Surdial X
INTELLIGENT THERAPY FOR A BETTER LIFE

HEMODIALYSIS MACHINE
A clear view to the future

Modern-day dialysis machines are becoming ever more complex. They must be able to perform multiple, demanding and complicated tasks, maintain high levels of performance whilst ensuring ease of use and patient safety.

When designing the new Nipro Surdial-X Dialysis machine, we focused on the overall human kidney function. We have created a user-friendly and logical platform incorporating all the treatments required to meet the patient’s current and future therapy needs.

For Nipro, every patient is unique. The Surdial-X offers the user the flexibility to set up treatments tailored to the patient’s needs.

The slim and ergonomic design of the Surdial-X takes up less space on the ward or dialysis unit giving more space to the patient and the operator.
**User Friendly**

Set up of the ‘tailor made’ dialysis treatment is facilitated by the ‘patient card’ and/or the LAN connection.

Each patient will have his or her own unique ‘patient card’ with predefined settings for his or her treatment. The card is designed to facilitate the quick and safe setup of the patient treatment parameters.

Alternatively, the Surdial-X dialysis machine can be connected to your local network where you can upload patient data directly to the machine and download back to your patient database. The machine software is fully compatible with modern-day patient data management software.

Users can adjust basic treatment mode settings; however, for more advanced adjustments the user must insert a user card. This safety feature helps prevent any accidental or unauthorised manipulation of the treatment settings.

The Surdial X is equipped with an easy to use, fully adjustable, 15” touch-sensitive screen, making the machine easier to operate.

The software is designed to guide the user quickly and safely through the treatment set up. When needed, there are help screens aiding the user in their decisions.

During treatment, the ‘dashboard’ mode gives users and patients a quick and clear overview of the treatment status.
Flexibility

The *Surdial-X* is designed to be flexible for both users and patients.

- Automatic online filling, degassing and rinsing
- Online infusate bolus and wash back reinfusion

By giving it a 3 pump system it can manage various treatment modes:

- HD double needle
- HD single needle
- HDF online double needle; pre or post dilution
- HDF online single needle; pre or post dilution
- Hemofiltration; pre or post dilution

Furthermore, we have designed the system to be future ready. With the optional scale the *Surdial-X* will soon be ready to support following patient treatment modes:

- AFB Therapy
- CVVH
- CVVHD
- CVVHDF
- Plasma Separation

Easy Handling

The *Surdial-X* is designed to allow machine assisted insertion and removal of the pump segments. Patented clips speed up this initial setup of the machine.

After treatment the machine ejects these clips so that the bloodline tubing can easily be removed.

The pumps are colour coded, clearly visible and enclosed by a cover; in case of an emergency they can be easily accessed.
**Safety**

The Surdial-X has been designed to passively and actively manage patient safety. During treatment the machine software monitors all settings closely and gives timely visual and audible warnings of any detected deviations.

The various clips and connection points secure the bloodlines in place and enable the user to quickly check that the lines are correctly inserted, and troubleshoot problems.

The Surdial-X is equipped with Blood Pressure Control, which handles:

- Automatic and non-invasive blood pressure monitoring
- Manual and automatic measurement
- Systolic, diastolic, MAP and pulse
- Individual control with links to UF and Sodium profiling
- Easy to read and follow on-screen graphics

**Multi-Functionality**

The Surdial-X has a sophisticated dialysate circuit designed to provide each patient with an individually optimised treatment:

- Bicarbonate and sodium profiling
- Online priming, infusate bolus and wash back reinfusion facilitated by two ultrafilters
- Ultrapure dialysate <0.1 CFU/mL
- Online HDF, HF
- 3 Acid concentrate connectors
- NIPRO assisted Quality Control
**Improved Quality of Life**

- Standard KT/V calculation and optionally by direct measurement
  - In vivo urea clearances
  - Actual dialysis dose
  - Plasma Sodium concentration monitoring
  - On-screen graphics

All these features are available at no cost.

**Blood Volume Control**
- Ultrasonic Blood Volume measurement
- Real-time measurement of changes in blood volume
- Real-time monitoring of Hct
- Real-time monitoring of Hb
- Individual control with links to UF and Sodium profiling
- Easy to follow on-screen graphics

**Hygiene and Disinfection**

The **Surdial-X** is equipped with a ‘flush fitting’ bicarbonate holder.

The substitution fluid and drain ports are designed to give a maximum level of security after disinfection. Automatic disinfection programmes are available after treatment.

Each **Surdial-X** is painted with an easy to clean, smooth and colourfast surface finish, which is hygienic and easy to clean.
**Maintenance**

The **Surdial-X** can be opened to give easy access to all internal parts.

A maintenance card gives the engineer access to maintenance software with detailed treatment history and error memories. Real-time hydraulic flow charts are accessible during machine preparation, treatment and disinfection.

Individual machine configuration and diagnosis via optional modem is possible*

### Unit Specifications

**MEASUREMENTS**

<table>
<thead>
<tr>
<th></th>
<th>without IV pole</th>
<th>with IV pole</th>
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</thead>
<tbody>
<tr>
<td><strong>Height</strong></td>
<td>161.5 cm</td>
<td>175.5 cm (min)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>200.5 cm (max)</td>
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<tr>
<td><strong>Width</strong></td>
<td></td>
<td>36 cm</td>
</tr>
<tr>
<td><strong>Depth</strong></td>
<td></td>
<td>40 cm</td>
</tr>
<tr>
<td><strong>Weight</strong></td>
<td></td>
<td>64.5 cm</td>
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</tbody>
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**ELECTRICAL**

| **Voltage**      | 230V AC ± 10%, 50Hz/60Hz | Power cable (3.0 m) can be changed to fit the local power socket design |
| **Frequency**    | 110V AC ± 10%, 50Hz/60Hz |

**Power consumption**

| **230V AC**      | 2.0kVA or less (treatment) | 2.5kVA or less (hot rinse) |
| **110V AC**      | 1.5kVA or less (treatment) | 2.0kVA or less (hot rinse) |

**EMC**

EMC compatible specification IEC60601-1-2: based on the 2004 version

**PROTECTION**

- Protection class and grade: Class 1, Type B
- Protection against water penetration: Drip Proof machine IPX 1 (all panels must be closed)

**WATER SUPPLY**

- **Pressure**
  - 0.05 – 0.74 MPa (normal pressure) (0.5 – 7.5 kgf/cm²)
- **Flow**
  - Average 1100 mL/min or more
- **Temperature**
  - 15 – 30°C
- **Drainage**
  - 1500 mL/min or higher

**ENVIRONMENT**

- **Water quality**
  - Has to be suitable for dialyzing. Water quality satisfying the provision of hemodialysis system, state code RD 5.2003 approved by AAMI. For ON-LINE HDF treatment, water quality must satisfy the provision of AAMI RD52:2004
  - Water quality should comply with the local regulations (e.g. European pharmacopoeia-Ph.Eur.)
- **Supply pressure range of concentrate dialysate fluid**
  - Min: 30MPa
  - Max: 98KPa
- **Supply pressure range of central system**
  - 5 to 98KPa (38 to 735 mmHg)
# Dialysate Flow

**Dialysate Flow**

- Min. 100mL/min - Max. 1,000mL/min
- Adjustable per 100mL

**UF Control**

- UF control method: Sealed volume control method using piston pump
- Setting range: 0.00, 0.10 – 4.00 L/h
- UF Accuracy: ± 0.3 g/h
- When the equipment adjustment condition is the same as factory shipment

**Temperature Control**

- Setting range: 32.0 to 39.0°C
- Stability: Set Value ±0.5°C or less
- Accuracy of indicated value: Indicated value of dialysate temperature
  Mean temperature within ±0.3°C

**Cleaning**

- Chemical disinfection (Sodium Hypochlorite)
  - Setting range: Original concentration: 4 to 12% (1% increment)
    Diluted concentration: 0.01 to 0.2% (0.01% increment)
  - Protection against corrosion:
    - Original concentration: 6% or less
    - Concentration after dilution/time: 0.03 to 0.1% or less
    - 0.03% or less
  - Time: 30 to 120 min (5 min increment)

- Peracetic acid
  - Setting range: Original concentration: 4 to 12% (1% increment)
    Diluted concentration: 0.01 to 0.2% (0.01% increment)
  - Protection against corrosion:
    - Original concentration: 6% or less
    - Concentration after dilution/time: 0.01 to 0.2% or less
    - 0.01% or less
  - Time: 30 to 120 min (5 min increment)

- Hot rinse
  - Setting range: Temperature (hot water): T7: 70 – 86°C (1°C increment)
  - Hot water circulation time: 40 to 60 min (5 min increment)

- Hot citric
  - Setting range: Original concentration: 10 to 50% (10% increment)
    Diluted concentration: 0.2 to 1.0% (0.1% increment)
    Temperature (hot water): T7: 70 – 86°C (1°C increment)
    Time: 40 to 60 min (5 min increment)
  - Protection against corrosion:
    - Original concentration: 50% or less
    - Diluted concentration: 0.8% or less

- Decalcification (Acetic acid)
  - Setting range: Original concentration: 30 to 70% (1% increment)
    Diluted concentration: 1 to 5% (1% increment)
    Time: 30 to 120 min (5 min increment)
  - Protection against corrosion:
    - Original concentration: 50% or less
    - Diluted concentration: 2% or less

- Water rinse
  - Setting range: Time: 5 to 120 min (5 min increment)

- IHR rinse
  - Setting range: Time: 15 to 60 min (5 min increment)

**Blood Pump (5/N Double Pump, On-Line HDF Pump)**

- Blood pump method: 2 rollers – auto space adjustment method
- Rotation direction: Counter clockwise rotation only (possible clockwise rotation of blood pump during priming process)
- Flow range: Normal tube: 10 to 600 mL/min
  Obtaining maximum flow may be impossible due to fatigue of the rolling tube
- Flow accuracy: Normal tube: ±8.00 to ±12.00 ± 0.15mm

**Heparin Pump**

- 1 tube method: Nipro Syringe GA 10, 20, 30 mL syringe
- Injection direction: Leftward only facing the equipment front side
- Flow setting: 0.0 to 0.9 mL/hour
- Flow accuracy: Machine accuracy ±1%

**Bubble Detector**

- Sensor method: Supersonic method
- Corresponding tube: Ø4.3 x Ø6.8 mm ±0.1 mm (normal tube)
- Detection capability: Alarm when over 10 μL single bubble are detected or over 0.3 μL bubbles are detected and integrated bubble in unit time (5 min) reaches the rate value
  - Rated value: three grades of 1, 50, 100 μL
  - Overload detection: Discharge pressure 500 to 800 mmHg
  - Flow 200 mL/min
  - Flow temperature 37 ± 1.0°C

**Blood Leak Detector**

- Sensor method: Optical
- Detection accuracy: ±200 ppm (when detected 500 ppm)

**Temperature Monitor**

- Sensor method: Thermistor
- Display reproducibility: ±0.6°C
- Precision is calculated for the sensor alone (true temperature time: 37°C)

- Alarm settings:
  - Maximum setting range: 37 – 40°C
    (set by 0.1°C step)
    - alarm precision: mean temperature ±0.8°C
  - Minimum setting range: 29 – 36°C
    (set by 0.1°C set)
    - alarm precision: mean temperature ±0.8°C
    - T3 – T4 difference alarm: 1.2°C
  - Average temperature is average of dialysate temperature per min