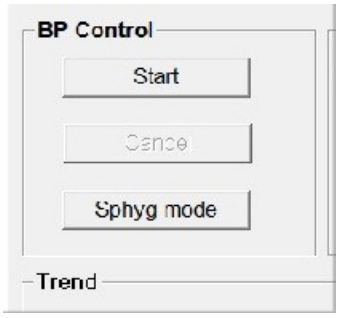
The user may set the target pressure of the cuff.



Blood Pressure screen.

To start a Blood Pressure measurement, click “Start”

To cancel a Blood Pressure measurement at any time click “Cancel”.

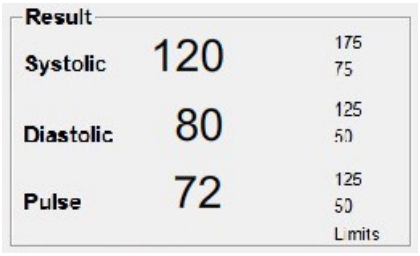


Once measurement has started, the user may observe displayed cuff pressure, the pulse signal height and the measurement time.

When the measurement is complete, the calculated blood pressure results are displayed.

If any of the measurements are outside of the alarm limits then an alarm condition will occur.

Silence the alarm by clicking on “Silence”



NIBP status display:
When in an idle state, “**Ready**.” will appear confirming that the system is ready to commence measurement.

During inflation of the cuff “**Inflating cuff**” is displayed.

During measurement phase “**Measurement**” is displayed.

Previous results are displayed in the results table with time and date and are shown graphically as Trend.

If an error occurs an error message is displayed.

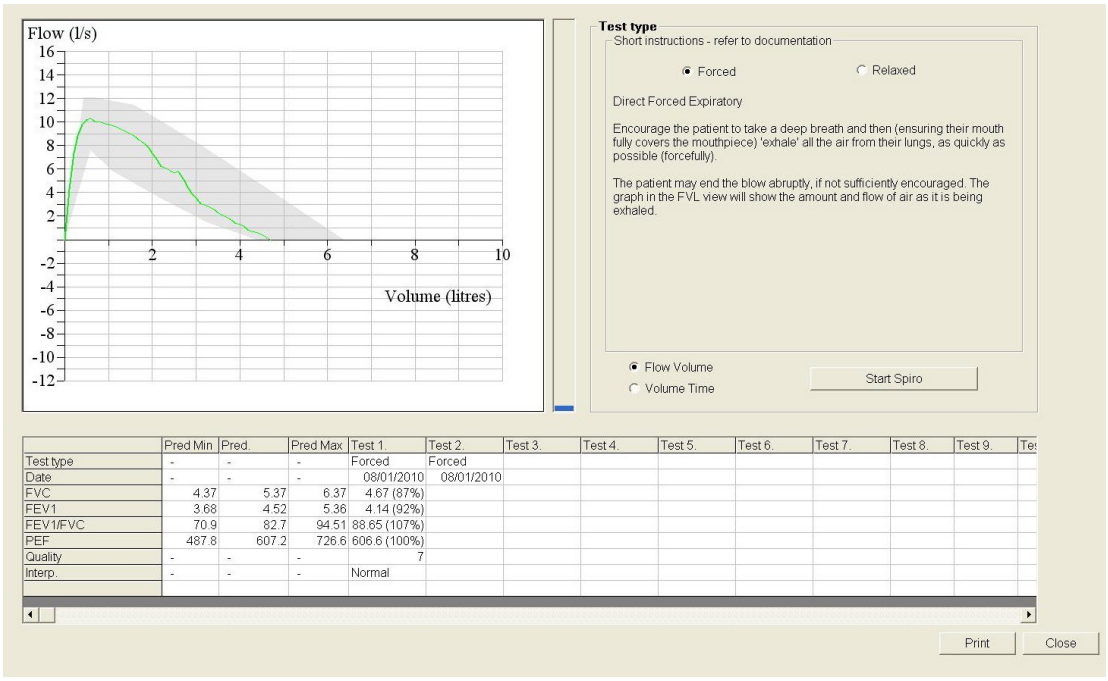
Possible NIBP error messages:

- “Primary overpressure detected” cuff pressure has exceeded safe pressure during the ready state
- “Primary overpressure detected, remove cuff now” cuff pressure has exceeded safe pressure during the inflation state
- “Hardware overpressure detected” D-MAS safety overpressure circuit has been activated
- “Error: deflation steps too small” possible blockage in cuff hose
- “Error: deflation steps too large” possible leak in cuff
- “Pressure released: determination time in access of 120s” NIBP measurement has taken to long
- “Error: Inflation failure” Check cuff is connected, possible leak

Spirometry measurement

1. Connect USB Spirometer to D-MAS
2. Launch D-MAS software.
3. Enter patient details:
    a. Name
    b. Date of Birth (Age)
    c. Gender
    d. Race
    e. Height
    f. Weight
4. Click on "Spirometry" button.
5. Select test type, forced or relaxed.
6. Select preferred graph setting, Flow volume or Volume Time.
7. Read on-screen short instructions to patient.
8. Click "Start Spiro" and after a short beep, perform the spirometry manoeuvre.

When the spirometry maneuver is completed, the results and an interpretive statement are presented.



	Pred Min	Pred.	Pred Max	Test 1.	Test 2.	Test 3.	Test 4.	Test 5.	Test 6.	Test 7.	Test 8.	Test 9.
Test type	-	-	-	Forced	Forced							
Date	-	-	-	08/01/2010	08/01/2010							
FVC	4.37	5.37	6.37	4.67 (87%)								
FEV1	3.68	4.52	5.36	4.14 (92%)								
FEV1/FVC	70.9	82.7	94.51	88.65 (107%)								
PEF	487.8	607.2	726.6	606.6 (100%)								
Quality	-	-	-	7								
Interp.	-	-	-	Normal								

Spirometry screen

Predicted Minimum, Mean and Maximum values are calculated from the patient's height, weight, age, gender and race, these predicted values occupy the first three columns of the results table.

Click 'Print' to produce a paper copy or create a Pdf if set up.

If a Spirometry manoeuvre has been performed and the results are saved, the results and flow loop graphics are available for review from the Welcome Screen by double clicking on the file name.

Monitor Mode

⚠	**WARNING!** Defibrillation and Electrosurgery: Do not touch the patient, or table, or instruments, during defibrillation. After defibrillation, the screen display recovers within 10 seconds if the correct electrodes are used and applied in accordance with the manufacturers instructions. ECG cables can be damaged when connected to a patient during defibrillation. Check cables for functionality before using them again. When using electrosurgical (ES) equipment, never place ECG electrodes near to the grounding plate of the ES device, as this can cause a lot of interference on the ECG signal. When you are connecting the electrodes or the patient cable, make sure that the connectors never come into contact with other conductive parts, or with earth. In particular, make sure that all of the ECG electrodes are attached to the patient, to prevent them from contacting conductive parts or earth.

Connect sensors to patient and to D-MAS:

- Pulse CO-Oximeter sensor
- ECG Electrodes and ECG Patient Cable
- Blood Pressure Cuff and hose

To view the Monitor Mode screen from the Welcome Screen, click the “Monitor” button:

Monitoring Screen

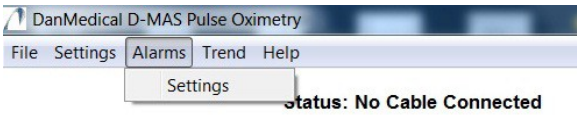
Monitoring Screen Description

Key	Description	Notes
1	Menu:	Use this to access File, Settings, Alarms and Help
2	Pulse CO-Oximeter Status display area	
3	Pulse CO-Oximeter Pleth waveform	
4	Pulse CO-Oximeter Signal IQ waveform	
5	ECG Lead label #1.	Click to change displayed lead position
6	ECG Lead trace #1	
7	ECG Lead label #2.	Click to change displayed lead position
8	ECG Lead trace #2	
9	ECG Lead label #3.	Click to change displayed lead position
10	ECG Lead trace #3	
11	Operating system 'Start' button.	
12	Close button.	Click to close Monitor Mode screen.
13	SpO2 display with alarm limits	
14	PI Display with alarm limits	
15	Pulse rate display with alarm limits	Derived from Pulse CO-Oximeter sensor
16	Silence button	Use to silence alarm for 2 minutes
17	ECG BPM display with alarm limits	
18	Blood Pressure Systolic/Diastolic displays with alarm limits	
19	Start button	Click this to initiate a Blood Pressure measurement
20	Target Pressure	Click and select desired cuff target pressure
21	3 minute semi-automatic mode	Select this to continuously perform Blood Pressure measurements for 3 minutes
22	Cuff pressure reading	
23	Blood Pressure BPM display with alarm limits	
24	Pulse waveform display	
25	Blood pressure trend results	
26	Battery indicator	

At the end of the patient monitoring session, close the Monitor Mode screen by selecting the close button (12).

Monitoring Alarms and limits

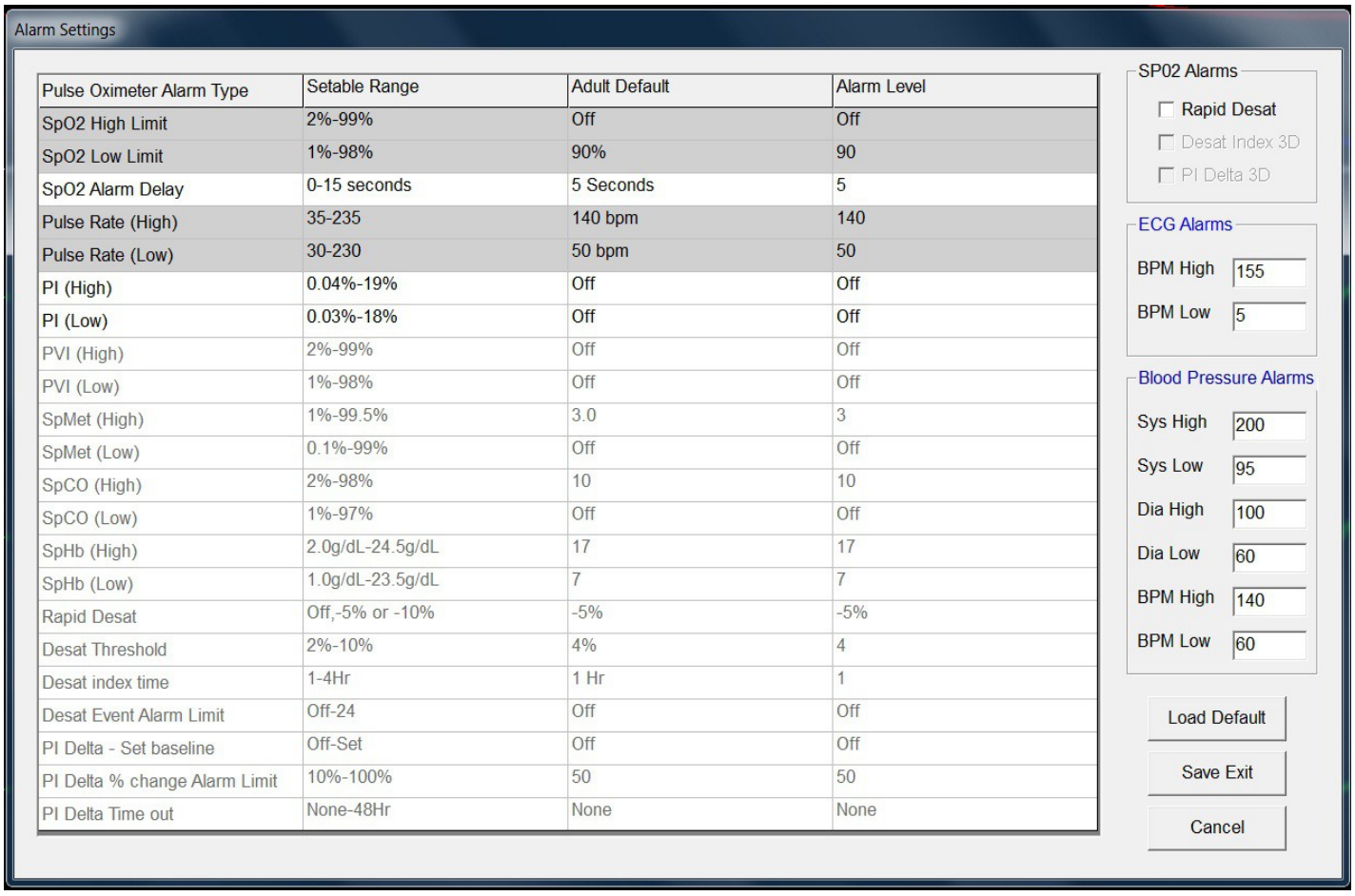
Click on 'Alarms' to access the 'Settings' menu.



When the alarm form is accessed Monitor Mode remains functional and all parameter readings will continue to be displayed.

The Alarms Setting menu allows the adjustment of alarm limits. Adjustment is made by clicking the alarm level box.

A selection drop down box allows easy adjustment of the selected alarm level.



Factory default setting can be selected by clicking 'Load Default'
The settings are saved by clicking 'Save Exit'
To cancel with making no change to the alarm limits, click 'Cancel'.

Parameters that are disabled are not available.

Retrieving patient data

To retrieve and view previously stored patient data, perform the following steps:

1. Click File – Open.
2. Select the required file.

If any further measurements are taken, the user will be prompted to save the results against the retrieved patient data.

Reviewing stored measurements.

Previous measurements associated with the patient record can be viewed by double clicking the required file name.

Printing reports

Ensure that a suitable printer is correctly installed before commencing with any print functions.

To print a summary report of the patient data:

1. Viewing the Welcome Screen.
2. Click “File” and then “Open”, then select the required file.
3. Once the data is displayed on the screen, select “File” and “Print”

To print a Resting ECG report:

1. View the Welcome Screen
2. Click “File” and then “Open”, then select the required file.
3. Previously stored 12 lead ECG recordings associated with the patient data file may be reviewed by double clicking the required file name.
4. Select “Print”

To print a Spirometry report:

1. View the Welcome Screen
2. Click “File” and then “Open”, then select the required file.
3. Previously stored Spirometry measurments are viewed by double clicking the required file name.
4. Select “Print”

Maintenance: General

D-MAS is required to be serviced annually. Service and maintenance should only be performed by DanMedical or a DanMedical approved service provider and includes calibration and safety checks to ensure the correct operation of the device.

Maintenance: Storage

When not in use, it is recommended that D-MAS and all accessories are stored carefully for safe keeping.

Cables should be coiled loosely before storage to prevent fracture of the cables over time.

For storage of long periods, the D-MAS should be stored in the original packaging with the battery removed.

Cleaning

D-MAS may be wiped clean with a slightly dampened cloth of warm water and a mild detergent solution.

Cables supplied with the D-MAS may be wiped with a damp cloth moistened with mild detergent solution.

The Pulse CO-Oximeter sensor cables and ECG patient cable may be damaged through excessive stretching, bending or kinking of the wires.

Do not immerse the NIBP hose. The NIBP hose may be wiped with a damp cloth moistened with mild detergent solution

The blood pressure cuff should be cleaned with a damp cloth or as instructed by the cuff manufacturer.

Spirometer mouth pieces are disposable and should be replaced after each use. The Spirometer turbine should be removed and placed into a sterilising solution between each patient use.

Note:

Care must be taken to avoid water or any other fluid from entering any connectors or ventilation slots. In the event of fluid ingress, as a precaution the D-MAS should be checked by authorized service personnel before use.

Battery Operation and Maintenance

D-MAS HyperSat is powered by Battery Blades or by a 19v power supply. Before using D-MAS the Battery Blades need to be fully charged.
To charge a battery ensure that AC power is attached to the AC Adapter and verify that the battery is charging with the battery charge LED.

The battery requires approximately 2 hours for charging. When the battery charging LED indicators turn green, additional trickle charging may occur to complete charging.

CAUTIONS:

- **AT LOW BATTERY CHANGE TO A FULLY CHARGED BATTERY TO PREVENT LOSS OF POWER.**

During battery operation of D-MAS, please note that the following operating conditions affect the estimated run-time of the included battery:

- **ILLUMINATION OF THE BACKLIT LCD SCREEN. TO CONSERVE BATTERY POWER, KEEP THE BACKLIT LCD SCREEN AT MINIMUM ILLUMINATION.**

- **VOLUME OF THE ALARM TONES. TO CONSERVE BATTERY POWER, KEEP THE FREQUENCY OF THE AUDIBLE ALARMS TO A MINIMUM AND AT MINIMUM VOLUME.**

Memory effects of the battery pack may shorten run-time. When battery run time is significantly reduced, it is advisable to completely discharge and fully recharge the battery pack.

CAUTION:

IF D-MAS HAS NOT BEEN USED OR CHARGED WITHIN SEVEN (7) DAYS OR MORE, THEN RECHARGE THE BATTERY BLADES PRIOR TO USE.

FOLLOW LOCAL GOVERNING GUIDELINES FOR PROPER DISPOSAL OF BATTERIES. DO NOT INCINERATE.

WARNING:	**FIRE HAZARD: TO PROTECT AGAINST FIRE HAZARD, REPLACE ONLY WITH CORRECT BATTERY OF THE SAME TYPE, CURRENT RATING, AND VOLTAGE RATING.** **DO NOT OPEN BATTERY BLADE. NO USER SERVICEABLE PARTS INSIDE. REFER TO QUALIFIED PERSONEL.**

Device function check performance verification

Under normal operation, no internal adjustment or recalibration is required. Safety tests and internal adjustments should be done by qualified personnel only. Safety checks should be performed at regular intervals or in accordance with local and governmental regulations.

To test the performance of D-MAS follow the procedure outlined in this section. If D-MAS fails any of the described tests, discontinue its use and correct the problem before returning the unit back to service.

Disconnect any patient cables and sensors from the instrument.

Power-On Test:

1. Connect D-MAS to power and verify that the Power LED Indicator is lit.
2. Turn D-MAS on by depressing the Power/Standby Button.
3. D-MAS begins normal operation.

Alarm Limit test:

1. With D-MAS Software running, select the Pulse CO-Oximeter button
2. Select Alarm Menu. Change the High SpO2 Alarm parameter to a value two points below the currently selected value, and save the change.
3. Verify that the newly set parameter is shown on the Saturation Alarm Limit Display, next to the SpO2 or pulse rate measurement display.
4. Return the High Saturation Alarm parameter to its original setting.
5. Repeat steps 2 to 4 for the following alarm parameters:
   - Low SpO2
   - High and Low BPM
6. Reset the alarm limits again to the original settings.

Pulse CO-Oximeter function test

7. Connect a Pulse CO-Oximeter Sensor to D-MAS and observe that sensor is detected.
8. Apply the sensor and observe SpO2, BPM and PI readings are displayed within 10 seconds.
9. If any sensor warnings are displayed, replace sensor and repeat from step 8.

Resting ECG function test

10. From the Welcome Screen, select Resting ECG button.
11. Connect the ECG Patient cable to D-MAS.
12. Remove all electrode clips and connect all electrodes together through the holes in the electrodes.
13. Observe the ECG trace is flat with no lead off messages.
14. Sequentially remove each C lead and observe the corresponding Lead Off label on screen.
15. Remove the Black 'N' electrode and observe that all waveforms are dashed lines and lead off label is displayed for all waveforms (Apart from aVR, aVL & aVF)
16. If any unexpected lead off labels are presented then suspect a broken ECG Patient cable and requires replacing.

Blood pressure function test & calibration check

Note: Ensure the NIBP cuff is not around a limb whilst performing the calibration check. Inspect the Blood Pressure cuff, hose and connectors for damage. Replace any parts that are worn out or frayed.

The pressure measurement accuracy may be checked against a calibrated mercury, aneroid or digital manometer.

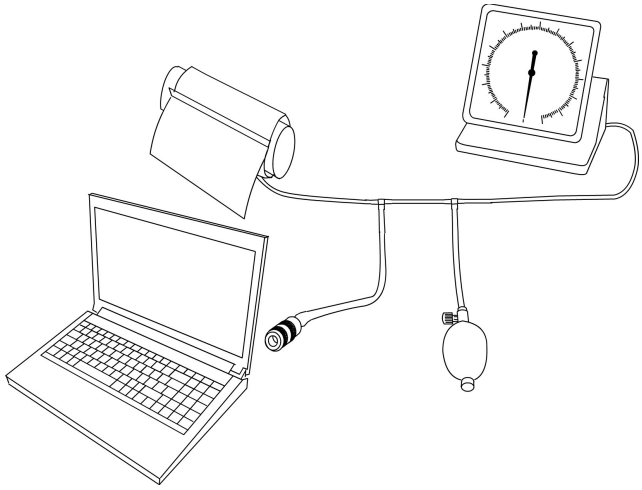
It is recommended that pressure measurement accuracy is performed annually. To do this perform the following:

Apparatus required:

1. Calibrated manometer

2. Tubing, “T” connectors and inflation bulb.

3. An arm sized cylindrical object to wrap the cuff around.



Method:

1. Connect the apparatus
2. From the Welcome Screen, select the Blood Pressure button.
3. Click “Sphyg mode”
4. Inflate the cuff using the inflation bulb.
5. Compare D-MAS pressure reading with the calibrated manometer.
6. If the pressure remains above 15mmHg for a period of 120 seconds, a safety feature will operate and the pressure will be reduced to zero.*
7. If the readings do not agree closely (within 3 mmHg) please call for technical assistance or refer the D-MAS to qualified technical personnel.

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Spirometer function test

1. With D-MAS Software running, select the Spirometry button
2. Connect the Spirometer to a spare USB port on D-MAS
3. Observe blue power LED on Spirometer body
4. Click 'Start' and observe audible beep from Spirometer
5. Secureley connect a calibrated 3Litre syringe and push the maximum amount of air through the Spirometer.
6. Observe graphic loop and measurement display.
7. Repeat test 3 times for repeatabilty.
8. If any degradations in performance are observed, contact technical assistance or refer the D-MAS to qualified technical personnel.

Troubleshooting general

When responding to a D-MAS alarm condition, you must check the patient first and then check the D-MAS performance. If D-MAS problems persist, notify DanMedical service personnel.

Description	Corrective action
General power failure	Check that any power switches are on, confirm mains is operational and power leads are connected to D-MAS Check fuse in power lead plug.
Degradations of performance	The D-MAS is not intended for use in conjunction with any high frequency generator or diathermy machine or when exposed to other strong radio frequency interference. Under such circumstances, it is possible that degradations in performance of the D-MAS may be observed Separate the D-MAS from any interference as far as reasonably possible (refer to EMC information).

The following chart describes what to do if D-MAS system does not operate properly or fails.

Problem	Possible Cause(s)	Recommendation
UNIT DOES NOT POWER ON.	AC power cord, AC power supply or battery defective	Replace AC power cord, AC power supply or battery
CONTINUOUS SPEAKER TONE.	Internal failure.	Unit requires service. If alarm continues to sound, power down unit and remove the battery if necessary.
KEYBOARD AND TRACKER PAD DOES NOT WORK WHEN OPERATED	Internal failure.	Unit requires service.
DEFECTIVE SENSOR MESSAGE	Sensor or cable is broken.	Visually check the sensor LED if it is flashing on and off. If not, reconnect the cable and check the LED again. If the LED still fails to come on, replace the sensor and/or cable.

Troubleshooting Pulse CO-Oximeter

The following charts describe what to do when encountering common problems:

Problem	Possible Cause(s)	Recommendation
SpO2 NUMBER FLASHES	Saturation alarm limit exceeded.	Assess/address patient condition Re-set alarm limits if indicated.
SENSOR OFF MESSAGE	Sensor not connected to patient properly. Sensor is damaged.	Properly reapply the sensor on the patient and reconnect the sensor to the unit or patient cable. If the sensor is damaged, replace the sensor.
NO SENSOR MESSAGE	Sensor is disconnected from patient cable. Sensor connected upside down into patient cable.	Check to see if the sensor LED is flashing. Disconnect and reconnect the sensor. If the LED fails to operate, replace the sensor.
LOW PERFUSION	Improper sensor type. Poorly perfused site. Sensor is too tight. A disorder such as hypothermia, vasoconstriction, hypovolemia, peripheral vascular disease or anemia. Sensor is damaged.	Verify proper sensor and sensor size for the patient. Check and see if blood flow to the site is restricted. Be sure that the sensor is not on too tight. Set unit to MAX sensitivity. Warm the patient or sensor site. Move sensor to better perfused site.
LOW SIGNAL QUALITY	Improper sensor type or application. Excessive motion relative to perfusion. Sensor is damaged or not functioning.	Check and see if blood flow to the site is restricted. Check the placement of the sensor. Re-apply sensor or move to a different site.
SpO2 VALUES DO NOT CORRELATE WITH CLINICAL ASSESSMENT OR ABGs.	Low perfusion or sensor displacement.	Check for error messages. See section 5 *System Messages* for recommended corrections. Check placement of sensor or if it is too tight. Reapply sensor or select a new site. Set to MAX sensitivity and confirm that the sensor is securely on the patient. Refer to sensor Directions For Use.
PULSE SEARCH MESSAGE	Unit is searching for pulse.	If unit fails to display within 30 seconds,disconnect and reconnect. If pulse search continues, move sensor to better perfused site.
UNEXPECTEDLY HIGH SpO2, SpCO OR SpMet READING	Low SIQ or Perfusion Index (PI) values.	Reposition sensor to site with strong SIQ and PI. Average readings taken from three different sites to improve accuracy. Submit blood sample for laboratory CO-Oximetry test for comparison.
	Inappropriate sensor size or sensor measurement location.	Verify proper sensor for patient size. Verify proper sensor site.
UNEXPECTEDLY HIGH SpCO READING	Possible elevated methemoglobin level*.	Submit blood sample for laboratory CO-Oximetry test.
DIFFICULTY OR NO SpO2/SPCO/SPMET READING	Low battery/ not plugged into AC power supply.	Connect to AC power
	Interference from line-frequency induced noise.	Verify/set 50/60hz menu setting.
	Inappropriate sensor or sensor size.	Verify proper sensor and sensor size for the patient.
	Excessive ambient or strobing light.	Shield the sensor from excessive or strobing light.

As with all CO-Oximeters, elevated methemoglobin levels may cause falsely elevated carboxyhemoglobin values.

Problem	Possible Cause(s)	Recommendation
DIFFICULTY OR NO SpCO/SpMet READING	Excessive motion	Minimize or eliminate motion at the monitoring site.
	Inappropriate sensor or sensor size.	Verify use of an SpCO/SpMet capable sensor. Verify proper sensor size for the patient.
	Excessive ambient or strobing light.	Shield the sensor from excessive or strobing light.

Troubleshooting Resting ECG

Description	Corrective action
ECG cable not detected	Use only ECG cables supplied by DanMedical.
ECG cable detected but no waveform or unexpected waveform displayed	Check patient condition & ensure correct patient preparation. Check that electrodes are correctly placed and attached to the patient. Check for residue build up on electrode clips. Check for ECG cable damage. Ensure correct function of ECG cable with an ECG simulator

Troubleshooting Blood Pressure

Description	Corrective action
No cuff inflation (inflation pump not running)	Possible overpressure situation occurred. Wait 30s for automatic reset and try again.
No cuff inflation (with inflation pump running)	Check cuff and all NIBP connections for leak.
Cuff inflation and deflation with no results displayed	Check cuff and all NIBP connections for leak. Ensure patient keeps arm still until determination is complete
Inaccurate results	Ensure correct cuff size. Ensure patients arm is at heart level. Patients arm must be still during determination. NIBP should be performed on patient's bare arm. Manually check for irregular heart rate. Manually check blood pressure. Note: Use the correct Korotkoff sound to determine diastolic when performing a manual determination. Use a high quality stethoscope. Temporal variation of up to 10 mmHg must be considered and may occur for many reasons. Same-limb sequential measurements are preferred to contralateral simultaneous measurements.
Cuff too tight	Check target pressure setting.
Cuff unravelling	Cuff applied inside out or cuff damaged.

Troubleshooting Spirometry

Description	Corrective action
Spirometer not powering	Check connection to USB port. Select alternate USB port.
Spirometer not communicating with D-MAS	Check connection to USB port. Select alternate USB port. Check turbine for damage.

Remote assistance

The D-MAS screen may be transmitted “live” to another computer if internet connected.

The D-MAS instrument has 'Remote viewer' software installed and is launched from the Welcome Screen by selecting Help from the menu and selecting Remote Assistance. Communicate the Identification (I.D.) and Password dialogue box to remote support personnel.

Remote assistance software

Replacement parts and accessories

D-MAS battery replacement is recommended annually.
Contact DanMedical Ltd. for spare parts or accessories.

Replacement parts	Part number
10 lead ECG Cable	DMPN-2013-V2-1001
BP Cuff- small adult	DMPN-2013-V2-1002
BP Cuff- adult	DMPN-2013-V2-1003
BP Cuff-large adult	DMPN-2013-V2-1004
BP Cuff- large adult long	DMPN-2013-V2-1005
BP hose	DMPN-2013-V2-1006
Electrode clips	DMPN-2013-V2-1007
D-MAS Remote Battery Blade	DMPN-2013-V2-1008
Battery Blade charger	DMPN-2013-V2-1009
Spirometer	DMPN-2013-V2-1010
Pulse CO-Oximeter sensor	DMPN-2013-V2-1011
General examcam	DMPN-2013-V2-1012
WiFi LAN Router	DMPN-2013-V2-1013

Specifications

*Subject to change

D-MAS is IP00 rated.

ELECTRICAL

AC Power requirements: 100 - 240 VAC, 2.5A, 50-60 Hz

PHYSICAL CHARACTERISTICS

Dimensions:

D-MAS: 376 * 260 * 74 mm

Weight

D-MAS: 3.6 kg

Computer technical specifications:

LCD + Size : `	15.6"(FHD) Matt type
CPU :	i3-3120M
HDD :	SSD 60GB
RAM :	4G RAM
Optical Device :	SATA 8X DVD SUPER MULTI
Battery & Option :	SLI(76.96WH)
Accessory :	ANTENNA(WLAN,MIMO) +CCD(2.0M,FHD) +COMBO(WLAN 802.11BGN 1X1+B/T4.0,HALF CARD)
VGA & OPTION:	AMD VGA(WIMBLEDON/2G)

Performance Specifications:

Category	Description	Model	Specification
Power source	Input Voltage Range	D-MAS HyperSat	19-16 V DC
	Input current	D-MAS HyperSat	3 A
	Capacity	Twin Battery Packs	10 Ah
Environmental	Operational temperature	All models	0 to 50°C
	Operational humidity	All models	0 to 95%NC
	Storage temperature	All models	-5 to 60°C
	Storage humidity	All models	0 to 95%NC
Pressure		D-MAS HyperSat	450msw (45 bar)

Patient population: The D-MAS is designed for use with adult patients.

Category	Description	Specification		
NIBP	Cuff pressure measurement range	0 to 300 mmHg		
	Cuff target pressure	100 to 275 mmHg		
	Cuff overpressure maximum	280 to 300 mmHg		
	NIBP limits of accuracy	**Parameter:**	**Max:**	**Min:**
		Systolic	275 mmHg	60 mmHg
		Diastolic	150 mmHg	30 mmHg
		MAP	166 mmHg	40 mmHg
		Pulse rate	175 bpm	40 bpm
		Determination time	165s	35 to 55s
		Overpressure limit	300 mmHg	280 mmHg
ECG	12 lead ECG recording	Multi-channel (I, II, III, aVR, aVL, aVf, V1-V6)		
	Frequency response	75Hz, -3dB(IEC); 100Hz, -3dB(AHA)		
	Input impedance	>5M		
	Common mode rejection	>96dB		
	Signal bandwidth	(-3dB) 0.05-250Hz		
	Resolution	3.75µV		
	Gain accuracy	2.5% per lead		
	DC dynamic span	±300 mV (95% gain accuracy)		
	AC dynamic span	±5mV		
	Recovery time after defibrillation	5s 80% gain accuracy		
	Degree of protection against electrical shock	CF		
	ECG limits of accuracy	Parameter	Max	Min
		Heart rate	240 bpm	30 bpm
		QRS amplitude	2 mV	0.5 mV
Spirometer	Type	Bi-Directional transducer		
	Resolution volume	10ml		
	Resolution flow	0.03l/s		
	Spirometer limits of accuracy	+/-3% To ATS recommendations		

Operation of D-MAS below the minimum specification may cause inaccurate results.

Compliance

EMC Compliance:	EN60601-1-2, Class B
Equipment Classification:	IEC 60601-1 / UL 60601-1
Type of Protection	Class II (on AC power) Internally powered (on battery power)
Degree of Protection-Patient Cable:	Type CF-Applied Part

Mode of Operation: Continuous

1 The D-MAS with LNOP Adt sensors has been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70-100% SpO2 against a laboratory CO-Oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population weight.

2 The D-MAS with LNOP Neo sensors has been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70-100% SpO2 against a laboratory CO-Oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population weight. 1% has been added to the saturation accuracy to account for the effects of fetal hemoglobin.
This variation equals plus or minus one standard deviation, which encompasses 68% of the population.

3 The D-MAS with LNOP Adt sensors has been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO2 against a laboratory CO-Oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

4 SpMet and SpCO accuracy has been validated on healthy adult male and female volunteers with light to dark skin pigmentation in the range of 0% - 40% SpCO and 0% - 15% SpMet against a laboratory CO-Oximeter. This variation equals plus or minus one standard deviation, which encompasses 68% of the population. The SpCO accuracy and SpMet accuracy have not been validated under motion conditions.

5 This represents approximate run time with the backlight at minimum and Power Save mode on, using a new, fully charged battery.

6 If the batteries are to be stored for extended periods of time, it is recommended that they be stored between -20°C to +30°C, and at a relative humidity less than 85%. If stored for a prolonged period at environmental conditions beyond these limits, overall battery capacity may be diminished, and lifetime of the batteries may be shortened.

7 With FastSat the averaging time is dependent on the input signal. For the 2 and 4 second settings the averaging time may range from 2-4 and 4-6 seconds, respectively.

8 Maximum sensitivity mode fixes perfusion limit to 0.02%.

9 Rainbow SET technology with LNOP, LNOPv, LNCS and Rainbow sensors has been validated for pulse rate accuracy for the range of 25-240 bpm in bench top testing against a Biotek Index 2 simulator. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

Pulse CO-Oximeter measurement range

Oxygen Saturation (%SpO2):	0 -100%
Carboxyhemoglobin Saturation (%SpCO):	0 - 99%
Methemoglobin Saturation (%SpMet):	0 - 99.9%
Pleth Variability Index	0 - 99%
Pulse Rate:	25 - 240 (bpm)
Perfusion Index:	0.02% - 20%

ACCURACY

Saturation	70% to 100%
No Motion1	
Adults, Pediatrics	±2 digits
Neonate*2*	±3 digits
Motion3	
Adults, Pediatrics	±3 digits
Neonate	±3 digits
Low Perfusion4	
Adults, Pediatrics	±2 digits
Neonate	±3 digits
Carboxyhemoglobin Saturation Accuracy (%SpCO)*5*	1% - 40% ±3 digits
Methemoglobin Saturation Accuracy (%SpMet)*5*	1% - 15% ±1 digit

Pulse Rate Accuracy

Pulse rate:	25 - 240 bpm
No Motion1	
Adults, Pediatrics, Neonate	±3 digits
Motion3	
Adults, Pediatrics, Neonate	±5 digits
Low Perfusion4	
Adults, Pediatrics, Neonate	±3 digits

Resolution

Saturation (%SpO2)	1%
Carboxyhemoglobin saturation (%SpCO), digital display	1%
Methemoglobin saturation (%SpMet), digital display .	1%
Pulse Rate (bpm)	1 bpm

Trending

72 hours of trending at 2 second resolution

Mode

Averaging mode:	2, 4, 8,10, 12, 14 or 16 seconds8
Sensitivity:	Normal and Maximum*9* and APOD

Alarms

Audible and visual alarms for high/low saturation and pulse rate (SpO2 range 1-100%, pulse rate range 25-240 bpm, SpCO range 1%-99%, SpMet range 1%-99.9%)

Sensor condition, system failure and low battery alarms

Alarm Volume: 70 dB (min)

Display/Indicators

Data display: %SpO2, %SpCO, %SpMet, pulse rate, pleth waveform, alarm status, trends, status messages, Signal IQ, perfusion index, pleth variability index, APOD and FastSat

Display update rate:	1 second
Response Time:	< 20 second delay

Factory defaults

D-MAS can be restored to factory default settings through the software menu.

USER DEFINED SETTINGS

D-MAS maintains set values and the following table outlines the options that may be changed by the user.

ECG settings:

Parameter	**Setting**	
Sensitivity	10mm/mV	
Trace speed	25mm/s	
Filter	On	
Alarm parameter	**High limit**	**Low limit**
Heart rate	140 bpm	45 bpm

NIBP settings:

Parameter	**Setting**	
Cuff target pressure:	150 mmHg	
Alarm parameter	**High limit**	**Low limit**
Systolic	200 mmHg	70 mmHg
MAP	175 mmHg	60 mmHg
Diastolic	155 mmHg	50 mmHg
Pulse rate	140 beats per minute (bpm)	45 bpm

Pulse CO-Oximeter settings:

OPTION	FACTORY DEFAULT SETTING	CONFIGURABLE SETTING
DISPLAY VIEW	Set to Pleth + SigIQ	Pleth + SigIQ, Pleth Only,
AVERAGING TIME	Set to 8	2, 4, 8, 10, 12, 14, or 16 seconds
FASTSAT	Set to No	Yes/No
DATE FORMAT	Set to mm/dd/yy	mm/dd/yy and dd/mm/yy
TIME FORMAT	Set to 12 hr.	12 and 24 hour
PULSE BEEP VOLUME	Set to Level HIGH	Level LOW, MED, HIGH
TREND DISPLAY	Set to %SpO2 + BPM	See Section 4, Display for all settings.
TREND PERIOD	Set to Autoscale.	See Section 4, Trend Setup for all settings.
LOW SpO2 ALARM LIMIT	Set to 90	
SpMet HIGH/LOW ALARM LIMIT	Set to High: 3.0/Low: ---	
SpCO HIGH/LOW ALARM LIMIT	Set to High: 10/Low: ---	
SMART TONE	Set to No	Yes/No
PULSE RATE HIGH/LOW ALARM LIMIT	Set to High: 140/Low: 50 BPM	
SpMet HIGH/LOW ALARM LIMIT	Set to High: 3.0/Low: ---	
SpCO HIGH/LOW ALARM LIMIT	Set to High: 10/Low: ---	
ALARM SILENCE	Set to 120 seconds	
ALARM DELAY	Set to 5 seconds	

Guidance and Manufacturer's Declarations

The DanMedical D-MAS needs special precautions regarding EMC and needs to be installed and put into service according to the following EMC information provided.

Portable and mobile RF communications equipment can affect the DanMedical D-MAS.

DanMedical declaration-Electromagnetic Emissions		
The D-MAS is intended for use in the electromagnetic environment specified below. The customer or the user of the D-MAS should assure it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment
RF Emissions CISPR 11	Group 1	The D-MAS uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The D-MAS is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic Emissions IEC 61000-3-2	Class D	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies	

<table>
<tr><th colspan="4">Guidance and manufacturer’s declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">D-MAS is intended for use in the electromagnetic environment specified below. The customers or the users of the D-MAS should assure that it is used in such environment.</td></tr>
<tr><td>Immunity test</td><td>IEC 60601 Test level</td><td>Compliance level</td><td>Electromagnetic environment – guidance</td></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 V rms
150 kHz ~ 80 MHz</td><td>3 V rms</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the D-MAS including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter.
Recommend separation distance
$d = [\frac{3,5}{V_1}]\sqrt{P}$
Radiated RF
IEC 61000-4-3
3 V/m
80 MHz to 2.5 GHz
3 V/m
$d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz
$d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.5 GHz
where P is the maximum output power rating of the transmitter in watts (W) and d is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b

Interference may occur in the vicinity of equipment marked with the following symbol:  </td></tr>
<tr><td colspan="4">Note1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</td></tr>
<tr><td colspan="4">a) Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the D-MAS is used exceeds the applicable RF compliance level above, the D-MAS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the D-MAS.
b) Over the frequency range 150 kHz to 80MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

Guidance and manufacturer's declaration – electromagnetic immunity			
D-MAS is intended for use in the electromagnetic environment specified below. The customer or the user of these D-MAS should assure that it is used in such environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial and/or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	±1 kV line to line ±2 kV line to earth	Mains power quality should be that of a typical commercial and/or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply IEC 61000-4-11	<5 % *U*T (>95 % dip in *U*T) for 0.5 cycle	<5 % *U*T (>95 % dip in *U*T) for 0.5 cycle	Mains power quality should be that of a typical commercial and/or hospital environment.
	40 % *U*T (60 % dip in *U*T) for 5 cycles	40 % *U*T (60 % dip in *U*T) for 5 cycles	
	70 % *U*T (30 % dip in *U*T) for 25 cycles	70 % *U*T (30 % dip in *U*T) for 25 cycles	
	<5 % *U*T (95 % dip in *U*T) for 5 sec.	<5 % *U*T (95 % dip in *U*T) for 5 sec.	
Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: *U*T is the A.C. mains voltage prior to application of the test level.			

Recommended separation distance between portable and mobile RF communications equipment and D-MAS

D-MAS is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled.

The customers or the users of D-MAS can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the DanMedical D-MAS as recommended below, according to the maximum output power of the communications equipment.

Output Power of Transmitter in Watt	**Separation distance according to frequency of transmitter in meter**		
	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$	***80 MHz to 800 MHz*** $d = [\frac{3,5}{E_1}]\sqrt{P}$	***800 MHz to 2.5GHz*** $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	*0.12*	*0.23*
0.1	0.38	*0.38*	*0.73*
1	1.2	*1.2*	*2.3*
10	3.8	*3.8*	*7.3*
100	12	*12*	*23*

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note: At 80MHz and 800MHz, the separation distance for the higher frequency range applies

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Warranty

DanMedical warrants to the initial purchaser that each new D-MAS will be free from defects in workmanship or materials for a period of one (1) year from the date of purchase. DanMedical's sole obligation under this warranty is to repair or replace any product that DanMedical deems to be covered under warranty with a repaired or a replacement D-MAS.

Batteries are warranted for six (6) months.
To request a replacement under warranty, contact DanMedical for a returned goods authorization. If DanMedical determines that a product must be replaced under warranty, it will be replaced and the cost of shipment covered. All other shipping costs shall be the responsibility of the purchaser.

Exclusions
This warranty does not extend to any product that has been subject to misuse, neglect or accident; that has been damaged by causes external to the Product; that has been used in violation of the operating instructions supplied with the Product. The warranty does not extend to any product that has been connected to an unlicensed instrument system, modified accessories or any unit that has been disassembled or reassembled by anyone but an authorized DanMedical agent. This warranty does not extend to sensors or patient cables that have been reprocessed, reconditioned or recycled.

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Service information:

If there is a technical problem with the D-MAS that you cannot resolve, please contact DanMedical Ltd. Technical support will be available during normal office hours Monday to Friday excluding bank holidays.

Before returning the D-MAS for repair you must obtain a work reference number from service personnel. The work reference number must be clearly noted on the shipping box. Items received by DanMedical Ltd. with no work reference number cannot be accepted for delivery.

Service and repair

Only DanMedical or an authorized DanMedical service provider can perform warranty repair, service and maintenance on D-MAS units. Do not use malfunctioning equipment.

WARNING: DO NOT REMOVE THE COVER OF D-MAS.

EXCEPT FOR BATTERY REPLACEMENT, AN OPERATOR MAY ONLY PERFORM MAINTENANCE PROCEDURES SPECIFICALLY DESCRIBED IN THIS MANUAL. REFER SERVICING TO QUALIFIED SERVICE PERSONNEL TRAINED IN THE REPAIR OF THIS EQUIPMENT