Operating Manual
SonoScope 30

1ˢᵗ Edition 1991

1. Contents

2. Safety instructions

The sonoScope 30 corresponds to safety requirements in accordance with DIN IEC 601 Part 1 / VDE 0750 Part 1 / 5.82, accident prevention regulations and the MedGV, so that the highest possible degree of safety for both patient and operator is guaranteed. However, the precondition for safe and trouble-free operation is careful attention to this operating manual and, in particular, the following notes:

1. The sonoScope 30 is intended for use in rooms used for medical purposes, not however for use in spaces liable to the danger of explosion or in the presence of flammable anaesthetics.

2. The equipment may only be connected to power outlets corresponding to valid safety requirements (installation in accordance with VDE 0107).

3. Where the earth connection on the unit is incorrectly connected there is a danger of electric shock.

4. Every time the unit is to be used it and its accessories should be subjected to external inspection and a function test should be carried out. Particular attention is to be paid to the mains lead; should the insulation or plugs be damaged, these parts must be immediately replaced by an authorised person. Similarly, damaged probes may not be used.

5. The equipment may only be used in conjunction with accessories prescribed by the manufacturer or approved expressly for this purpose.

6. The housing may under no circumstances be opened by non-authorised persons, since the equipment contains dangerous voltages.

7. When exchanging the equipment fuses, only components of the prescribed type may be used.

8. The equipment is not suitable for use in moist atmospheres; because of its limited drip and spray cover it should not be placed below transfusion stands etc.

9. During an examination neither repairs nor maintenance work may be carried out.

10. Customer Services and maintenance may be performed exclusively by:

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MEDIZINISCHE SYSTEME GMBH
Beethovenstraße 239
D-5650 Solingen 11
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or by our representatives.

of adults as well as for pre-natal diagnosis towards the end of the gestational period. Thanks to its small contact area and its wide sector angle the 3.5 MHz convex array with a 25 mm radius is particularly suited to ultrasound penetration using the smallest of acoustic windows, in particular also for carrying out basic echocardiographic examinations.

The 5 MHz scanheads with their higher resolution and lesser depth of penetration of 10 to 15 cm were developed for use in pediatrics, in orthopedics, for examinations during early pregnancy as well as for mammary gland diagnosis. For the examination of the smallest organs close to the surface, such as the thyroid gland, the 7.5 MHz scanheads, in particular the linear array version, with their even greater resolution are ideally suited. The depth of penetration of these scanheads however lies around the 5 - 6 cm mark.

3. General description of equipment

3.1. Fields of application

The sonoScope 30 is a medicinal diagnostic unit for producing two-dimensional images of the inside of the body. Image refreshing is carried out automatically and at a high rate of repetition, so that even such movements as pulsations etc. may be displayed.

Depending on the configuration of the equipment, it meets the requirements for the following applications:

- Cerebral and sinus diagnosis (with a 5.0 or 7.5 MHz scanhead)

- Soft facial parts, throat organs with parotis (with a 5.0 or 7.5 MHz scanhead)

- Pectoral organs

- Heart (with a convex scanhead and an ECG module)

- Abdominal organs and retroperitoneal space, including kidneys

- Uro-genitals; external diagnosis, excluding the kidneys, urogenitals; internal diagnosis as well as external diagnosis of the scrotum (with a 5.0 or 7.5 MHz scanhead)

- Pregnancy diagnosis

- Mammary diagnosis (with a 5.0 or 7.5 MHz scanhead, if necessary with an additional stand-off)

- Hip joints (with a 5.0 MHz scanhead)

- Soft tissue, including muscles, and joints (with a 5.0 or 7.5 MHz scanhead)

Low dosage ultrasonic intensity, as generated and emitted by the sonoScope 30 appear, according to the current scientific state of knowledge, to have no harmful effects on the human organism. Despite intensive international research work, it has not been possible to observe either sonographically triggered pseudo-cavitations or any direct effects on cell nuclei.

Since, on the other hand, the harmlessness of low dosage ultrasonic intensity could not be proven either, both the esteemed and leading "American Institute of Ultrasound in Medicine" and the "Watchdog Group" recommend the use of diagnostic ultrasound only where indications warrant its use and not indiscriminately.

In the opinion of leading perinatologists, a sufficient indication is given within the context of pre-natal care. The ultrasonic scans for assessing growth and in order to exclude the possibility of deformity can therefore be carried out without hesitation and in harmony with the current state of our knowledge of sonographic biological effects.

The sonoScope 30 is equipped with an ECG option for echocardiographic diagnosis. In this respect, the overlay of the ECG's on the screen serves merely as a temporal point of reference in order to be able to relate the displayed echocardiographs retrospectively to a certain temporal phase of the heart functions. The ECG curve itself should not be used for interpretation of the cardiac function itself, since the signal passes through artifact-reducing filter circuitry and is therefore subject to some alteration in form and amplitude compared with the original signal.

MedGV

> In accordance with the Medical Equipment Regulations (MedGV), the sonoScope 30 is categorised within equipment group 3 (§ 2, Abs. 3 MedGV).
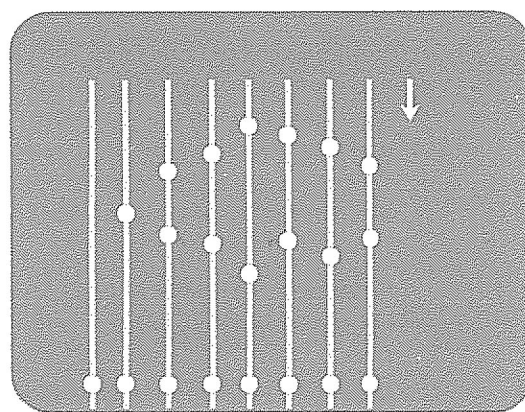
3.2. Description of functions

The sonoScope 30 is equipped with so-called "array scanheads" for the acoustic scanning process and for producing ultra-sonic sectional images. With these scanheads, the contact area facing the body consists of a multitude of quartz crystals adjacent to each other in lines. Each quartz crystal functions both as a transmitter, emitting short ultrasound pulses, and as a receiver, detecting the echo signals reflected back from tissue and outer surfaces. In order to form an image, the array is activated crystal by crystal in lines, scanning the structures below the scanhead in this way one line at a time.

Each acoustic line is allocated a vertical image line on the screen. The echo signals returning from within the body are displayed on these screen lines depending on their distance from the scanhead, and therefore depending on the moment of their arrival, in the form of white dots.
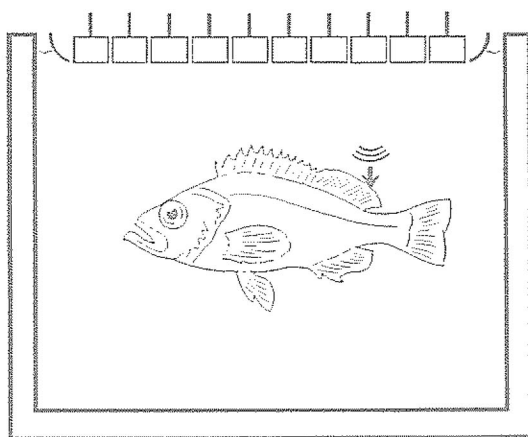
Each echo signal corresponds to a white dot on the screen. Depending on the intensity of the echo signal, the corresponding point will be displayed with a greater or lesser degree of brightness. Very strong echo signals are in this way represented by very bright dots, tissue returning a weak echo will, depending on its density and its structure, appear light or dark grey. Where the ultrasound beams penetrate liquid-filled areas, the screen shows black.

In order to achieve well-directed radiation of the ultrasound pulses, and therefore good beam concentration and good lateral resolution, as many as 32 piezoelectric crystals are grouped together. In this way, the first acoustic line is generated by crystals 1 to 32, the second acoustic line by crystals 2 to 33 and so on.

In connection with its extremely finely segmented scanheads, the sonoScope 30 produces 194 acoustic lines.

The quality of lateral resolution is, however, not only dependent on line density but also on the focussing of the ultrasound beams. By means of an electronic focussing system, this resolution can be improved. This involves

activating the individual crystals in a group in a temporally staggered fashion. As a result, the transmitted ultrasound signals come together as a concentrated beam at a certain depth and simultaneously. That is, the focal point depends on the staggered order in which the crystals are activated.

With the sonoScope 30, between 1 and 4 focal zones may be selected. Where all 4 focal zones are activated at any one time, the time required for creating an image becomes very great, so that the image frequency drops markedly to about 5 images per second.

In order to reduce the occurrence of side-lobe artifacts, the sonoScope 30 is equipped with "receiver dynamic focussing". The aim of this is to subject the ultrasound signals received by the corresponding crystals of a group to an electronic comparison. If all the crystals within a group receive identical information, the signal path is approved, since this is clearly a reflection from the beam axis. If, on the other hand, the crystals within a group receive signals that differ from each other in form and amplitude, this indicates that a side-lobe echo has been intercepted and the comparison circuitry prevents the image from reaching the screen.

A wide range of scanheads with various scanning geometries, frequencies and shapes is available for the sonoScope 30. These may be categorised into two types: using "linear" or "parallel scan" technology and the "sector" or "convex scan" technology.

Linear scan

Parallel or linear scan technology is today the preferred method for ultrasound diagnosis in advanced pregnancies, for displaying organs close to the surface such as the thyroid gland and also for mammary gland diagnosis. With this process, the structure to be displayed is scanned with the aid of tightly bundled parallel ultrasound beams, so that a rectangular image is created.

Thanks to its homogeneous line density and the resulting uniform resolution throughout the overall display depth, the linear method is particularly suited to the discovery of extremely fine parenchyme nonhomogeneity. Since the entire scanned width is available even at very close range, the method is well suited to the examination of larger organs just below the surface.
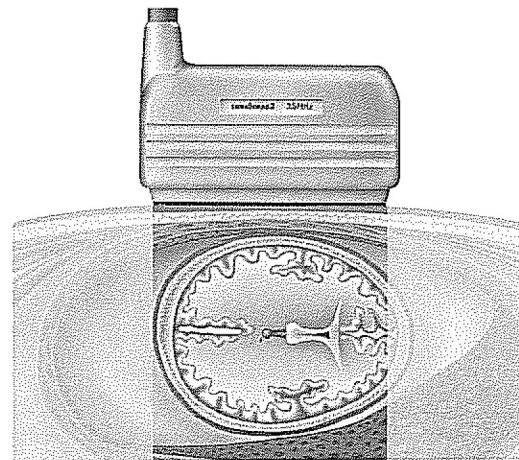
Convex scan

With the convex scan method, the scanning beams form a fan-shaped pattern radiating out from the scanhead, so that at close-range the acoustic lines are closer together than at a greater depth. As a result, the image has a trapezoid or triangular geometry. This method therefore presents an image virtually devoid of artifacts of organs more difficult to reach with ultrasound. To achieve this aim, small acoustic windows are used to penetrate the tissue using the fan-shaped patterns and avoiding bony or gas-filled structures. The most important fields of application are sonography in early pregnancy and diagnosis in the epigastric area.

When describing the scanning geometry, reference is made to the radius of the contact area and the sector angle. The smaller the radius and the larger the sector angle, the better these small acoustic windows may be utilised. However, at the same time, resolution diminishes with increased depth.
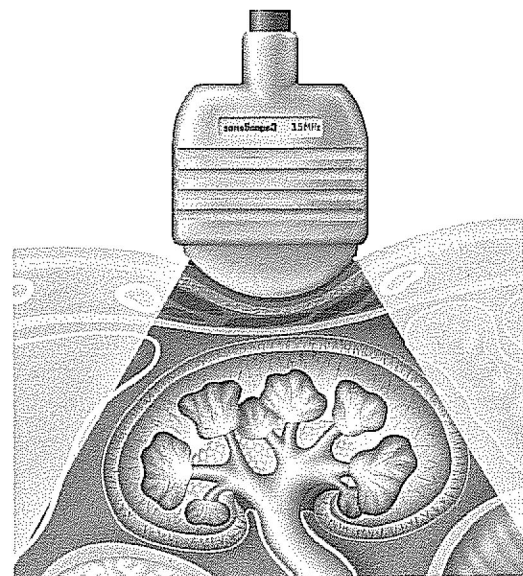
3.3. The range of scanheads

In order to cater for the widest possible range of applications using ultrasound diagnosis, the sonoScope 30 is available with a correspondingly broad range of scanheads.
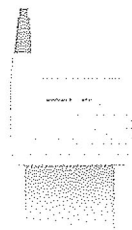
Low-frequency scanheads in general offer a wider field of view and a high depth of penetration and are as a result particularly suitable for the examination of the epigastric organs
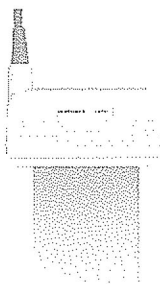
LSU-3 D
3.5 MHz
Electronic
linear array,
field of view 100 mm,
384 elements

LSU-3 A
3.5 MHz
Electronic
linear array,
field of view 85 mm,
384 elements

LSU-5 A
5 MHz
Electronic
linear array,
field of view 85 mm,
384 elements

LSU-5 G
5 MHz
Electronic
linear array,
field of view 50.2 mm,
384 elements

LSU-7 A
7.5 MHz
Electronic
linear array,
field of view 40.5 mm,
384 elements
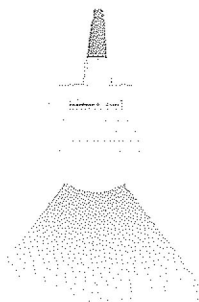
CSU-3 B
3.5 MHz
Electronic
convex array,
array radius 45 mm,
sector angle 75.4°,
384 elements
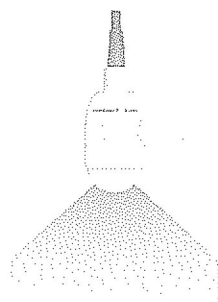
CSU-3 C
3.5 MHz
Electronic
convex array,
array radius 25 mm,
sector angle 97.3°,
384 elements

CSU-5 B
5 MHz
Electronic
convex array,
array radius 40 mm,
sector angle 60°,
384 elements
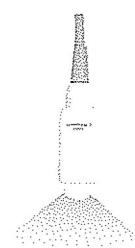
CSU-5 C
5 MHz
Electronic
convex array,
array radius 15 mm,
sector angle 97.3°,
384 elements

CSU-7 B
7.5 MHz
Electronic
convex array,
array radius 15 mm,
sector angle 97.3°,
384 elements
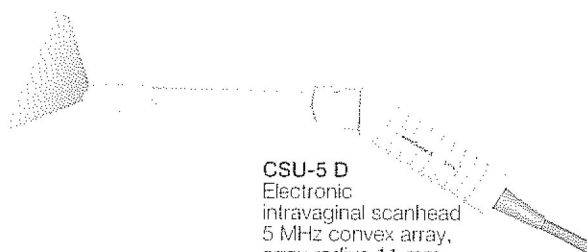
CSU-5 D
Electronic
intravaginal scanhead
5 MHz convex array,
array radius 11 mm,
sector angle 97.3°,
384 elements

LSU-5 F
Electronic
transrectal scanhead,
5 MHz linear array,
field of view 70.8 mm,
270 elements

4. Inputs and outputs; Connecting up accessories

4.1. Front of the unit

Remote connection

For video printer.
("PRINT" key)

Video output

For documentation printer.

Connections for video recorders

Where no video recorder is used, both connections must be jumpered with the aid of a connecting cable.

Video output

For additional video monitor etc.

Computer interface RS232

For data transfer of patient's name, ID, measured values etc. (not with model sonoScope 30 eco)

Connection for the ECG derivation cable

(optional extra)

Connection for the scanhead for general purposes (1)

Connection for a second scanhead (2)

Connection for the foot-switch

For activating the freeze frame function or the MACRO mode.

220 V Power supply

Only for such accessories as video printer and video recorder.

Caution:
Only units approved expressly by KRANZBÜHLER MEDICAL SYSTEMS for use in connection with the sonoScope 30 may be connected up.

Fuse for the 220 V connections

When exchanging damaged fuses ensure they are of the prescribed type.

4.2. Rear of the unit

Mains fuses

These fuses will burn out if the sonoScope 30 - usually as a result of a fault - draws excessive current from the mains. The fuses can however also burn out due to age, so that it becomes necessary to change them. When exchanging damaged fuses ensure they are of the prescribed type (6.3 A/T).

Connection for the mains lead for the power supply to the sonoScope 30.

Only the mains lead supplied may be used. Should in the individual case a replacement or longer mains lead be necessary, seek the advice of an authorised person.

The equipment may only be connected to 220V power outlets corresponding to valid safety requirements.

(Installation in accordance with VDE 0107).

4.3. Connecting up a video printer

A video printer is recommended for producing hardcopies of sonographs. The sonoScope 30 is factory-set to accommodate the Mitsubishi printer model P66E.

In order to transfer the ultrasound image, the (upper) video output connection of the sonoScope 30 is connected to the video input of the printer using a BNC cable. To allow the video printer to be operated from the keyboard of the sonoScope 30, the "remote connection" socket of the unit has to be connected to the "remote connection" of the printer. This will ensure that pressing the key "PRINT" on the keyboard will result in the printout of an ultrasound image.

Caution

In the interests of the safety of patients and personnel, the video printer should not be connected to a normal power outlet. In order to guarantee the greatest possible safety, we urgently recommend that accessories be connected exclusively to the 220 V outlets on the sonoScope 30. These outlets are voltaically isolated from the mains supply by means of the isolating transformer integrated in the sonoScope 30 so that even in the event of a fault in the supply, the danger to patients and operatives is minimised.
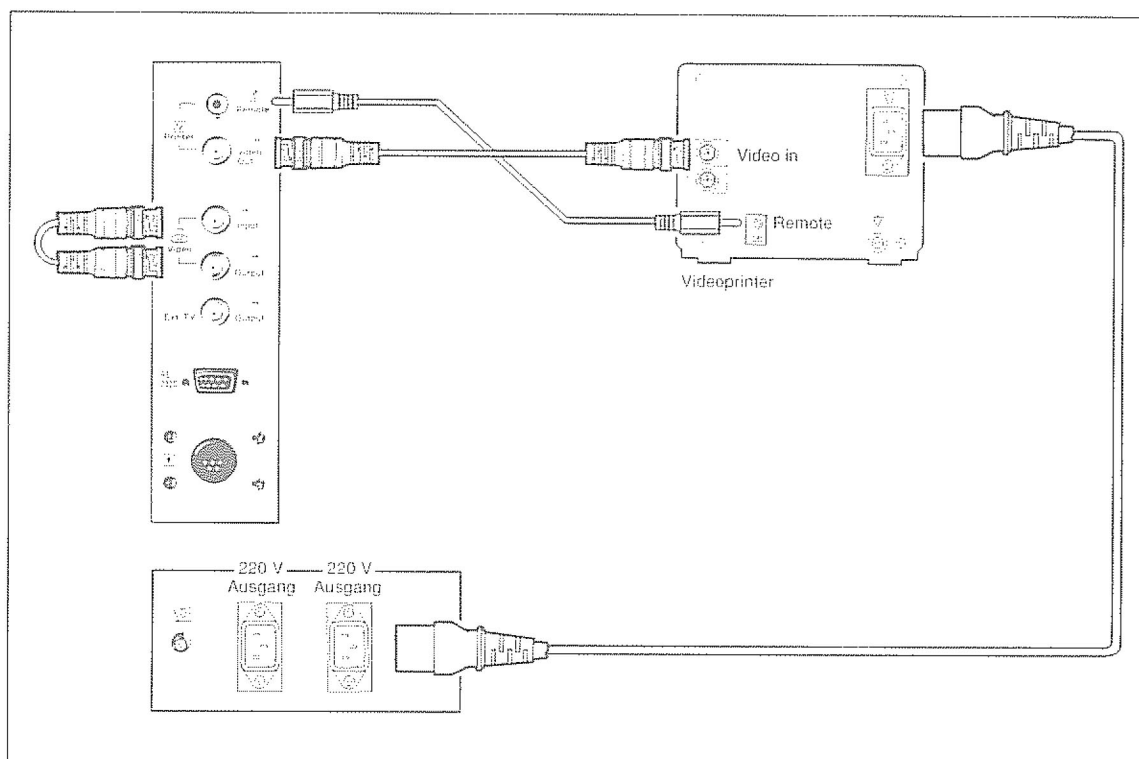
4.4. Connecting up a VCR

If it is required to connect up a VCR, both BNC connections marked "video input" and "video output" on the front of the unit are used. The image signal to be recorded and also displayed on the monitor is available at the "video output" connection, so that this output has to be connected to the input of the VCR. In order to monitor the image currently being recorded on the screen of the sonoScope 30, the output of the VCR has to be connected to the "video input" connection on the front of the unit.

Important

Only if the video recorder is switched on and the AV input of the recorder has been selected the inputs and outputs inside the recorder are connected directly to each other enabling the image from the scanhead to be viewed directly on the monitor screen. This applies as a matter of course to the "record" mode. If the video recorder is switched off or the TV receiver inside the recorder activated, no viewing of ultrasound images is possible.

If, on the other hand, existing video recordings are to be viewed on the monitor of the sonoScope 30, the recorder has to be switched to the "play" mode.

Should the VCR facility not be used, it is absolutely essential to connect up the video output and video input sockets using the cable supplied with the unit.

Caution

In the interests of the safety of patients and personnel, the video recorder should not be connected to a normal power outlet. In order to guarantee the greatest possible safety, we urgently recommend that accessories be connected exclusively to the 220 V outlets on the sonoScope 30. These outlets are voltaically isolated from the mains supply by means of the isolating
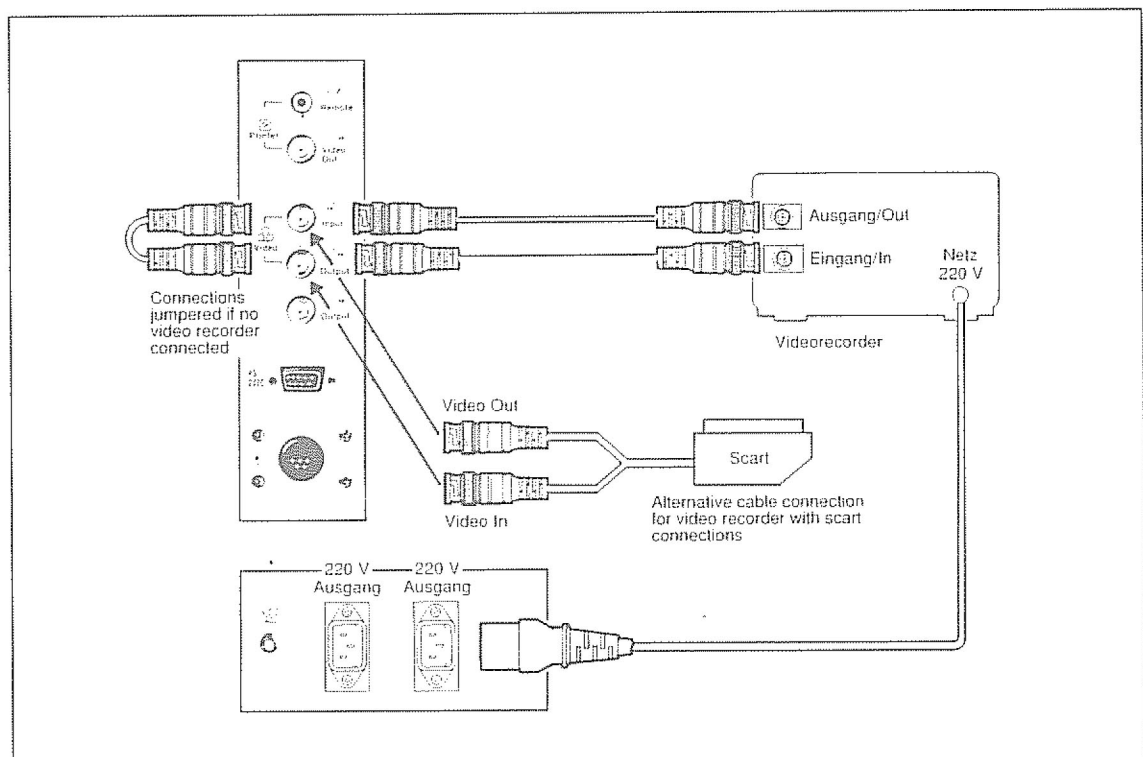
transformer integrated in the
sonoScope 30 so that even in the event
of a fault in the supply, the danger to
patients and operatives is minimised.

4.5. Connecting up an additional monitor

The application of an additional, larger monitor
can always be recommended where a larger
number of spectators are to be shown the
interpretation of sonographs, for example
during seminars. A further possible field of
application is the installation of a special
monitor for the patient. Placed in a suitable
position, that is, where possible, high up and
near the end of the examination couch, such a
monitor allows the user to display his findings
to the patient.

Only video monitors having a standardised
video input for BAS signals may be used.
Television sets equipped merely with an aerial
connection cannot be used.

Caution

In the interests of the safety of patients
and personnel, the video monitor
should not be connected to a normal
power outlet. In order to guarantee the
greatest possible safety, we urgently
recommend that accessories be
connected exclusively to the 220 V
outlets on the sonoScope 30. These
outlets are voltaically isolated from the
mains supply by means of the isolating
transformer integrated in the
sonoScope 30 so that even in the
event of a fault in the supply, the
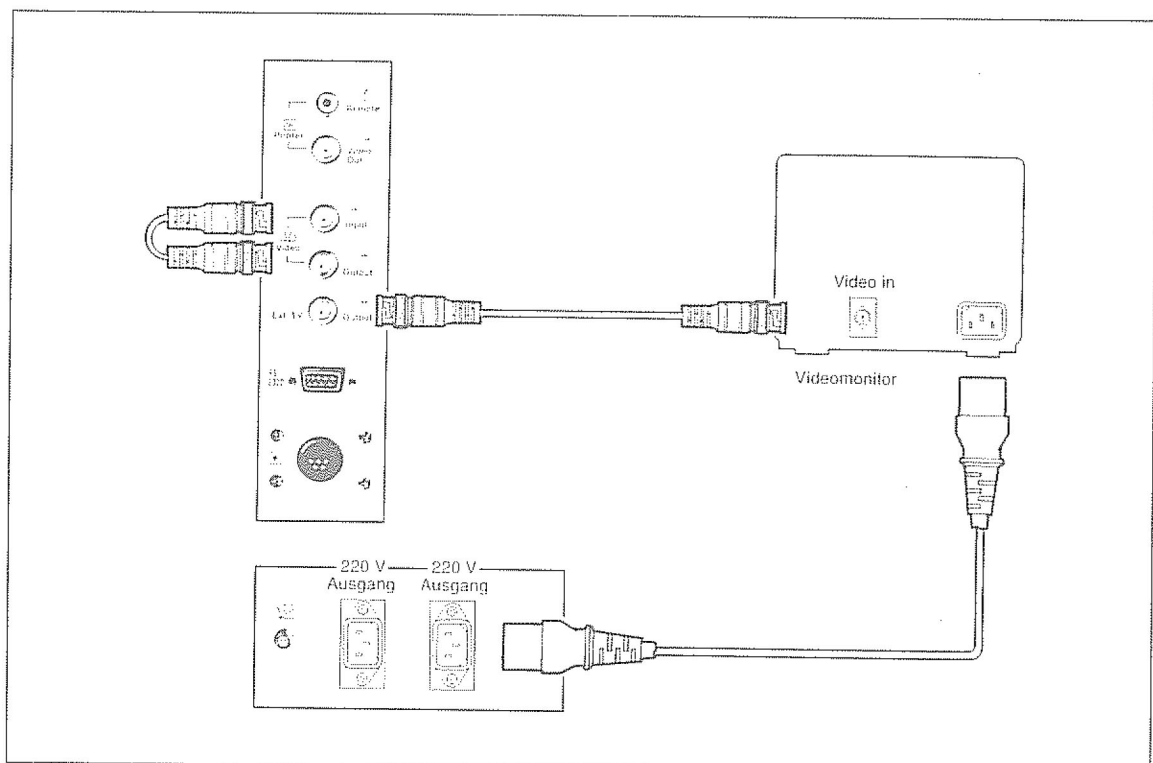danger to patients and operatives is
minimised.

4.6. Connecting up EDP systems

(Not possible with the sonoScope 30 eco model)

To facilitate data exchange with EDP systems the sonoScope 30 is equipped with an RS232 interface. With the aid of this interface the patient's personal data, measured values and results of calculations, for example, may be transferred from the sonoScope 30 to an external computer system. Similarly, a transfer in the opposite direction is also possible. This means that it would no longer be necessary, for instance, before the start of each examination to enter the name of the patient into the sonoScope 30 manually.

The interface requires a standard nine-pole sub-D plug-in connection which is to be found on the front of the unit below the video outputs (refer to section 4.1.).

The data output of the sonoScope 30 will require matching to the interface requirements of the computer to ensure trouble-free signal exchange:

– press the key marked | MENU |
The screen now displays the main menu.

– press menu key "5"(→), and the screen displays the second part of the main menu.

– use menu key "3" (RS232C) to select the interface, and the screen shows the following menu:

| SPEED | | BITS | | PARITY | | STOP | | → |
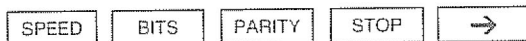
– as soon as menu key "5" (→) is pressed, the continuation of the RS232 menu appears.

| X ON/OFF | | | | | | PREV | | |
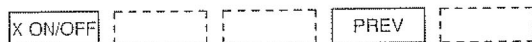
Functions:

SPEED   alters the baud rate. Each time the "SPEED" key is pressed, the display switches between 1200, 2400, 4800 and 9600.

BITS   offers the possibility of selecting a byte size of 7 or 8 BITS.

PARITY offers the possibility of selecting PARITY checks. Each time the "PARITY" key is pressed, the display changes between non, even and odd.

STOP   offers the possibility of selecting between a bit format of 1 or 2 for the STOP BITS.

X ON/OFF
   offers the possibility of switching the buffer control on or off.

The parameters selected are displayed above the corresponding menu fields.

Caution

When connecting up accessories which cannot, as a result of their physical distance from the sonoScope 30, be connected to the unit's 220 V outputs, there exists the possibility that the leakage current through the patient may reach unacceptably high values and become a hazard for the patient and user. For this reason, we urgently recommend that only computer components bearing the "GS" symbol be connected. In addition, after the computers have been connected up, a leakage current test must be performed to VDE 750-1/IEC 601.1 on the whole system. If required, the computer will have to be supplied from an isolating transformer designed for medical purposes.

5. Controls

5.1. Monitor

Brightness

Contrast
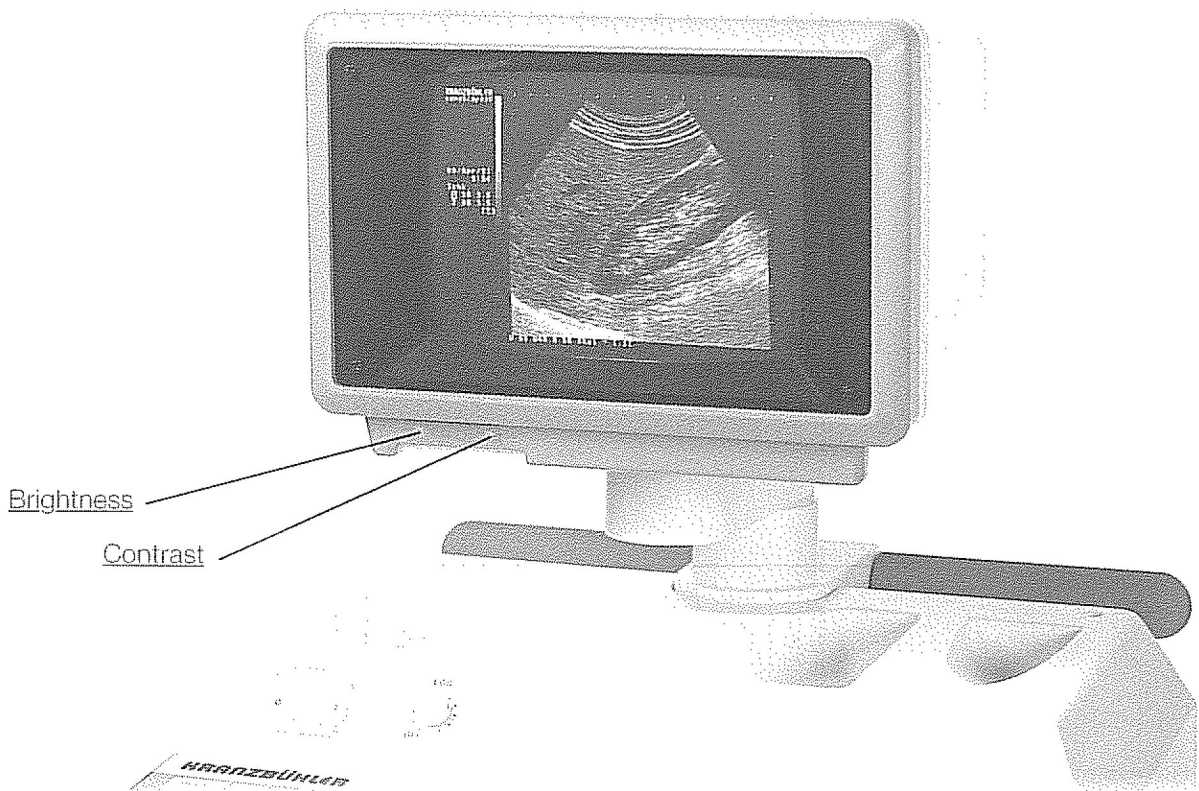
Since the human eye is constantly adapting to the brightness of its environment, and strong light leads to a lowering of the eye's sensitivity, additional light sources of only low intensity are difficult for the eye to adjust to.

However in order that even the dark grey shades of less echogenous structures may be clearly viewed on the video monitor of the ultrasound equipment, the eye must be distracted as little as possible by external light sources. The examination room should, therefore, be darkened to a large extent.

Using the controls "brightness" and "contrast" the light intensity of the monitor is adjusted to suit the brightness of the environment. In this respect turning the "brightness" control in a clockwise direction will increase the strength of all grey shades, so that even echo-free areas no longer appear black, but attain a certain degree of brightness.

This setting is necessary if the examination room cannot be sufficiently darkened.

The "contrast" control influences the brightness range of the monitor image. With a low contrast setting, the strong echoes are shown only slightly lighter than weak echogenous structures. With increasing contrast (turn clockwise) strong echoes appear lighter and weak echoes darker. In any case, brightness and contrast should be set in such a way that all the shades of the grey bar shown in the top left-hand corner of the monitor are recognisable and differentiated from each other. If the two brightest or the two darkest shades cannot be distinguished from each other and "blur" into each other, either the contrast must be reduced or the brightness altered.

5.2. Keyboard

ECG
Knob in combination with switch for switching ECGs on and off and for setting the amplitude.

MACRO
(Not available on sonoScope 30 eco model)
Activates the MACRO mode for the automatic selection of operating sequences.

Preset
Selects the first or second set of programmed default settings of the unit.

Scanhead
Switches over between the two connected scanheads 1 and 2.

Image annotation
Activation of the annotation cursor.

Mains switch
For switching on and off the sonoScope system and the additional 220 V connections.

Menu keys
For seldom required default settings and for selection of special functions (setting of date/time, programming growth tables etc.).

TGC
Time gain compensation setting for the echo signals.

Patient
It is absolutely essential to press this key with every change of patient. This deletes all patient's data and measured values from the preceding examination, resets the system to the switch-on status and activates the "enter patient's data" cursor.
Caution:
Without resetting, the measured values of different patients would be confused in an inadmissible way.

Zoom
Changes size of the displayed image.
Equally effective both in the real-time mode and with frozen images.

Dual-purpose knob
For setting the echo gain or the acoustic transmission power.

Echo gain
Use dual-purpose knob to set gain for the echo signals (overall gain).

Acoustic power
Use dual-purpose knob to set the transmitted acoustic power.

Pictograms
Overlaying body and scanhead symbols.
1st push:
   Trackball positions scanhead symbol.
2nd push:
   Trackball rotates scanhead symbol.
3rd push:
   Symbol fixed, use of the trackball is complete.
4th push:
   Pictogram is deleted.

Programs
MENSES:
   Enter the first day of the last menstruation to determine normal growth.
GEST. MENU:
   Lists the various biometry parameters for determining gestational age or normal growth.
cm³: Selects the program for calculation of volume.
   Calls up the program for determining angle relations at child's hip-joint.

Left/right inversion of the ultrasound image.

PRINT
Sends image to the video printer for documenting the screen display.

FREEZE
"Freezes" the ultrasound image.

Measuring function
+ + Activates the + cursors.
✕✕ Activates the ✕ cursors.
▭ Activates the circumference and area calculation modes.
CLR CLR resets the activated function.
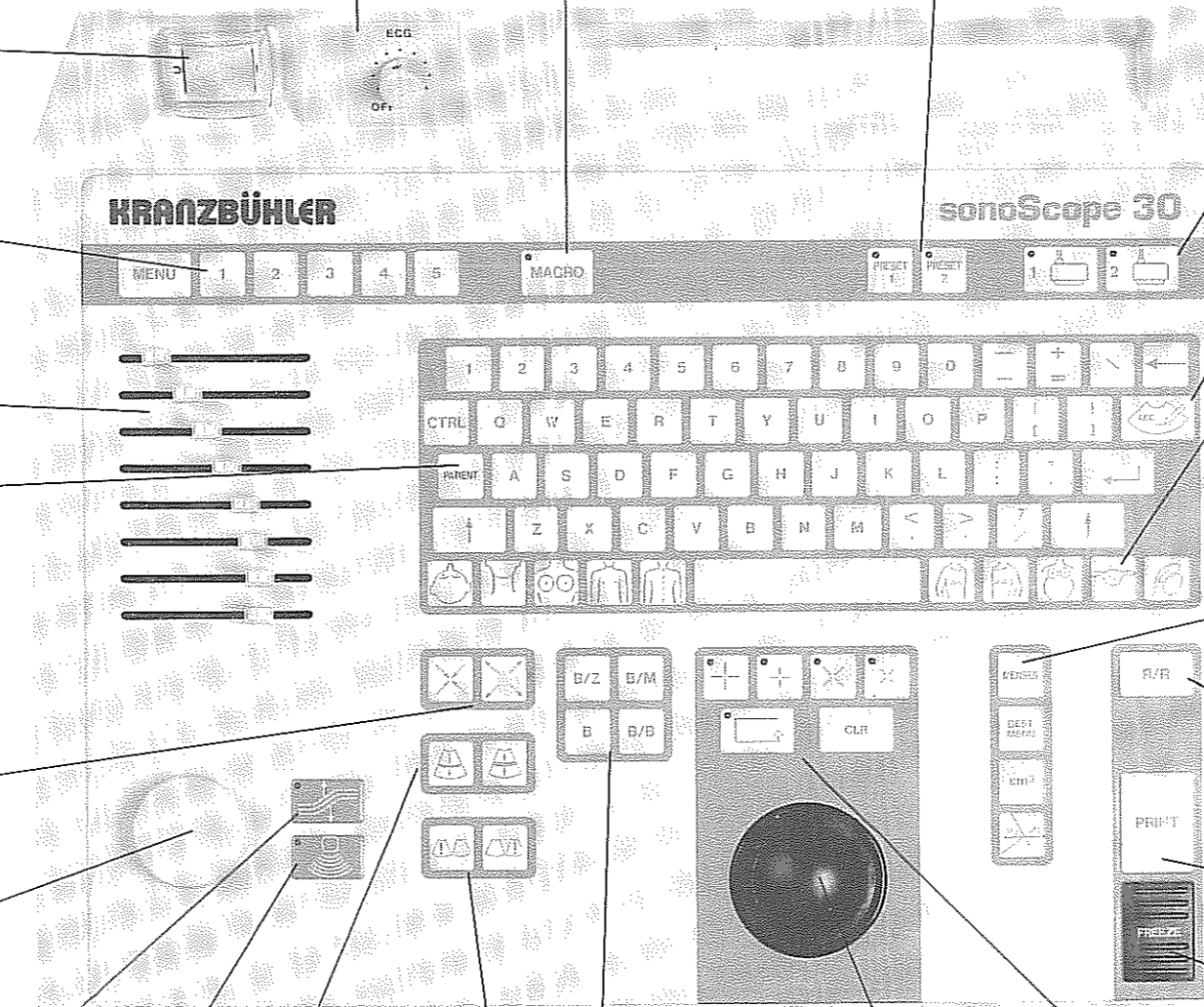
Focus
Alters the number of transmission foci in 4 stages. The more focus zones are activated, the lower the image frequency is.

Split screen selection
In the B/B-mode, this selects either the left or right half of the image; applies all subsequent operating steps to that half of the image (e.g. cursors, pictogram etc.).

Mode
B/Z: Simultaneous display of full-format image and magnified partial image.
B/M: Simultaneous display of 2D ultrasound image and M-mode.
B: Standard 2D mode.
B/B: Displays 2 images side-by-side.

Trackball
Depending on mode and selected operating step, the trackball allows the following functions:
– Horizontal and vertical scrolling of the zoomed image.
– Vertical shift of the zone of focus.
– Positioning of cursors and reference lines.
– Positioning of the scanhead symbol within the pictograms.
– Horizontal shift of the M line.
– Positioning of the annotation cursor.

KRANZBÜHLER   sonoScope 30

6. Initial commissioning

6.1. Mains connection

Caution

- Only the mains lead supplied with the unit may be used.

- Before connecting the mains cable, check whether the operating voltage of the unit is compatible with the local mains voltage (refer to rating plate on the rear of the unit).

- The mains lead supplied is to be connected to the mains input connection at the rear of the unit. The mains socket must comply with all valid safety instructions to VDE0107.

- If required, the potential compensation pin at the rear of the unit must be connected to the potential compensation at the place of installation.
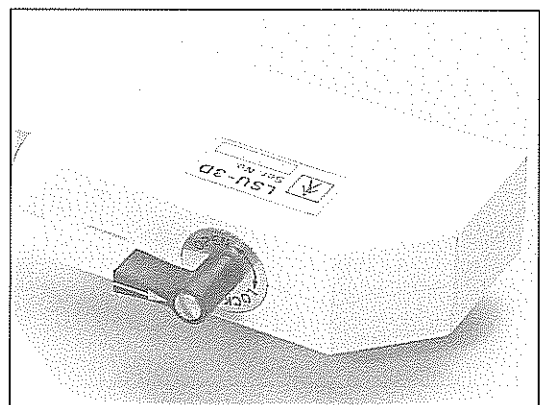
6.2. Scanhead connection

The scanheads are connected to the input connections marked "scanhead 1" and "scanhead 2" at the front of the unit. Before connecting the scanheads, check that the locking lever which stands proud of the plug casing is in the "OPEN" position. Insert the plug straight and without tilting into the socket (cable outlet to right), lock the plug in position by turning the lever in a clockwise direction through 90°.
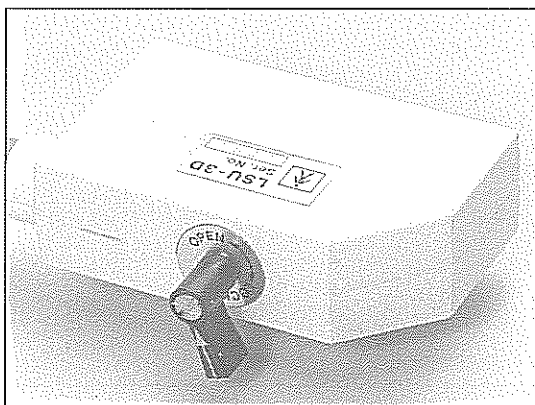
Position "open"

Position "lock"

Caution

- When connecting or changing the scanheads, the equipment should be either switched off or in the "freeze" mode.

- Large resistance encountered when connecting the scanhead plug indicates that it is tilted or the locking lever is in the wrong position. Check the alignment of the plug and position of the lever and, if required, correct. If the plug is fitted in a tilted position or with the locking lever locked, the contact pins may be damaged.

- Excessive bending or twisting of the scanhead lead can result in breakage of the connecting wires and lead to complete or temporary failure of the scanhead.

- Scanheads contain sensitive ceramic crystals which can be damaged by knocking or dropping.

- For details on cleaning the scanheads refer to section 14.

6.3. Connection of the foot-switch

A foot-switch is supplied as standard with the sonoScope 30, which may perform one of two tasks, depending on the mode the unit is in:

- In the "MACRO" mode, it activates the next operating step
  (not with sonoScope 30 eco model)

- In the normal mode, that is with the "MACRO" function deactivated, it "freezes" the ultrasound image.

The connection for the foot-switch is to be found on the left towards the bottom of the front of the unit. When inserting the plug ensure that the slot in the inner plug sleeve is at the top. As soon as the inner part of the plug locks in place, turn the union nut in a clockwise direction and simultaneously push the plug into place. After no more than half a turn, the bayonet lock of the outer sleeve will lock in place, and the plug is secure.

6.4. Switching on the sonoScope 30

Switch on by setting the mains switch above the keyboard to the position marked "I". The green status lamps in the keys marked "preset 1", "scanhead 1" and "overall gain" light up; at the same time, the fan motors at the rear of the unit should start and be just audible. After some seconds the background graphics should also appear on the screen - that is the grey bar, the centimetre scale, date, time etc. If this is not the case, check whether the contrast control on the monitor has erroneously been left turned hard to the left. If required, adjust brightness and contrast of the monitor so that all shades of the grey bar are recognisable and distinguishable from each other (refer also to section 5.1.).
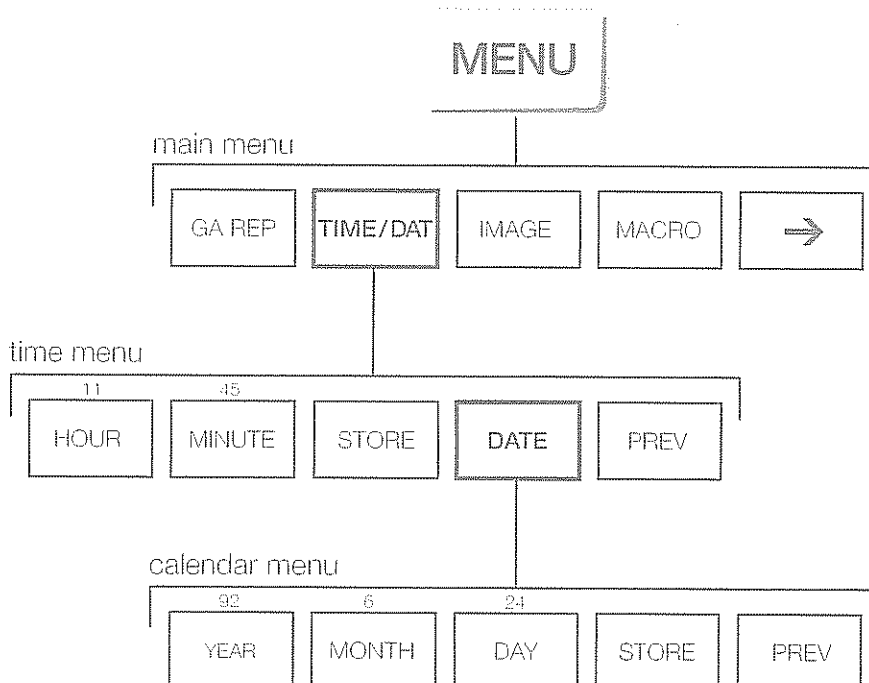
6.5. Programming the time, date and name of the clinic

The sonoScope 30 is equipped with a calendar and clock fed by a long-life lithium battery. The clock is set on installation by the installing technician. If it should become necessary to reset the clock, proceed as follows:

6.5.1.Setting the time

MENU

– Press the key marked
The monitor displays the five fields of the main menu.

– Press menu key "2" (TIME/DAT). The screen shows the menu for setting the time.

– If the hour setting needs changing, press menu key "1" (HOUR) as long as it takes to display the correct hour above the hour field.

– If the minute setting needs changing, press menu key "2" (MINUTE) as long

as it takes to display the correct minute above the minute field.

– Pressing menu key "3" (STORE) confirms the entry and completes the procedure.

– If it is not desired to confirm and store a new time (e.g. due to erroneous selection of the time menus), the menu may be left by pressing key "5" (PREV).
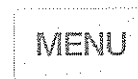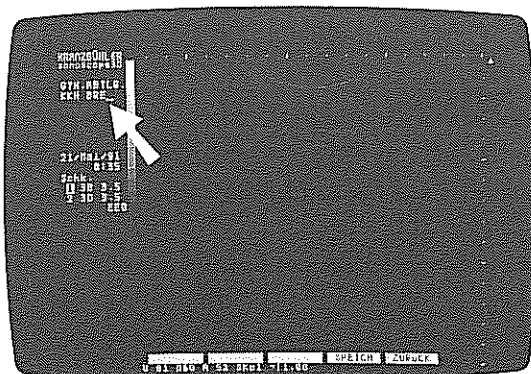
MENU

main menu

| GA REP | TIME/DAT | IMAGE | MACRO | ⇒ |

time menu

| HOUR | MINUTE | STORE | DATE | PREV |

calendar menu

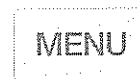| YEAR | MONTH | DAY | STORE | PREV |

6.5.2. Setting the date

– Press the [MENU] key. The screen displays the five fields of the main menu.

– Press menu key "2" (TIME/DAT); the screen shows the menu for setting the time.

– Press menu key "4" (DATE), and the screen shows the menu for setting the date.

– To set the year, press menu key "1" (YEAR), until the desired year appears above the menu field.

– To set the month, press menu key "2" (MONTH) until the number of the corresponding month appears above the menu field.

– To set the day, press menu key "3" (DAY) until the number of the desired day appears above the menu field.

– Menu key "4" (STORE) confirms the entry and completes the procedure.

– If it is not desired to confirm and store a new date (e.g. due to erroneous selection of the date menus), the menu may be left by pressing key "5" (PREV).

6.5.3. Entry of name of clinic or name of doctor.

In the upper left-hand corner of the screen below the logo "sonoScope 30" is a three-line field for permanently displaying the name of the clinic or doctor. In order to program this name, proceed as follows:

– Press the [MENU] key. The screen shows the five fields of the main menu.

– Press menu key "5" (→), so that the second part of the main menu is displayed.

– Press menu key "2" (HOSPITAL); in the upper left-hand corner of the screen appears a cursor.

– Key in the clinic or doctor's name (three lines with 10 characters each).

– Press menu key "4" (STORE). This confirms the entry, saves it and completes the procedure.

This completes the preparatory steps for using the sonoScope 30. The unit is now ready for use.

7. Operating steps during the examination

7.1. Deleting redundant data

Caution

It is absolutely essential to press the [PATIENT] key with every change of patient in order to prevent confusion of patient's data and in particular to prevent data becoming merged in an inadmissable way.

7.2. Entering the patient's name

Pressing the [PATIENT] key activates the cursor in the upper lefthand corner of the screen – below the name of the clinic or doctor. With the aid of the alphanumeric keyboard, enter the name, date of birth, patient's number etc. in this space.

The trackball also controls the position of the cursor directly, so that it is possible to jump a line or reposition the cursor very quickly to carry out corrections.

Pressing any function key will deactivate the new patient cursor again and the trackball.
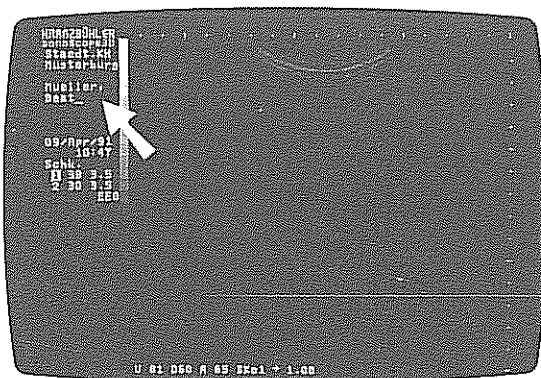
7.3. Entering the last·menstruation date

If, during a sonographic pre-natal examination where the gestational age is known, it is required to check the foetal growth, we recommend entering the last menstruation date before the beginning of the examination. To do this, press the [MENSES] key.

In the lower right-hand corner of the screen, enter the DAY, the MONTH and the YEAR in that order as two-digit numbers.

Pressing any function key will store the date entered in the data memory and the screen display is cleared.
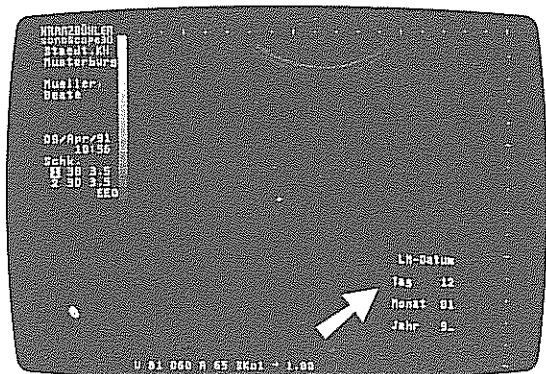
7.4. Scanhead selection

Press the scanhead buttons to activate the scanhead required (when the sonoScope 30 is switched on, scanhead 1 is automatically activated).

7.5. Setting the acoustic transmission power

The sonoScope 30 offers the user the possibility of varying the transmitted acoustic power to a large degree. The application of a high power output will, however, only be beneficial if the transmitted ultrasound pulse is considerably weakened by strong echogenous tissue or where there is a marked change in tissue density or elasticity so that the deeper structures, despite correct setting of gain and depth compensation, are disturbed by strong background noise. In such cases, it is possible to improve the depth of penetration by about 2-4 cm by using the full power output.

The setting is carried out using the dual-purpose knob, assuming the [image]

key has been pressed beforehand. The selected power is displayed on the lower edge of the screen in % (1 - 100), e.g. A 12.

Before beginning the examination, the power should be set initially to a low value – for example between 1 and 10 % and, if necessary, raised during the examination to a greater intensity.
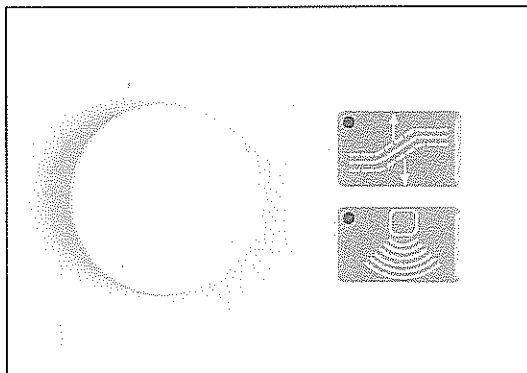
7.6. Setting the depth-independent overall gain

Before beginning the examination it is advisable to set the depth-independent overall gain to a "default value" of approx. 80 dB. To do so, press the key marked [image]

so that the dual-purpose knob functions as the control for the overall gain. The selected

amplification factor is displayed at the lower edge of the screen, e.g. V 80.

During the examination and after setting the depth compensation the overall gain is set and, if necessary, adjusted when the image level changes, in such a way that liquid-filled areas, including larger veins, are displayed to a large extent free of artifacts and noise, but, on the other hand, weak echogenous structures appear dark grey but not completely black.
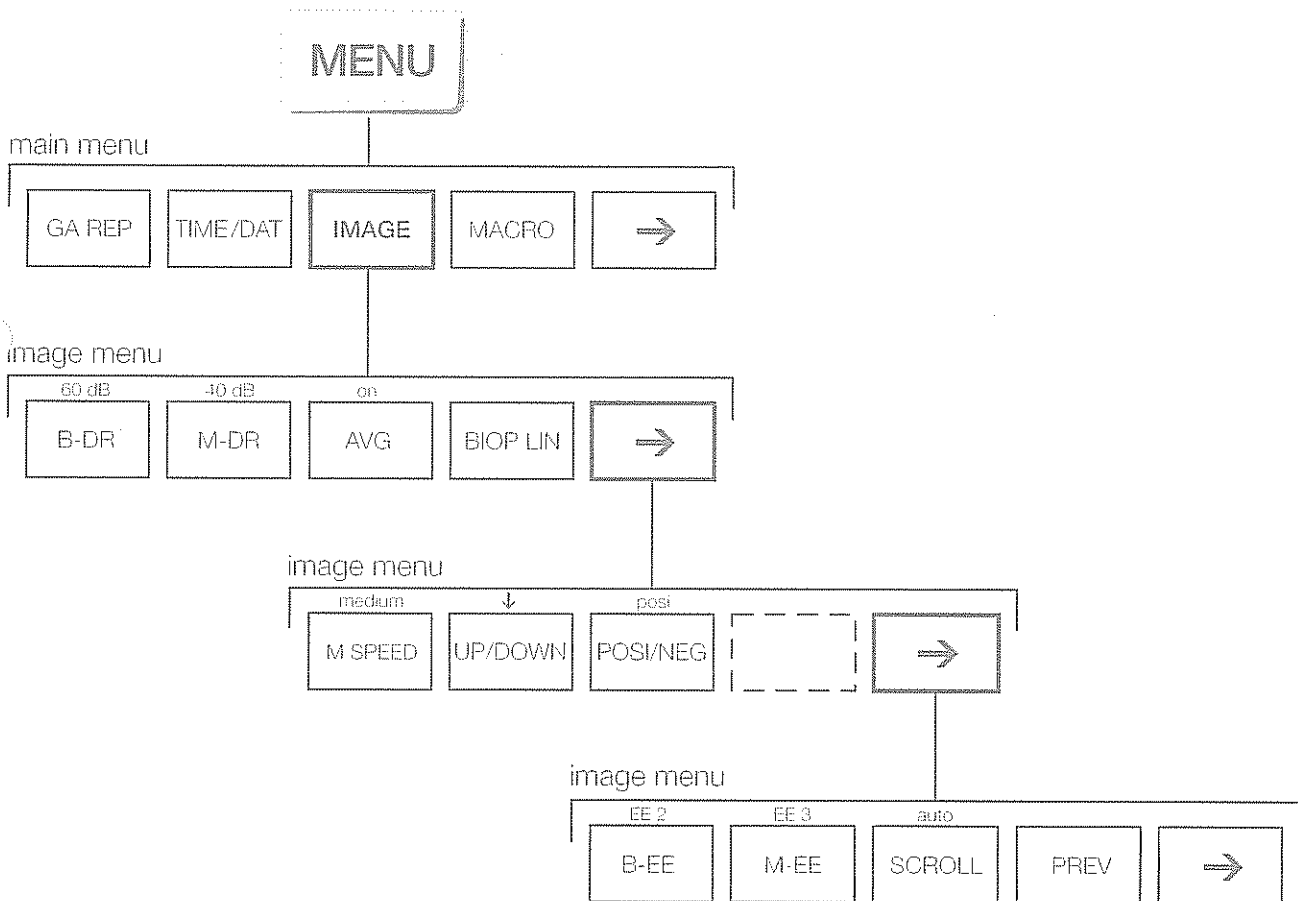
7.7. Depth selective setting of the gain compensation (TGC)

After the scanhead has been applied to the area to be examined using a suitable ultrasound contact jelly, and the required region located, the time gain compensation (TGC) is set. The 8 slide controls of the TGC allow the optimum echo gain to be selected for each depth range, so that uniform echo imaging throughout the overall display depth is achieved.
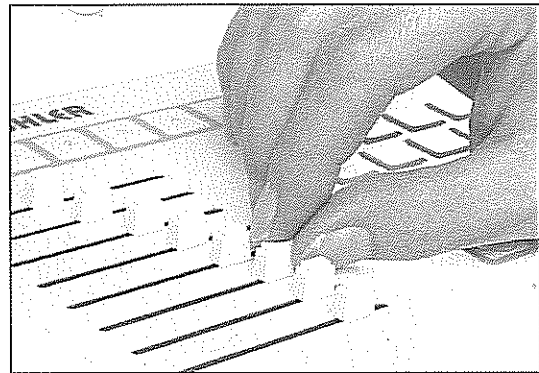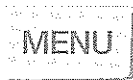

7.8. Dynamic range

The sonoScope 30 offers a large dynamic range of 60 dB (decibels), so that as wide a spectrum as possible of most varied echo intensity is converted into corresponding grey values. For some applications – e.g. in foetometry or the angle measurement of hip joints – however a hard, strong contrast and the suppression of weak echoes is of

MENU

main menu

| GA REP | TIME/DAT | IMAGE | MACRO | → |

image menu

| 60 dB | 40 dB | on | | |
| B-DR | M-DR | AVG | BIOP LIN | → |

image menu

| medium | ↓ | posi | | |
| M SPEED | UP/DOWN | POSI/NEG | | → |

image menu

| EE 2 | EE 3 | auto | | |
| B-EE | M-EE | SCROLL | PREV | → |

advantage, so that bone contours are better distinguished. In this connection, the sonoScope 30 offers the possibility of reducing the dynamic range:

MENU

– Press the [MENU] key; the main menu appears on the screen.

– Press menu key "3" (IMAGE), and the menu for adjustment of the dynamic range appears.

– By means of repeated pressing of menu key "1" (B-DR), the unit switches from 30 dB to 60 dB in 5-dB steps. The dynamic range selected appears above the menu field.

Apart from the above-mentioned cases, the full dynamic range of 60 dB should, wherever possible, be made use of, so that weak echogenous structures are not erroneously displayed as black.
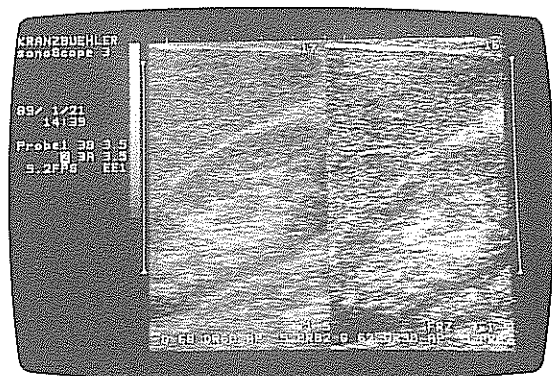
7.9. Edge enhancement

When radiating ultrasound pulses, every quartz crystal is inclined to oscillate longer than actually desirable. As a result, each transmitted pulse and thus also each echo has a certain temporal and therefore physical expansion in an axial direction. For this reason, each echo point displays a certain blurred image around its edges.

The "edge enhancement" function improves the contours of each echo point artificially by not displaying the echoes returning from within the body to their full extent.

The overall effect of edge enhancement in this way is a clarification of the contours; the texture of the tissue is made clearer.

The sonoScope 30 offers edge enhancement in three steps which can be activated as required:

                                    MENU

–   Press the ⌐MENU⌐ key; the main menu appears on the screen.

–   Press menu key "3" (IMAGE), and the first part of the image-processing menu appears.

–   Press menu key "5" (→) twice, and the menu for adjustment of edge enhancement appears.

–   Press menu key "1" (B-EE) repeatedly. Above the menu field appear in the form of a single-digit number the details of the selected EE step (0 = without edge enhancement, 3 = maximum edge enhancement).

7.10. Frame averaging for suppressing noise

The sonoScope 30 offers the possibility of frame averaging, that is the complementary overlay of two consecutive images with the aim of reducing background noise.

As a consequence of this normally advantageous frame averaging, however, the system loses the ability to represent faster movements realistically.

For this reason we recommend that the frame averaging function be switched off during echocardiographic examinations and particularly also during examination of the foetal heart:

–   Press the ⌐MENU⌐ key; the main menu appears on the screen.

–   Press menu key "3" (IMAGE), and the menu for changing the dynamic range and for switching frame averaging on and off appears.

–   Press menu key "3" (AVG) to activate or deactivate frame averaging. The selected status – ON or OFF – is displayed above the menu field "AVG".

7.11. Selecting the focal zones

The number of transmitted foci is selected with the two keys for magnification or for diminution of the range of focus.
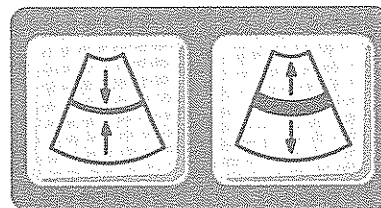

The user has the possibility to select from a total of 4 focal zones and in this way to decide whether to focus on a point – at a certain depth – or to display virtually uniform image resolution of the overall depth. In this respect it is to be noted that the greater the number of transmitted foci the lower the image frequency becomes. This means that,

where all four focus levels are in use, image frequency is reduced to only about 4 – 5 images per second, so that the representation of fast movement is no longer possible.

Where single-point focus is used, the focal point may be vertically displaced with the aid of the trackball and positioned in an area of particular interest for the examination. The position and length of the range of focus are displayed on the right side of the screen by means of a vertical bar.

7.12. Zooming / changing image size

Image size or scale of representation are altered with the two zoom keys.
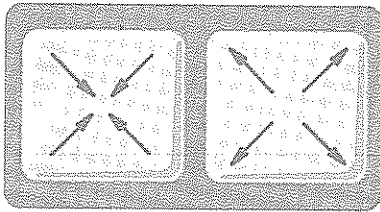
Size alteration is carried out in extremely small steps* and covers a setting range of approx. 1:2 up to 3.8:1 (dependent on the scanhead used).

The section of the image to be displayed is selected and positioned with the aid of the trackball.

The setting of the image size can take place both during the examination - that is, in the real-time mode - and also after an ultrasound image has been frozen. This results in the interesting possibility of being able to zoom in on details after the examination has been completed.

7.13. Left / right inversion

As far as the direction of projection is concerned, the scanhead is normally placed in such a way that for lateral sections the patient's right-hand side appears on the left of the screen, so that the user is looking at the patient's section from a caudal position. With longitudinal scans, the cranial side of the patient should be displayed on the left of the screen.

If, during the examination process the user decides that the direction of projection is not in accordance with the usual standard, he should – as much as anything to prevent the scanhead lead becoming twisted – not rotate the scanhead but rather invert the image "electronically". To do this, the ⌐ R/R ⌐ key is pressed.

Every time this key is pressed, the screen image is inverted from left to right or vice versa.

* With the sonoScope 30 eco model there are only four steps

## 7.14. Selecting the display and operating mode

Apart from display type "B", the simple display of the ultrasound image, the sonoScope 30 additionally offers the following modes:

B/B-mode
The screen shows two ultrasound images one beside the other. When this mode is selected, the ultrasound image jumps across to the left half of the screen. Pressing the [key symbol] key activates the right half of the screen and the image on the left is frozen. Pressing the [key symbol] key will once again activate the left half of the screen and the image displayed on the right remains frozen. If both halves of the screen are to appear frozen simultaneously, the "freeze" key must be pressed.
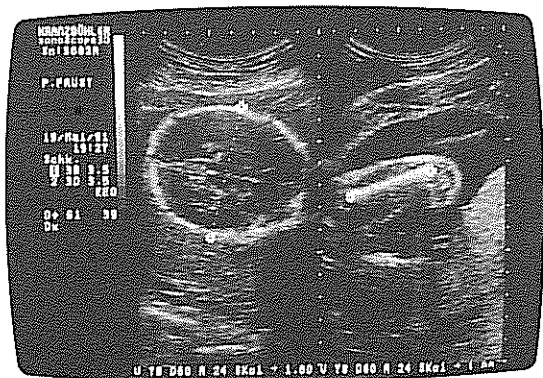
B/Z mode
This mode offers the possibility of displaying a full-format image and a partial magnification side-by-side. The left-hand side of the screen displays the full-format image and, additionally, a white frame, corresponding to the magnified area shown on the right-hand side of the screen. With the aid of the trackball, this frame may be positioned at will; the zoom keys allow a change of the scale of magnification.
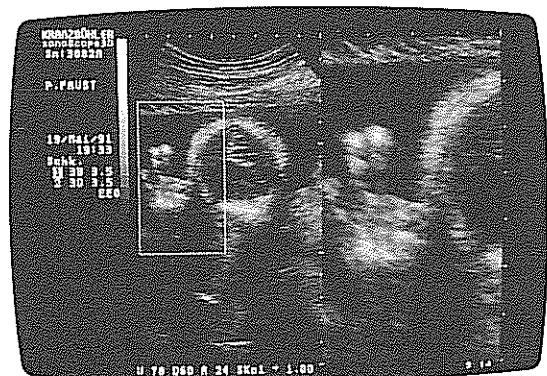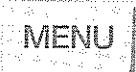
B/M-mode
In this mode a basic echocardiographic diagnosis may be carried out and evidence of foetal heart activity documented. When the B/M-mode is selected, the ultrasound image jumps to the left half of the screen; the M-mode appears on the right. The so-called "M line", the line the M-mode is gained from, can, with the aid of the trackball, be displaced horizontally on the screen and overlaid over the structures to be analysed.
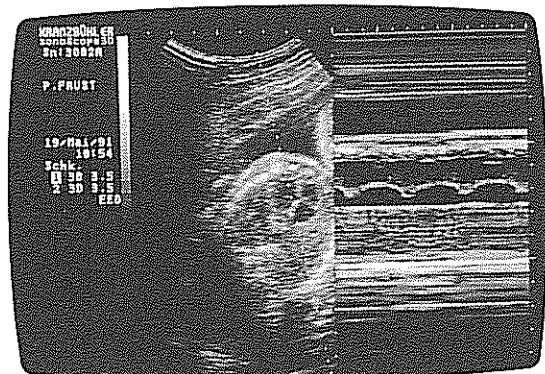
The scroll speed in the M-mode can be altered in the menu:

– Press the **MENU** key, the main menu appears.

– Press menu key "3" (IMAGE), and the screen shows the image-processing menu.

– Press menu key "5" (→), and a further image-processing menu appears.

– Press menu key "1" (M SPEED) repeatedly; every time the key is pressed, the M-mode scroll speed moves between "slow", "medium" and "fast". The current status is displayed above the menu field.

– Independent of the setting for the B-image, a number of special settings are available for the M-mode for the dynamic range and for edge enhancement. The possible settings are to be found in the menu under the field marked "IMAGE".

MENU

main menu

| GA REP | TIME/DAT | IMAGE | MACRO | → |

image menu

| 60 dB | 40 dB | on | | |
| B-DR | M-DR | AVG | BIOP LIN | → |

image menu

| medium | ↓ | posi | | |
| M SPEED | UP/DOWN | POSI/NEG | | → |

image menu

| EE 2 | EE 3 | auto | | |
| B-EE | M-EE | SCROLL | PREV | → |
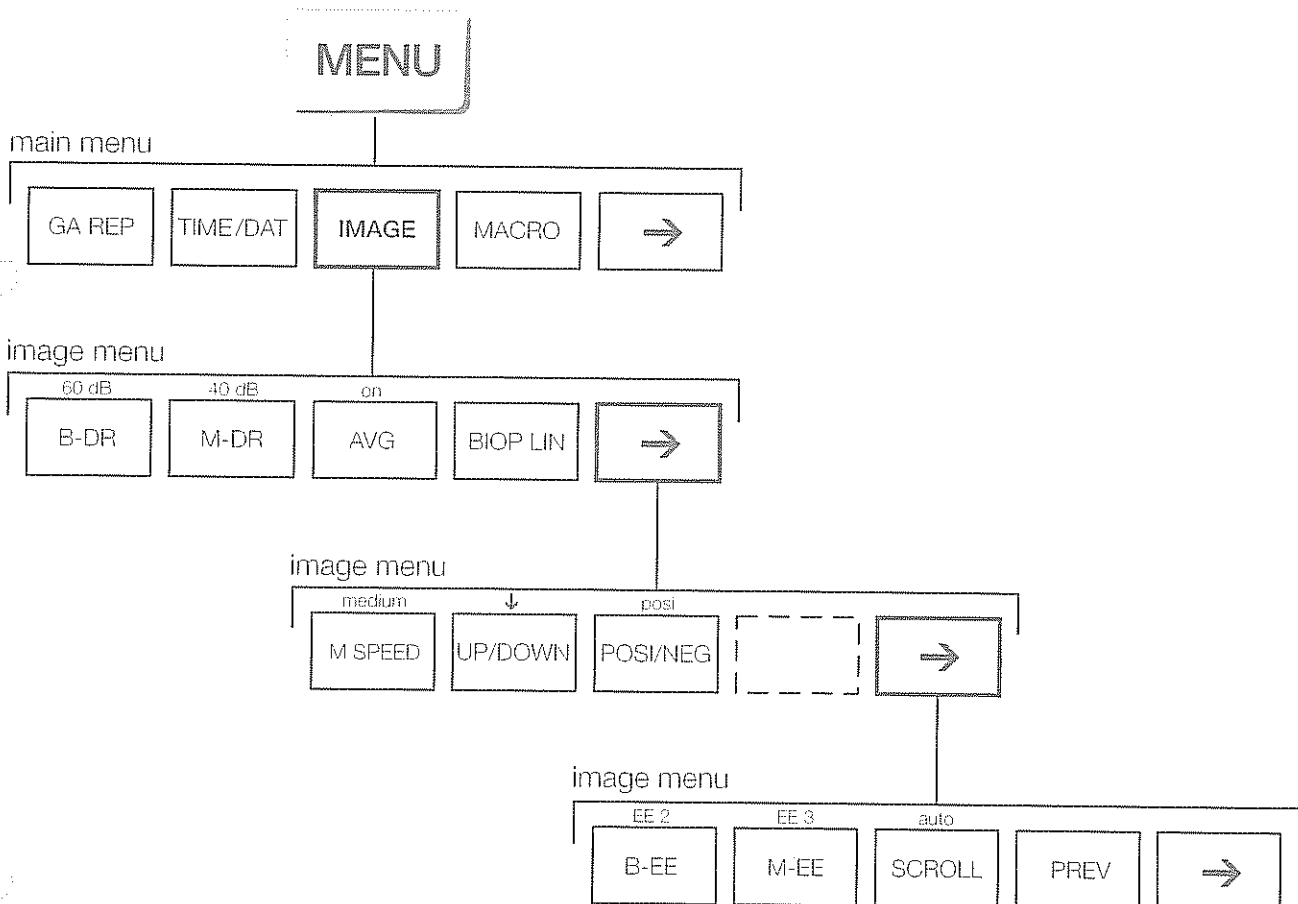
7.15. Freeze frame

Measurements, calculation and additional image annotation are facilitated if the ultrasound image has been frozen on the screen beforehand. In this connection, the sonoScope 30 offers two possibilities, namely

− with the freeze-key on the keyboard

and

− with the foot-switch.

The image can be retained as long as desired and without loss in quality. The contents of the image storage facility are not impaired or lost until the unit is switched off or as a result of a power failure.


7.16. Displaying pictograms

In order to aid documentation of an examination, the sonoScope 30 is equipped with the possibility of displaying body symbols on the screen. In addition, a scanhead symbol is overlaid which retrospectively allows exact reconstruction of the scan plane examined.

In order to display a pictogram proceed as follows:

− Press the desired pictogram key, and immediately the selected body symbol appears on the screen.

− Using the trackball, position the scanhead symbol.
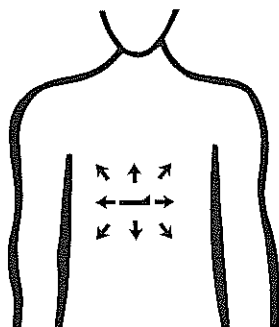
− Press the pictogram key once again.

− Using the trackball, rotate the scanhead symbol to represent the scan direction.
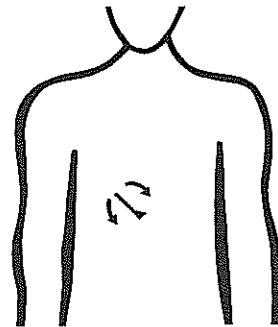
− Press the pictogram key once more; the pictogram is now fixed, and the trackball function is reset.

− A pictogram may be deleted simply by pressing the corresponding pictogram key again.

In the double image mode (B/B-mode) the sonoScope 30 allows a separate pictogram to be displayed over each half of the screen. The allocation is carried out with the [⚠] key for the left half of the image and with the [⚠] key for the right side.

7.17. Image annotation

In order to round off the documentation functions, the ultrasound images may be marked and for example the examination results noted. Press the image annotation key and the cursor appears

in the upper left-hand corner of the ultrasound image. This may now be positioned at any point in the ultrasound image using the trackball. Results and comments of unlimited length may now be entered with the aid of the alphanumeric keyboard.

If the measuring function is activated or another function key pressed, the annotation cursor will be deactivated. The text entered remains on the screen until the annotation key is pressed again. In this case, image annotation will be deleted and the annotation cursor returns to the upper left-hand corner of the screen.

Similarly, any text entered will be deleted if the PATIENT key is pressed before a new examination begins.

7.18. Printing out an image

In order to produce hardcopies of the sonographs for documentation of results, it is advisable to make use of the video printer model P66E by Mitsubishi for which model the sonoScope 30 has been prepared.

Provided the video printer has been correctly installed, it is sufficient to press the PRINT key on the keyboard of

the sonoScope 30 to start the printout of an image. In order to accelerate the process, the current content of the screen is transferred to the video printer where it is stored in a frame memory. For this reason it is not necessary to interrupt the

examination until the printout of the image is complete. Quite the contrary, as soon as the "PRINT" key has been pressed, the examination may be continued.

7.19. Special settings

Top / bottom inversion

In order to be able to approach special applications more efficiently, the sonoScope 30 has the facility to invert the ultrasound image displayed on the monitor in such a way that the structures nearest to the scanhead are at the bottom and those furthest away from the scanhead at the top of the screen. To do so, proceed as follows:

– Press the MENU key, the screen shows the main menu.

– Press menu key "3" (IMAGE), and the screen shows the initial image-processing menu.

– Press menu key "5" (→), and the screen shows the second part of the image-processing menu.

– Using menu key "2" (UP/DOWN) the operator may now switch between the "normal" and the inverted display.

Note:
  When the intravaginal scanhead is used, the ultrasound image is automatically inverted.

Black / white inversion

Normally, when ultrasound images are displayed, the echo information is displayed in the form of white dots on a dark background. However, for some particular applications, the sonoScope 30 has the facility to invert this display mode, that is the echo information is represented as black dots on a white background.

To do this, proceed as follows:

- Press the **MENU** key; the screen shows the main menu.

- Press menu key "3" (IMAGE), and the screen shows the initial part of the image-processing menu.

- Press menu key "5" (→), and the screen shows the second part of the image-processing menu.

- Menu key "3" (POSI/NEG) now offers the possibility to switch back and forth between both display types.

7.20. Overlaying biopsy lines

In order to facilitate ultrasound aided puncture, the cannulization prescribed by the needle path may be shown on the screen. The needle path used is automatically recognised depending on the scanhead connected (TRT, IVT or 45 mm convex scanhead).

- Press the **MENU** key; the screen shows the main menu.

- Press menu key "3" (IMAGE), and the screen shows the initial part of the image-processing menu.

- Menu key "4" (BIOP LIN) permits the biopsy guidelines to be displayed or suppressed.

8. Measuring programs

Rapid measurement of biometric data plays an essential role where sonographic diagnosis is concerned. For this reason, the sonoScope 30 offers the possibility of measuring two distances independently of each other as well as calculating circumference and surface area. In the B/B-mode this possibility exists in each half of the image separately, so that in total 4 distance measurements and 2 circumference and surface area measurements can be carried out independently of each other. The cursors are positioned for all measurements using the quick-reacting and delay-free trackball.
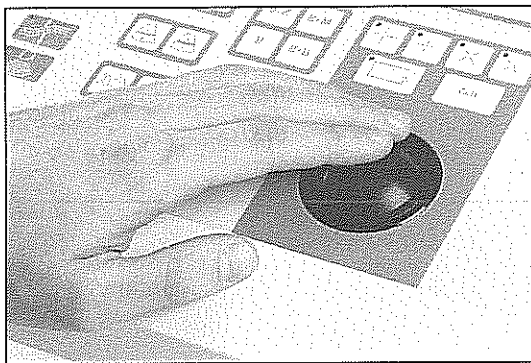

8.1. + distance measurements

Pressing the [key] key (large + symbol) activates the first distance-measuring process. Use the trackball to position the large cursor at the starting point of the object to be measured.

Pressing the [key] key (small + symbol) activates the first distance-measuring process. Use the trackball to position the large cursor at the starting point of the object to be measured.
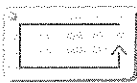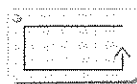
8.2. ✕ distance measurements

For the second independent distance measurement, proceed as described before but using only the keys marked

[key] and [key] . The measured distance is again displayed at the left-hand edge of the screen beside the ✕ symbol.

8.3. Circumference measurement

The [key] key activates circumference calculation. The trackball is used to position the cursor at the starting point of the measurement. Pressing the key again permits the cursor to be moved in a circle around the object using the trackball, whereby a line is displayed on the screen.

Pressing the [CLR] key enables the operator to delete the last section of the line if an error is made. Once the circumference of the object has been marked, circumference calculation is completed by pressing the [key] key again.

The circumference is displayed at the left-hand edge of the screen:

$$C = ...mm.$$

8.4. Calculation of surface area

In order to calculate the surface area of the figure, proceed as described above. After the circumference has been displayed, press the [key] key again. The area of the figure marked is displayed at the left-hand edge of the screen:

$$A = ...cm^2.$$

8.5. Deactivating the measuring program

In order to delete the cursors, measuring lines and measurements, press the [CLR] key.

Similarly, if another mode or a different scale is selected or the "PATIENT" key pressed, the graphic display will also be deleted.
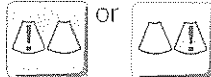
8.6. Measurements in the B/B-mode

In the B/B-mode two distance measurements and a circumference calculation can be carried out independently of each other in each half of the screen. To do this, before calling up the measuring program, select the desired half of the screen with the key marked [△△] or [△△]

On completing the measurements in one half of the screen, the other half of the screen must first be selected and then the measuring function activated again.

8.7. M-Mode measurements

The presentation of echo signals and their movement on a horizontal time axis are typical features of an M-mode, which provides the possibility to quantitatively determine amplitudes as to movement and velocity, as well as time intervals.

If measurement cursors are activated in the M-mode and placed at the anterior mitral leaflet (see the picture), the sonoScope 30 provides information on:

– the axial (vertical) distance "D" between the measurement cursors, i.e. the amplitude of the valve leaflet movement,

– the time (horizontal distance) interval "Z" between the measurement cursors, i.e. the time spent for mitral valve closing,

– the velocity "G", which is automatically calculated from these two values.

All three values can be made use of during "+" distance measurements as well as during "x" distance measurements. When activating the "+" measurement cursors the time interval (horizontal distance) between the cursors is additionally used to calculate and display the number of periodically returning movements per minute. If, for example, one of the measurement cursors is placed at the beginning of one heart action, and the other one is placed at the ending point of the same heart action, the corresponding heart rate in "Beats per Minute (BpM)" is displayed behind "+ Rate".
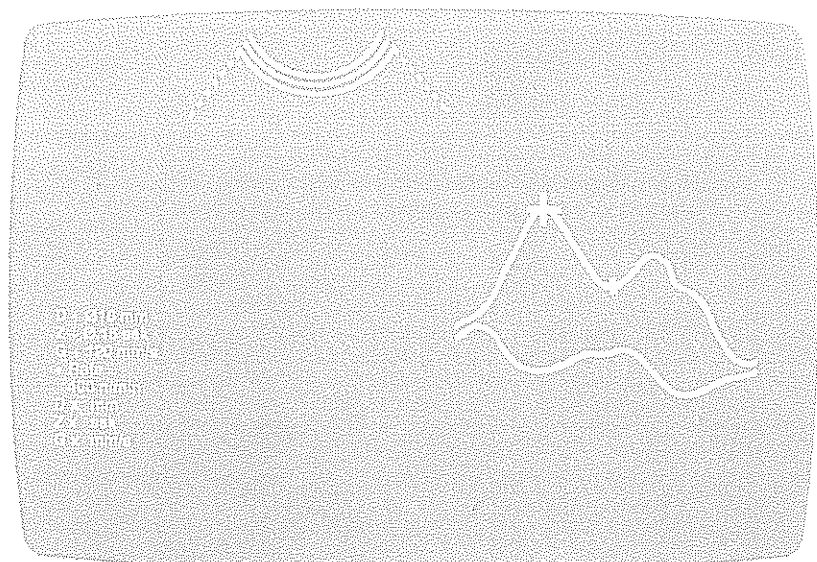
9. Calculation programs

9.1. Estimating unknown gestational age

For estimating gestational age where the date of the last menstruation is not known, the sonoScope 30 provides an evaluation program based on the following biometry programs:

— chorionic cavity diameter according to Rempen (average taken from 2 or 3 measurements)

— crown/rump length according to Rempen

— crown/rump length according to Hansmann

— biparietal cephalometry according to Rempen

— biparietal cephalometry according to Hansmann

— fronto-occipital cephalometry according to Hansmann

— head circumference according to Hansmann

— abdominal transverse diameter according to Hansmann

— femur length according to Hansmann

In addition to this the unit offers memory space for three freely selectable biometry programs.

A list of these biometry tables appears on the screen when the ⌜GEST. MENU⌟ key is pressed.
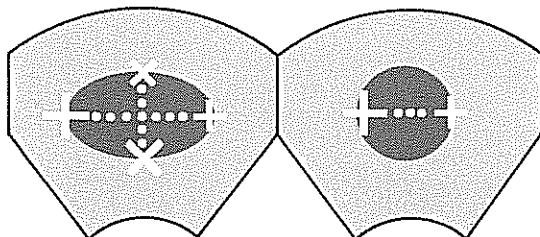
9.1.1. Measurement of the chorionic cavity diameter

Since the chorionic cavity only very rarely and only at a very early stage has the geometrical shape of a globe, not only one diameter but at least two, and preferably three planes should be measured. For measurements in two planes a single image will suffice, but for measurements in three planes the chorionic cavity must be displayed as a lateral and as a longitudinal scan adjacent to one another, so that for this purpose the "B/B"-mode is recommended.

After the image, or both images have been frozen, the measuring function is activated and the two or three distance measurements carried out as required. For this process, the user may determine himself the order in which the measuring steps are carried out, similarly, he may choose freely between +cursors and ✕cursors.

As soon as the four or six cursors have been positioned, the key marked "1" is pressed and the two or three diameters previously measured are automatically averaged out, and the curve with the estimated gestational age appears on the screen.
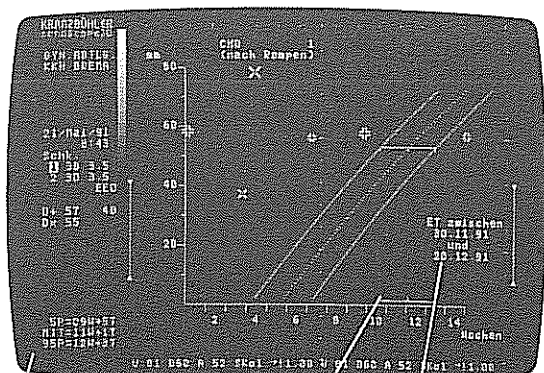
Numerical gest. week display with details of the 5th and 95th percentiles.

Graphic gest. week display taking into account biological variance.

Details of the period of time in which the birth is anticipated.

9.1.2. Measuring the crown/rump length by means of transvaginal sonography (according to Rempen)

For the measuring process, position the ┼ cursors; after pressing key "2", the corresponding figure for estimating gestational age is displayed.

9.1.3. Measuring the crown/rump length by means of abdominal sonography (according to Hansmann)

For the measuring process, position the ┼ cursors; after pressing key "3", the corresponding graph for estimating gestational age is displayed.

9.1.4. Measuring the biparietal head diameter by means of transvaginal sonography (according to Rempen)

For the measuring process position the ┼ cursors; after pressing key "4", the corresponding graph for estimating gestational age is displayed.

> If the diameter thus calculated is more than 27 mm, the system automatically switches to the biometry values given by Hansmann for the BPD.

9.1.5. Measuring the biparietal head diameter by means of abdominal sonography (according to Hansmann)

For the measuring process position the ┼ cursors; after pressing key "4", the corresponding graph for estimating gestational age is displayed.

> If the diameter thus measured is less than 28 mm, the system automatically switches to the biometry values given by Rempen for the BPD.

9.1.6. Measuring the fronto-occipital head diameter by means of abdominal sonography (according to Hansmann)

For the measuring process position the ┼ cursors; after pressing key "5", the corresponding graph for estimating gestational age is displayed.

9.1.7. Calculation of the head circumference by means of abdominal sonography (according to Hansmann)

The head circumference is not measured manually but is automatically calculated by the unit, provided the BPD and the FRO have been measured beforehand and entered with the corresponding keys ("4" and "5"). The calculation of the head circumference is carried out as soon as key "6" is pressed; simultaneously, the screen displays the corresponding curve for estimating gestational age.

9.1.8. Measuring the abdominal transverse diameter by means of abdominal sonography (according to Hansmann)

For the measuring process position the ┼ cursors; after pressing key "7" the corresponding graph for estimating gestational age is displayed.

9.1.9. Measuring the femur length by means of abdominal sonography (according to Hansmann)

For the measuring process position the ┼ cursors; after pressing key "8", the corresponding graph for estimating gestational age is displayed.

Notes:

Operator guidance:

Should the operator be in any doubt after carrying out measurements which numerical keys to press, the operator guidance may be invoked. To do this the [GEST. MENU] key is pressed, and a list of all parameters appears with the numerical keys assigned to them. Press the corresponding numerical key, and the screen displays the desired curve for display of the estimated gestational age.

Suppressing the curve:

Should the display in the form of a line curve not be desired, this may be switched off. In this case the sonographically calculated gestational age is displayed exclusively numerically.

Activating and suppressing the curve:

– press the [MENU] key; the screen displays the main menu.

– press menu key "5" (→), the second part of the main menu appears.

– press menu key "4" (BIO PG). the screen displays the menu for the evaluation programs.

– press menu key "1" (GA DISPL), and the screen displays the menu fields for changing the gestational age display.

– press menu key "1" (CURVE); above the menu field appears information as to whether the curve display is activated or not.

– for switching over, press menu key "1" once more.

MENU

main menu

| GA REP | TIME/DAT | IMAGE | MACRO | → |

main menu

| PRESET | HOSPITAL | RS 232 C | BIO PG | → |

BIO PG menu

cran →

| GA DISPL | HIP | FREE | | PREV |

GA display menu

on   off

| CURVE | US ECHO | | | PREV |

Background image:

If the line curve is selected as the display type for foetal growth, the possibility exists to display the corresponding sonogram simultaneously as a background image. In order to activate or deactivate the function proceed as follows:

— press the MENU key; the screen displays the main menu.

— press menu key "5" (→), the second part of the main menu appears.

— press menu key "4" (BIO PG). The screen displays the menu for the evaluation programs.

— press menu key "1" (GA DISPL), and the screen displays the menu fields for changing the gestational age display.

— press menu key "2" (US ECHO); above the menu field information appears as to whether the background image is activated or not.

— every time menu key "2" is pressed, the background image is alternately switched on and off.

9.2. Programs for assessing foetal growth

The calculation programs for assessing normal growth assume that, before starting the measurements, the date of the last menstruation has been entered. The date is entered with the "MENSES" key (refer also to section 7.3.).

After completion of a measurement, a graph showing normal growth appears on the screen together with the 5th and the 95th percentiles in which the sonographically calculated biometrical dimension is displayed in the form of a small star. In this way, it is easy to detect quickly whether a measured foetal dimension lies outside the natural biological dispersion area and, if so, by how much.

For sonographic growth assessment, the same parameters may be applied as already described for the program for estimating gestational age.
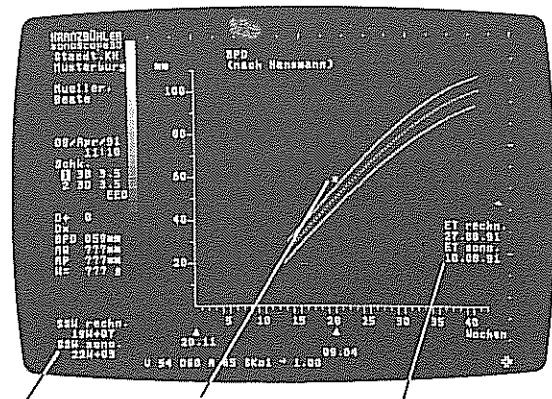
| Display of sonographically calculated and mathematical gest. week | Actual value in relation to the normal-growth curve | Display of sonographically calculated and mathematically estimated date of delivery |

Note:
Sonographically determined values are only displayed if they lie outside the biological deviation of the calculated gestational age.

9.2.1. Measurement of the chorionic cavity diameter

Since the chorionic cavity only very rarely and only at a very early stage has the geometrical shape of a globe, not only one diameter but at least two, and preferably three planes should be measured. For measurements in two planes a single image will suffice, but for measurements in three planes the chorionic cavity must be displayed as a lateral and as a longitudinal section adjacent to one another, so that for this purpose the "B/B"-mode is recommended.

After the ultrasound image, or both images have been frozen, the measuring function is activated and the two or three distance measurements carried out as required. for this process, the user may determine himself the order in which the measuring steps are carried out, similarly, he may choose freely between -|- cursors and ✕ cursors.

As soon as the four or six cursors have been positioned, the key marked "1" is pressed and the two or three diameters previously measured are automatically averaged out, and the graph for assessing foetal growth appears on the screen.

9.2.2. Measuring the crown/rump length by means of transvaginal sonography (according to Rempen)

For the measuring process position the -|- cursors; after pressing key "2", the corresponding graph for assessing normal growth is displayed.

9.2.3. Measuring the crown/rump length by means of abdominal sonography (according to Hansmann)

For the measuring process position the -|- cursors; after pressing key "3", the corresponding graph for assessing normal growth is displayed.

9.2.4. Measuring the biparietal head diameter by means of transvaginal sonography (according to Rempen)

For the measuring process position the -|- cursors; after pressing key "4", the corresponding graph for assessing normal growth is displayed.

> If the diameter thus measured is more than 23 mm, the system automatically switches to the biometry values given by Hansmann for the BPD.

9.2.5. Measuring the biparietal head diameter by means of abdominal sonography (according to Hansmann)

For the measuring process position the -|- cursors; after pressing key "4", the corresponding graph for assessing normal growth is displayed.

> If the diameter thus measured is less than 24 mm, the system automatically switches to the biometry values given by Rempen for the BPD.

9.2.6. Measuring the fronto-occipital head diameter by means of abdominal sonography (according to Hansmann)

For the measuring process position the -|- cursors; after pressing key "5", the corresponding graph for assessing normal growth is displayed.

9.2.7. Calculation of the head circumference by means of abdominal sonography (according to Hansmann)

The head circumference is not measured manually but is automatically calculated by the unit, provided the BPD and the FRO have been measured beforehand and entered with the corresponding keys ("4" and "5"). The calculation of the head circumference is carried out as soon as key "6" is pressed; simultaneously, the screen displays the corresponding curve for assessing normal growth.

9.2.8. Measuring the abdominal transverse diameter by means of abdominal sonography (according to Hansmann)

For the measuring process position the -|- cursors; after pressing key "7", the corresponding graph for assessing normal growth is displayed.

9.2.9. Measuring the femur length by means of abdominal sonography (according to Hansmann)

For the measuring process position the -|- cursors; after pressing key "8", the corresponding graph for assessing normal growth is displayed.

Notes:

Operator guidance:

Should the operator be in any doubt after carrying out measurements which numerical keys to press, the operator guidance may be invoked. To do this the | GEST. MENU | key is pressed, and a list of all parameters appears with the numerical keys assigned to them. Press the corresponding numerical key, and the screen displays the desired curve for assessing normal growth.

Suppressing the curve:

Should the display in the form of a line curve not be desired, this may be switched off. In this case the sonographically calculated gestational age is displayed exclusively numerically.

Activating and suppressing the curve:

- press the | MENU | key; the screen displays the main menu.

- press menu key "5" (→), the second part of the main menu appears.

- press menu key "4" (BIO PG). the screen displays the menu for the evaluation programs.

- press menu key "1" (GA DISPL), and the screen displays the menu fields for changing the gestational age display.

- press menu key "1" (CURVE); above the menu field appears information as to whether the curve display is activated or not.

- for switching over, press menu key "1" once more.

Background image:

If the line curve is selected as the display type for foetal growth, the possibility exists to display the corresponding sonogram simultaneously as a background image. In order to activate or deactivate the function proceed as follows:

- press the | MENU | key; the screen displays the main menu.

- press menu key "5" (→), it the second part of the main menu appears.

- press menu key "4" (BIO PG). The screen displays the menu for the evaluation programs.

- press menu key "1" (GA DISPL), and the screen displays the menu fields for changing the gestational age display.

- press menu key "2" (US ECHO); above the menu field information

appears as to whether the background image is activated or not.

– every time menu key "2" is pressed, the background image is alternately switched on and off.

9.3. Weight estimation

The sonoScope 30 is equipped with the program for foetal weight estimation as propounded by Merz. For this calculation, the values for the biparietal head diameter, the abdominal transverse diameter and for the AP diameter of the abdomen are employed.

Provided these biometrical dimensions have been measured and entered with the aid of the corresponding numerical keys (BPD = 4, AQ = 7, AP = 9), then the details of the estimated foetal weight are automatically displayed on the left side of the screen. This position on the screen also provides constant information as to which parameters for calculating foetal weight have not yet been measured.
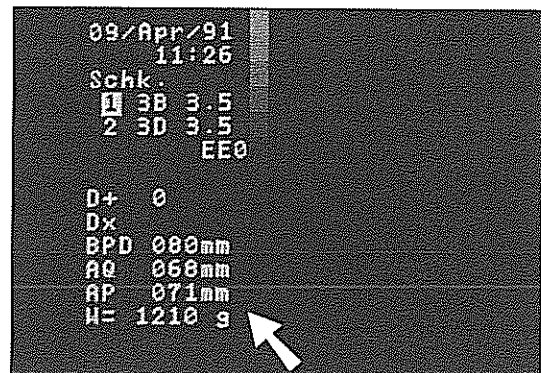
9.4. Listing measurements

The sonoScope 30 provides a facility for listing all measured values for determining gestational age or normal growth in the form of a log at the end of an examination session. This function considerably facilitates the documentation of foetobiometric findings, since the results need not be noted during the examination.
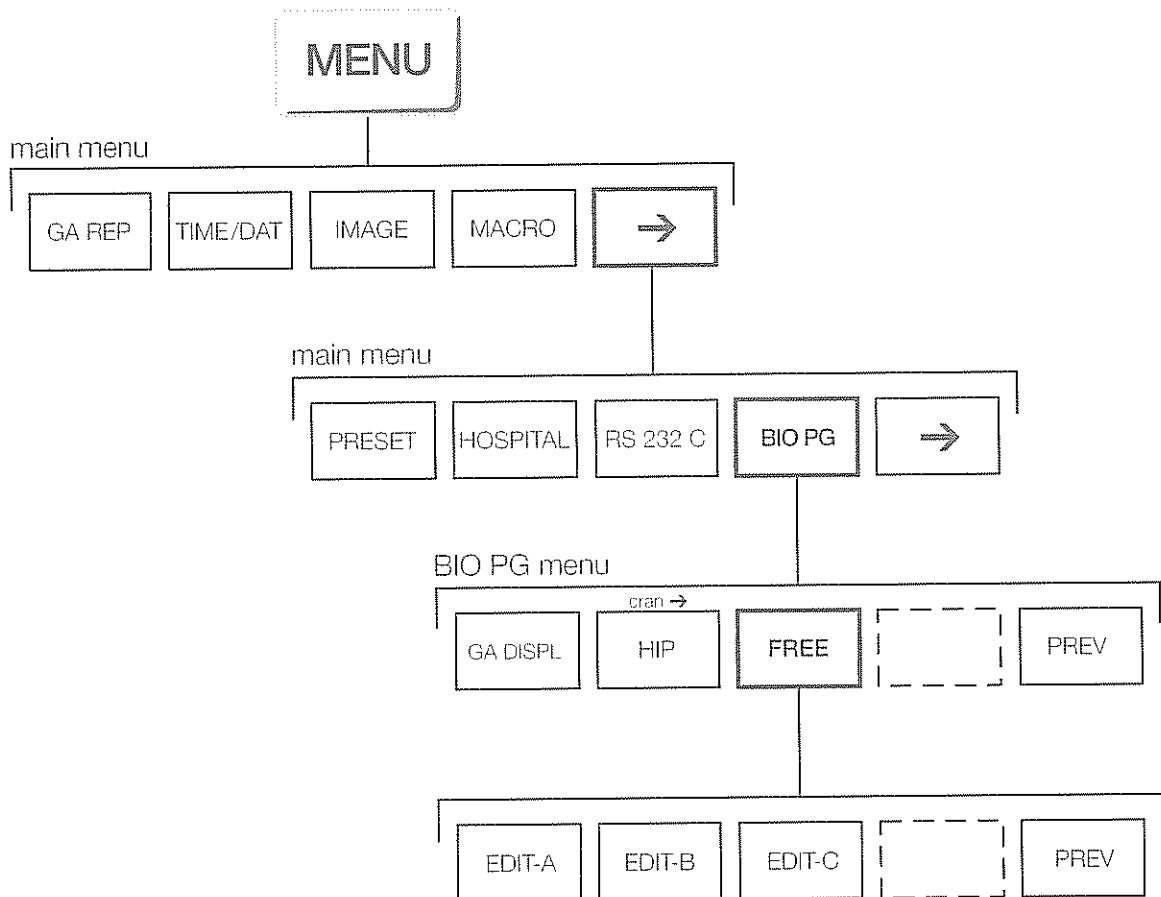
Invoking the log:

– press the **MENU** key, the main menu appears.

– press menu key "1" (GA REP); the screen displays the list of the measuring results.

– pressing the key **MENU** once more clears the screen

9.5. Programming growth tables

The sonoScope 30 offers the user the possibility, apart from the growth curves integrated as standard, to use his or her own biometry tables or those of other authors. For this purpose, the unit has sufficient storage capacity for three tables to be freely programmed. These are stored under the designation "A", "B" and "C" and can be selected in same way on completion of measurements as the standard tables (1 to 8). One restriction is that gest. week values calculated using the freely programmed tables are displayed exclusively numerically and not as a line curve.

```
                    ┌──────────────┐
                    │    MENU       │
                    └──────────────┘
                            │
main menu
  ┌──────────┬──────────┬──────────┬──────────┬──────────┐
  │ GA REP   │ TIME/DAT │  IMAGE   │  MACRO   │    →     │
  └──────────┴──────────┴──────────┴──────────┴──────────┘
                                                    │
main menu
  ┌──────────┬──────────┬──────────┬──────────┬──────────┐
  │ PRESET   │ HOSPITAL │ RS 232 C │  BIO PG  │    →     │
  └──────────┴──────────┴──────────┴──────────┴──────────┘
                                        │
BIO PG menu
              cran →
  ┌──────────┬──────────┬──────────┬ ─ ─ ─ ─ ┬──────────┐
  │ GA DISPL │   HIP    │   FREE   │         │   PREV   │
  └──────────┴──────────┴──────────┴ ─ ─ ─ ─ ┴──────────┘
                              │
  ┌──────────┬──────────┬──────────┬ ─ ─ ─ ─ ┬──────────┐
  │  EDIT-A  │  EDIT-B  │  EDIT-C  │         │   PREV   │
  └──────────┴──────────┴──────────┴ ─ ─ ─ ─ ┴──────────┘
```

Programming process:

MENU

– press the ⟦MENU⟧ key, the main menu appears on the screen.

– with menu key "5"(→) advance to the second part of the main menu.

– press menu key "4" (BIO PG); the menu for alterations within the calculation programs is displayed.

– press menu key "3" (FREE). Using the menu now displayed, select whether the table to be programmed is stored under "A", "B" or "C".

– select desired memory – "A", "B" or "C". The screen displays the input mask above the menu. The data input cursor is positioned in the field marked "TITLE".

– using the alphanumeric keyboard, enter the name or parameters of the gestation table to be programmed. There are a total of six spaces available for the name. After the 6 characters have been entered, the cursor jumps automatically to the field marked "MIN". The value entered here determines at what biometrical dimension the table is to begin. It is absolutely essential to key in this value as a three-digit figure, for example 008 mm.

– After the minimum value has been entered, the cursor jumps to the first data field of the table, which can contain up to 96 values. Enter now the gestational week corresponding to the first value as a two-digit figure. Additionally the days and the standard permissible deviation are entered in the same way as two-digit figures in days.

– After completion of the first data field the cursor jumps automatically to the next line, i.e. for the next value (1 mm greater), and the procedure is repeated.

– Once all 96 data fields have been filled, it is absolutely essential to press menu key "4" (STORE) so that the entire table is accepted by the system and stored in the data memory.

– In connection with pre-natal examinations, the table is available on completion of measurements under the letter "A", "B" or "C" for display of the corresponding gestational age.
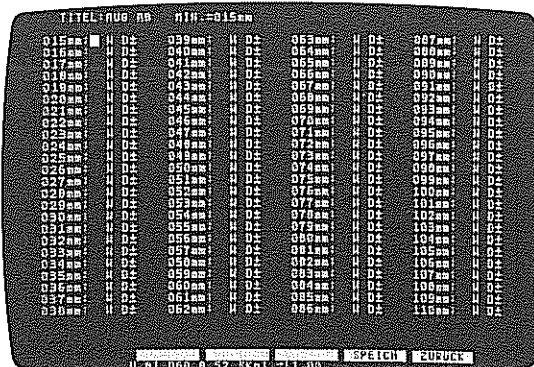
9.6. Determining the severity of hip joint dysplasias (according to Graf)
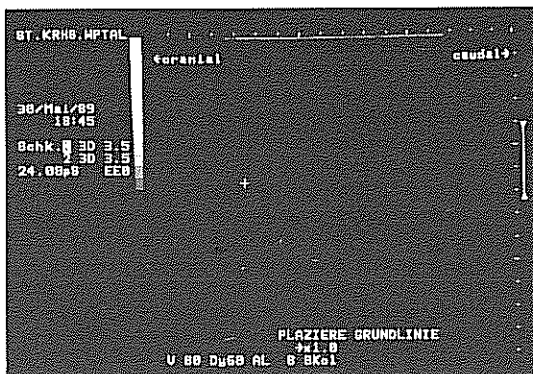
Pressing the [⊿α β key] key displays on the screen the step-by-step explanation of the examination procedure for determining hip joints.

To begin with, position the starting point of the base line with the trackball.

By means of the [α β key] key the entry is confirmed, and a line appears on the screen which is aligned with the ilium again using the trackball.
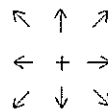
Pressing the [α β key] key once more displays the starting point of the bone line.

Positioning and alignment of the line take place in the way described above using the key and the trackball. Now the third line – the cartilage line – is positioned.
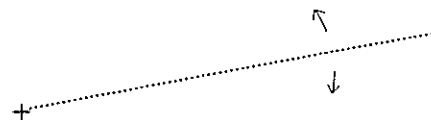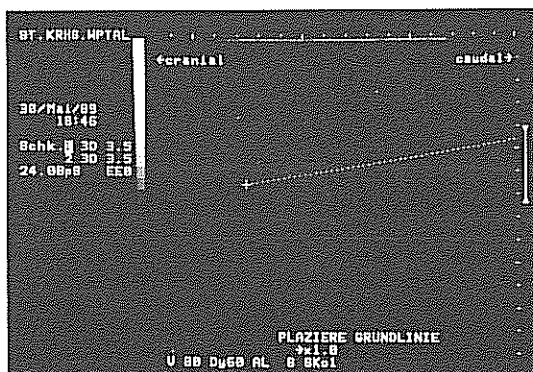
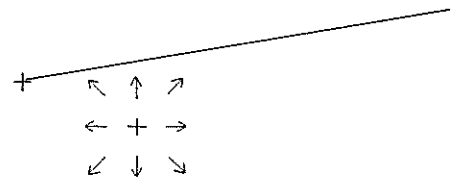By means of the [α β key] key confirm the entry and the hip program is concluded.
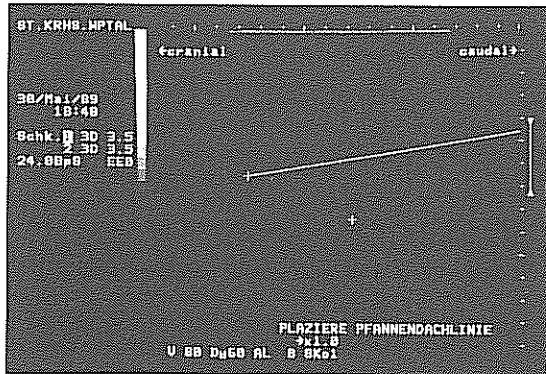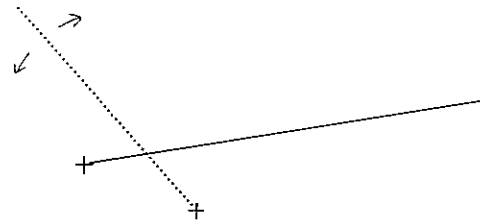
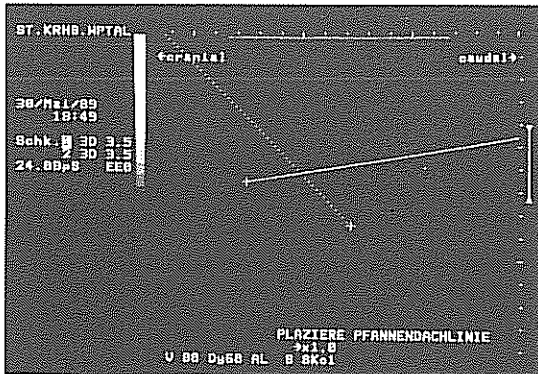Position the starting point of the base line; then press [α β key].

Align base line along the ilium; then press [α β key].

ST.KRHS.HPTAL
←cranial   caudal→
30/Mai/89
    18:48
Schk.1 3D 3.5
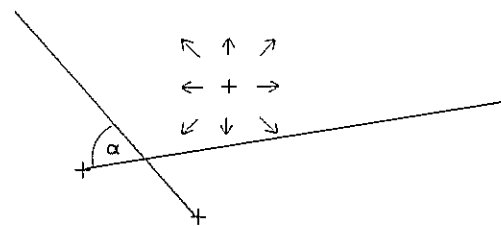   2 3D 3.5
24.00pS   EEB
PLAZIERE PFANNENDACHLINIE
→×1.0
V BB Dy6O AL B SKol

Position the starting point of the bone line; press [α β].

ST.KRHS.HPTAL
←cranial   caudal→
30/Mai/89
    18:49
Schk.1 3D 3.5
    2 3D 3.5
24.00pS   EEB
PLAZIERE PFANNENDACHLINIE
→×1.0
V BB Dy6B AL B SKol

Place the bone line through the bony rim, which is caudally positioned at the ilium; press [α β].

ST.KRHS.HPTAL
←cranial   caudal→
30/Mai/89
    18:49
Schk.1 3D 3.5
    2 3D 3.5
24.00pS   EEB
PLAZIERE AUSSTELLUNGSLINIE
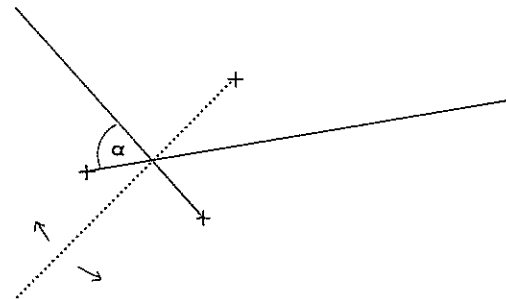→×1.0
V Bl Dy6B AL B SKol
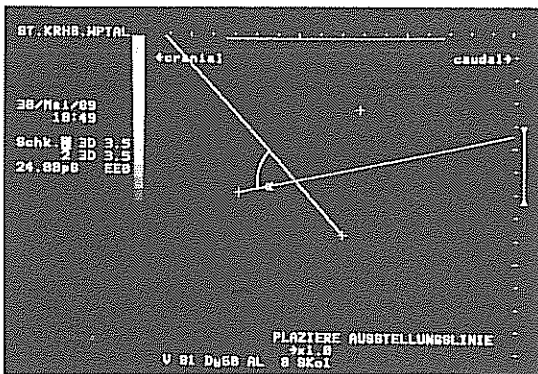
Position the starting point of the cartilage line; press [α β].
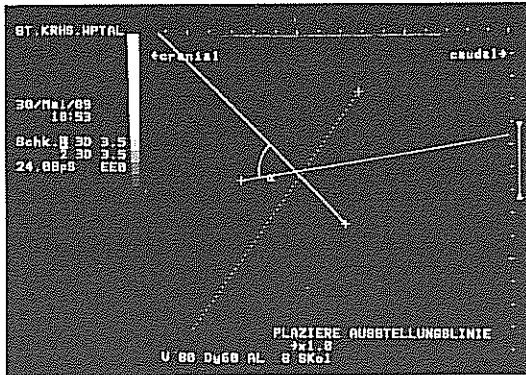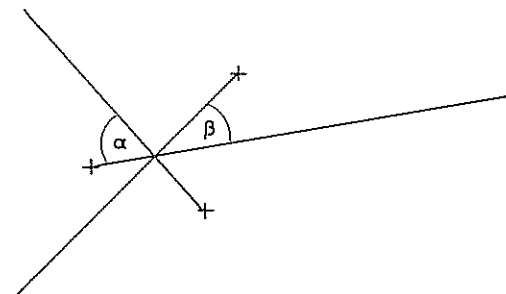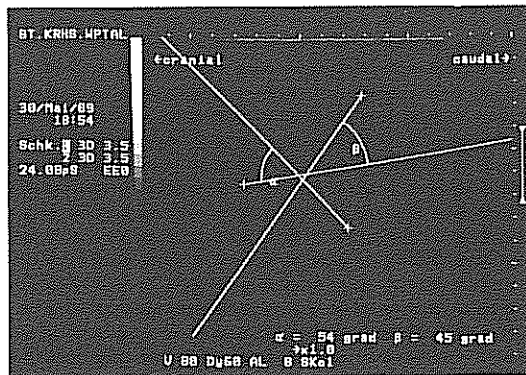
Place the cartilage line through the bony rim, which is caudally positioned at the ilium; press .

The angle of the bone line and the angle of the cartilage line are numerically displayed.

If the user prefers to have cranial-orientated structures displayed on the right-hand side of the screen, the evaluation program must be adapted to this type of projection, i.e. rotated through 180°.

To do this proceed as follows:

−   press the menu key, the screen displays the main menu.

−   press menu key "5" (→), and the second part of the main menu appears.

−   press menu key "4" (BIO PG); the screen displays the menu for selecting various calculations.

−   press menu key "2" (HIP), and the arrow above the menu field alters its direction and points to the right. Now the display program has been switched over in such a way that even with an inverted direction of projection (cranial-orientated structures on the right, caudal-orientated structures on the left), the angle measurement according to Graf's principle is carried out correctly.

−   every time menu key "2" is pressed, the evaluation program switches to and fro between the two displays.

9.7. Program for determining volume

For sonographic estimation of organ volume the sonoScope 30 is equipped with a simple calculation program, based on the ellipsoid equation:

volume = length X width X depth X 0.523

In order to register all three axes - length, depth and width - the organ to be measured has to be sonographed and displayed in two planes. For this reason it is necessary to display a longitudinal and a transverse image of the organ adjacent to each other in the B/B-mode and to freeze them.

Then proceed as follows:

– Press the $\boxed{cm^3}$ key, in the left-hand lower corner of the screen appears "LENG = ".

– activate the -|- cursors and, using the trackball, measure the longitudinal extension.

– press the $\boxed{cm^3}$ key once again; the screen displays the calculated distance as the length, and the word "WIDTH =" appears.

– using the $\boxed{\triangle\triangle}$ key

or the $\boxed{\triangle\triangle}$ key swap screen sides in order to carry out the measurement of the width and depth.

– activate the measuring function again (-|- cursors) and determine the width extension of the organ.

– press the $\boxed{cm^3}$ key, and the screen displays the measured distance beside the word "WIDTH". Simultaneously, the word "DEPTH =" appears.

– invoke the -|- cursors and determine the depth extension of the organ

– press the $\boxed{cm^3}$ key; behind the word "DEPTH" the measured value is displayed and simultaneously the calculated volume in cm³

– press the $\boxed{cm^3}$ key once again to

reset the volume program and to delete all graphs on the screen.
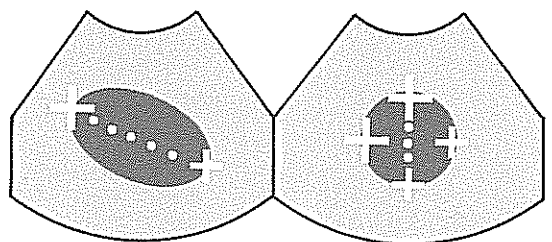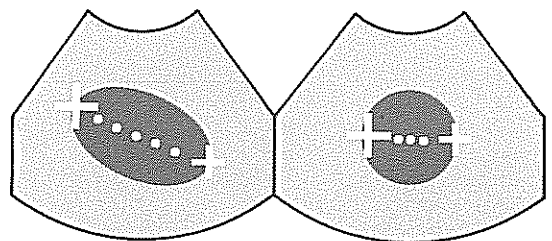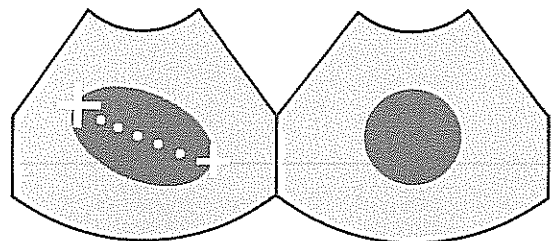
9.8 Programme for the determination of left ventricular functional parameters

In order to be able to also semi-quantitatively evaluate the function of the left ventricle in cardiac applications, the sonoScope 30 provides a calculation programme for the automatic computation of various corresponding functional parameters. This programme comprises the computation of the percental increase of thickness of septum and posterior wall, the computation of the fractional shortening and the calculation of the circumferential shortening.

All these calculations are performed in the M-mode and a correct positioning of the M-line therefore is essential; most favourably the M-line is placed just below the free edges of the mitral leaflet, crossing the septum in a 90° angle.

After having frozen the M-mode procede as follows:

```
                        ┌─────────┐
                        │  MENU   │
                        └────┬────┘
main menu                    │
  ┌──────────┬──────────┬────┴─────┬──────────┬──────────┐
  │  GA REP  │ TIME/DAT │  IMAGE   │  MACRO   │    →     │
  └──────────┴──────────┴──────────┴──────────┴────┬─────┘
                                                    │
        main menu                                   │
          ┌─────────┬──────────┬─────────┬──────────┬─────────┐
          │ PRESET  │ HOSPITAL │ RS 232 C│  BIO PG  │    →    │
          └─────────┴──────────┴─────────┴────┬─────┴─────────┘
                                              │
            BIO PG menu            cran →      │
              ┌──────────┬─────────┬──────────┬──────────┬─────────┐
              │ GA DISPL │   HIP   │   FREE   │ KARD BER │  PREV   │
              └──────────┴─────────┴──────────┴────┬─────┴─────────┘
                                                   │
                KARD BER menu                      │
                  ┌──────────┬─────────┬──────────┬─ ─ ─ ─┬─────────┐
                  │ DIASTOLE │ SYSTOLE │  REPORT  │       │  PREV   │
                  └──────────┴─────────┴──────────┴─ ─ ─ ─┴─────────┘
```
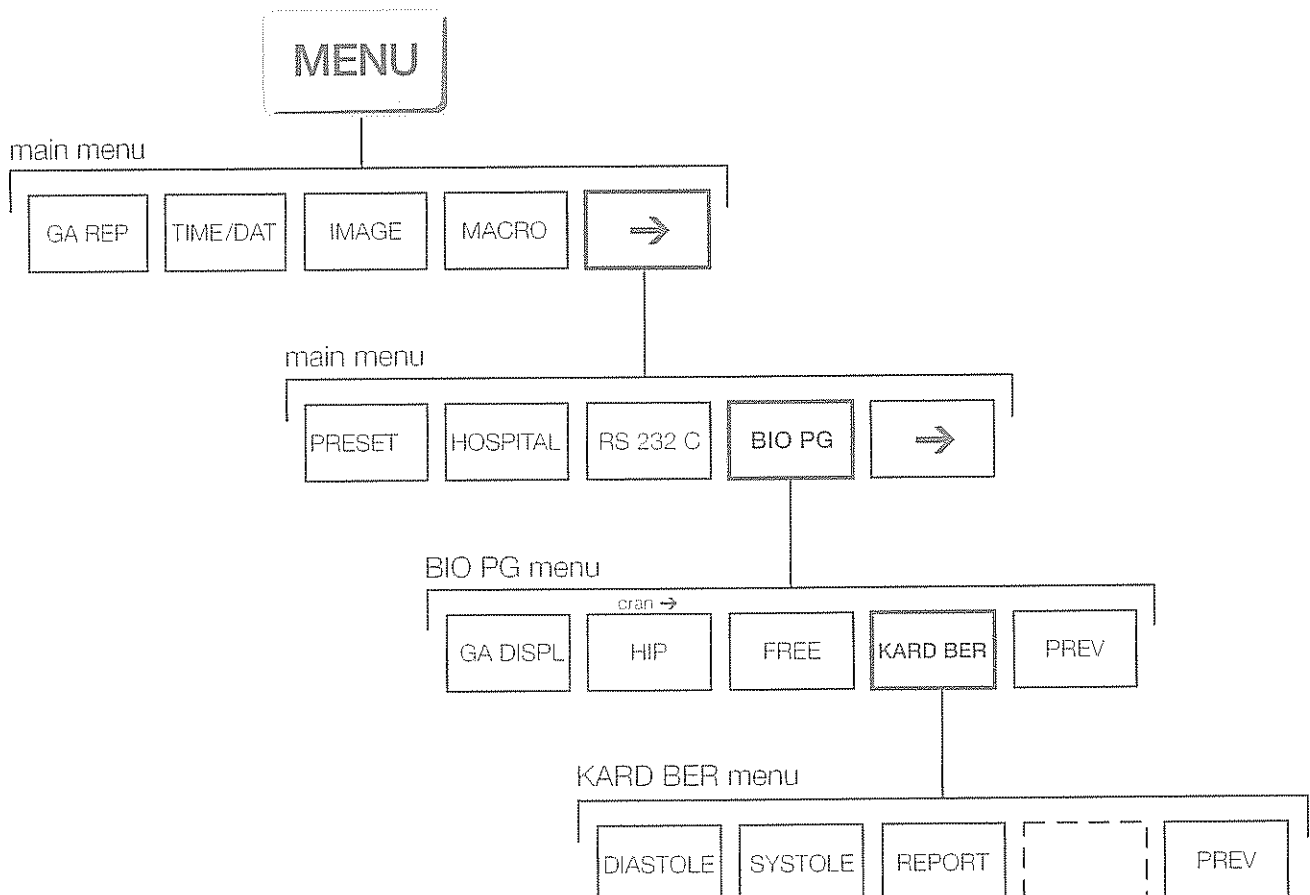
Press the MENU key.
The main menu is inserted on the screen.

– Press menu key "5" (-->), the second part of the main menu appears.

– Press menu key "4" (BER PROG); the screen displays the menu for the selection or modification of the calculation programmes.
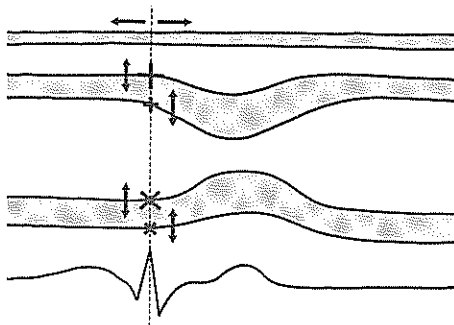
– Push menu key "4" (KARD BER) and the cardiac calculation programme is activated. A vertical dotted line as well as the menu for this calculation programme are displayed on the screen.

– With menu key "1" (DIASTOLE) the trackball is switched to the dotted line, which can now horizontally be moved and placed at the ending point of the diastole (R-wave) according to the ECG curve.

– Activate the "+" measurement cursors and place the large cursor at the anterior

Position of measurement cursors
for measuring the ventricle during late diastole.

Position of measurement cursors
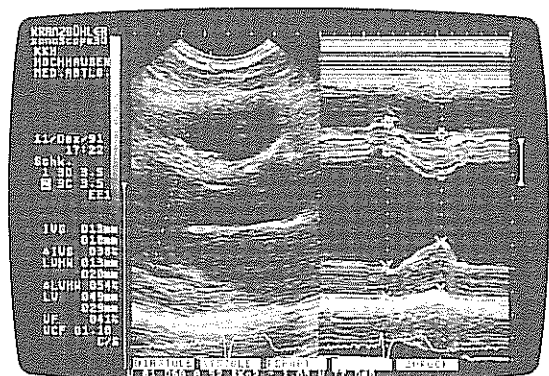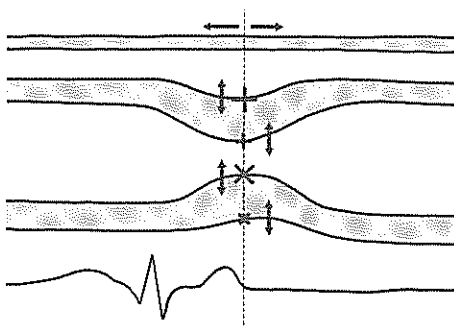for measuring the ventricle during late systole.

boundary and the small one at the posterior boundary of the septum (see picture).

– Activate the "x" measurement cursors, the large cursor is to be placed at the anterior, the small cursor at the posterior boundary of the posterior wall.

– Press menu key "2" (SYSTOLE) and a second vertical line is displayed on the screen, which is to be positioned with the trackball to assess and calculate the maximum ventricular contraction. For correct positioning refer to the point of time the posterior wall reaches its peak.

– Activate the "+" measurement cursors, place the large one at the anterior, the small one at the posterior boundary of the septum.

– Select the "x" measurement cursors - place the large cursor at the anterior and the small one at the posterior boundary of the posterior wall.

– Press menu key "3" (REPORT) and in the lower left-hand corner of the screen all measurement values and results, including the percental increase of thickness, fractional shortening and circumferential shortening are inserted.

10. Programmable default settings

In order to avoid the necessity for resetting the unit for each user and change of application, the sonoScope 30 is equipped with programmable default settings. For each scanhead two complete sets of default settings can be programmed and activated at the push of a button. If for example, your unit is equipped with three scanheads, a total of 6 sets of presettings may be stored.

To program your presettings, proceed as follows:

– activate desired scanhead and set it correspondingly for the first default settings to be programmed.

– adjust transmission power, reception gain, magnification factor, zone of focus and all further settings as desired.

– press the MENU key, the screen displays the main menu.

– press menu key "5" (➔) the second part of the main menu appears.

– press menu key "1" (PRESET). The screen displays the menu for entering and correcting the presettings.

– press menu key "1" (WRITE 1); the current settings of the unit are registered and stored under preset 1. When subsequently the key "PRESET 1" is pressed, the sonoScope 30 will automatically load the corresponding settings, adjusting the gain, magnification factor, the number of focus zones etc. to the programmed values.

– if, in connection with the same scanhead, a further set of presettings deviating from preset 1 is desired, these may also be stored in the same way using menu key "3" (WRITE 2).

– in order to save further presettings under preset 1 and preset 2, the scanheads intended for this application must be connected in turn.

There is also the possibility to modify certain setting parameters specifically without having to connect up the corresponding scanhead.

To do this proceed as follows:

– press the MENU key, the screen displays the main menu.

– press menu key "5"(➔), the second part of the main menu appears.

– press menu key "1" (PRESET). The screen displays the menu for entering and correcting the presettings.

– depending on whether the parameters to be modified are stored under preset 1 or preset 2, press menu key "2" (EDIT 1) or menu key "4" (EDIT 2). The screen displays a tabular list of all essential setting parameters for each scanhead available for the sonoScope 30.

- when the list is invoked, a modification cursor jumps to the first data field in the upper left-hand corner of the screen (B-mode gain for the L3A scanhead) and can, with the aid of the trackball, be positioned at will.

- position the modification cursor over the parameter to be altered.

- with menu key "1"(↑) or menu key "2" (↓) increase or decrease the value as required.

- after completing the setting press menu key "4" (STORE), the new setting is stored and the screen cleared.

11. MACRO function

During the course of routine sonographic diagnosis, in particular biometry, a number of operating sequences are repeated over and over again. An example is pre-natal diagnosis and foetometry: first of all the desired image is frozen, then the first cursor activated, a second cursor is invoked and positioned, the BPD calculation program is selected... etc. The sonoScope 30 is in a position to record any desired operating sequence and to play it back step by step on demand. Each step of the recorded sequence is played back in turn by pressing the foot-switch once.
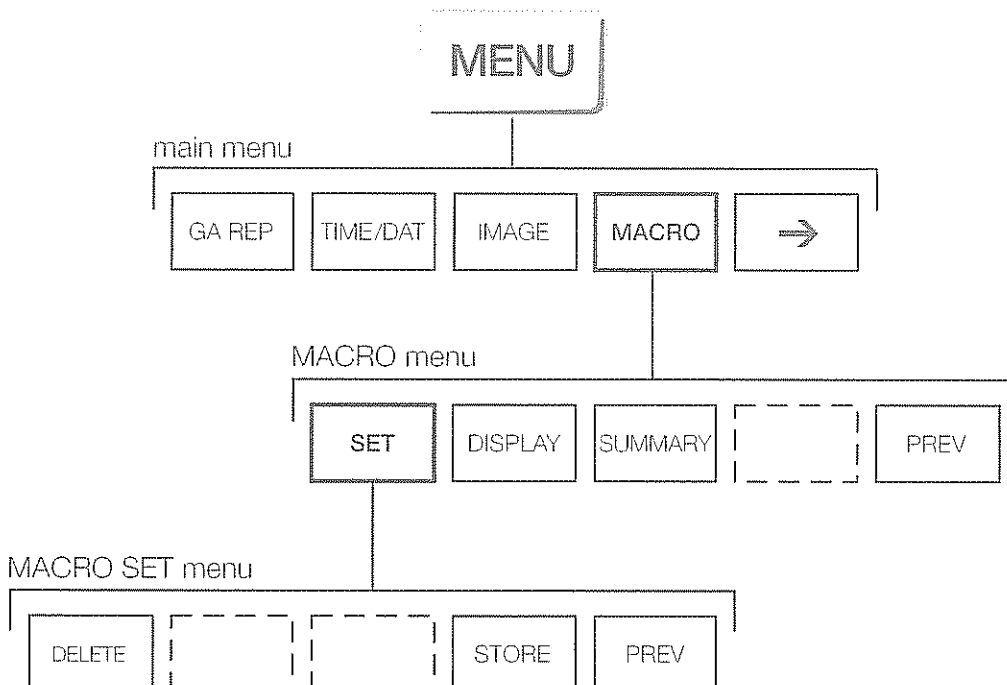
11.1. Programming MACRO sequences

To program a sequence proceed as follows:

– press the **MENU** key, the screen displays the main menu.

– press menu key "4" (MACRO). The screen displays the MACRO menu.

– press menu key "1" (SET), and the system is ready to record and store an operating sequence.

– invoke the first operating step to be recorded (e.g. the "freeze" key). If it is desired to invoke a further function together with this one, then carry out that step as well (e.g. activating the large $-\!\!\!\mid\!\!\!-$ cursor).

– press the foot-switch. This interrupts the sequence at this point, the automatic playback of the operating sequence is therefore interrupted, allowing the user to carry out certain settings (e.g. positioning the $-\!\!\!\mid\!\!\!-$ cursor with the trackball).

– perform the next operating step (e.g. activating the small $-\!\!\!\mid\!\!\!-$ cursor).

– press the foot-switch. This later enables the user to carry out the selected operating step, for example positioning the $-\!\!\!\mid\!\!\!-$ cursor.

– invoke the next operating step, e.g. selecting a foetometric parameter such as the BPD.

MENU

main menu

| GA REP | TIME/DAT | IMAGE | MACRO | $\Rightarrow$ |

MACRO menu

| SET | DISPLAY | SUMMARY | | PREV |

MACRO SET menu

| DELETE | | | STORE | PREV |

- if necessary, invoke further functions, e.g. the "PRINT" function, to print out the growth curve displayed on the screen.

- press the foot-switch.

- if the course of the examination is now complete, the image may be "unfrozen" and, using the "CLR" key, the curve on the screen deleted.

- use menu key "4" (STORE) to save the entire operating sequence for future use.

In total up to 16 operating sequences may be stored, where each operating step may consist of several operations (e.g. freeze, zoom in and activate first cursor).

Should an error be made unintentionally during the programming process, that is, a key is pressed by accident, this error may be remedied and the corresponding operating step deleted. To do this, press menu key "1" (DELETE) very briefly (not longer than 0.5 seconds). By means of this key, the last block of operating steps (that is, all the functions entered between the last two presses of the foot-switch) are deleted.
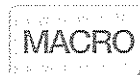
Pressing "DELETE" for a longer period has the effect of deleting a number - or indeed all - operating sequences, depending on how long the key is pressed for.

In order to delete a complete stored sequence, menu key "1" (DELETE) is repeatedly pressed until an acoustic signal is heard. Then press menu key "4" (STORE). This action will clear the MACRO memory and prepare it for recording a new operating sequence.

Menu key "3" (SUMMARY) in the MACRO menu can be used to display a stored operating sequence in the form of a list on the screen.

11.2. Using the MACRO function

The MACRO mode is activated by pressing the [MACRO] key.

The examination is started and the first operating sequence or sequences invoked by means of pressing the foot-switch. In most cases this will involve "freezing" the image and activating the first cursor.

After that the user has the possibility to perform actions himself, for example positioning the first cursor.

Pressing the foot-switch once again informs the system that this action has been completed and the next function is invoked (e.g. activating the next cursor).

After that the user once again has the possibility to perform actions himself, for example positioning the second cursor. Pressing the foot-switch again completes the procedure and, in turn, invokes the next functions.

In this way, the entire operating sequence for carrying out biometrical measurements, for the evaluation and documentation of results, may be automated and executed simply by means of alternate use of trackball and foot-switch.

Example:

1. | MACRO |

2. perform examination

3. (foot-switch symbol) ⇨ – image is "frozen"
– ╬ cursor appears

4. position first cursor by means of trackball.

5. (foot-switch symbol) ⇨ – ╬ cursor is fixed
– + cursor appears

6. position second cursor by means of trackball.

7. (foot-switch symbol) ⇨ – + cursor is fixed
– BPD table is invoked
  and appears on the screen
– printer is activated

8. (foot-switch symbol) ⇨ – image is "unfrozen"
– curve overlays are deleted

End of the process.

When using the MACRO mode it is of advantage if the user is informed at each stage of the next step which will be triggered by the foot-switch. For this reason, we recommend switching on menu key "2" (DISPLAY) in the MACRO menu. The current status (ON or OFF) is then displayed above the menu field.

Where the display is switched on and the MACRO function is in use, information is constantly displayed above the ultrasound image as to the function the system is currently in and which steps will be triggered by the next operation of the foot-switch.

12. ECG

In order to provide a time-reference for echocardiographic examinations – in particular with the evaluation of the M-mode, the ECG must be derived and simultaneously displayed with the echocardiogram on the screen.

To do this the ECG derivation cable is connected to the ECG input connection at the front of the unit. KRANZBÜHLER offers optional equipment for the sonoScope 30:

– a derivation cable for use with adhesive electrodes (chest lead)

or

– a derivation cable for use with electrode clamps (extremity derivation).

The ECG derivation function is switched on, by turning the knob marked "ECG" on the upper side of the unit in a clockwise direction, whereby slight resistance – the switch function – will be noted. After switching on, the ECG curve is displayed on the lower edge of the ultrasound image. The amplitude may be adjusted as desired using the knob.

13. Function test

- Check all cables, in particular the mains lead, for damage.

- Ensure that the mains lead is correctly connected to the rear of the unit and to the mains socket.

- Check that at least one scanhead is connected up to the equipment.

- Check that a video recorder or a jumper lead is connected.

- Switch on the mains power and check whether the status display on the keyboard lights up.

- Apply the selected scanhead to the body. The screen must display an ultrasound image.

- Check that the gain compensation reacts as described under 7.6. and 7.7.

- Check that the power setting reacts as described under 7.5.

- Save the image as described under 7.15.

- Operate the measuring programs as described under point 8.

- Invoke a calculation program as described under point 9.

Should the equipment not react or react in a way different to that described to the procedure for the function test, please inform Customer Services immediately:

KRANZBÜHLER
MEDIZINISCHE SYSTEME GMBH

Beethovenstrasse 239
D-42655 Solingen
Tel.: (+49) 2 12 / 28 02-22
Fax: (+49) 2 12 / 28 02-28

or our representative.

14. Notes on cleaning

14.1. Cleaning the unit

Dust on the external surfaces of the unit is removed with a soft, dry cloth. For cleaning use a soft, moist cloth with a mild cleanser or pure alcohol. Ensure that no liquid is allowed to penetrate the equipment.

Caution

In order to avoid the hazard of electrical shocks, the system must always be disconnected from the power supply before surfaces are cleaned with a moist cloth.

14.2. Cleaning the scanheads

After every examination the scanheads must be cleaned with a very moist cloth. Ensure in particular that all residues of contact jelly are completely removed; in particular when the equipment is not to be used for several hours. Since the scanheads, however, are hermetically sealed on the contact surfaces only, they should never be completely immersed in liquid.

Scanheads may never be sterilised since the high temperatures and moisture involved in sterilisation would cause irreparable damage. Even cold sterilisation with gaseous ethylene oxide is not considered advisable.

Surface disinfection using "Cutasept" disinfectant spray is possible.

Furthermore, a normal 5% solution of "Lysetol FF" disinfectant is recommended for the contact surfaces of the scanheads. In this respect, note that **the whole scanhead may under no circumstances** be immersed in this solution. Only the arrays themselves, i.e. the contact surfaces of the scanheads up to the seam with the scanhead body which is sealed with silicone are protected against the ingress of moisture.

As far as scanheads for intracorporal applications are concerned, the whole shaft, including the arrays but with the exception of the handle may be immersed in the liquid.

Caution

The scanheads contain sensitive ceramic crystals which may be damaged if subjected to knocks.

14.3. Cleaning the cables

Proper cleaning of the cable connections between the probes and the equipment is carried out in the same way with a soft cloth moistened with water and, if necessary, a disinfectant.

14.4. Cleaning the air filters

In order to avoid excessive warming the heat producing components of the sonoScope 30 are cooled by a flow of air generated by two fans.

To prevent dust and other suspended particles penetrating the equipment and thus causing soiling, the air inlets at the rear of the unit are protected with an air filter made of foam rubber. It is absolutely essential to re-move these filters from the equipment from time to time and to clean them.

Soiled filters lead to an obstruction of the flow of cooling air and could cause excessive warming of the unit as a result.

The frequency with which these filters will require cleaning is dependent to a large extent on the degree of soiling of the air used for cooling and on the frequency of use of the unit. Under normal circumstances, cleaning in 4-week intervals should be sufficient.

To clean the filters, proceed as follows:

1. Switch the equipment off.

2. Pull off the outer frames of both filter housings. We recommend grasping the two diagonally opposed corners of the frame with the thumb and middle finger.

3. Remove the foam rubber pad and tap or carefully clean with a vaccuum cleaner or under running water. After cleaning, replace and fix with the frame.
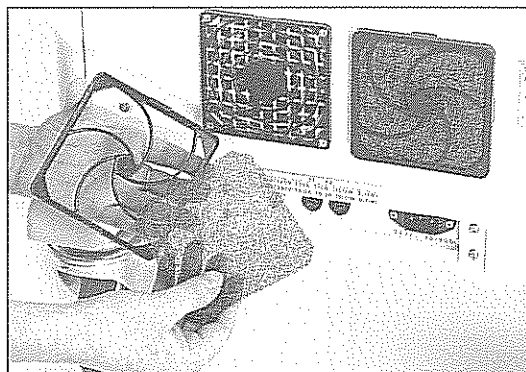
Caution

The pads may only be replaced in a dry state. Where moist cleaning is preferred, ensure the filters are allowed several hours to dry out.

15. Technical data

System

Two-dimensional ultrasound imaging system with automatic realtime scanning.

- for electronic linear array technology
- for electronic convex array technology

Signal processing:

- 32-channel beam-former for multistage focussing and optimum suppression of side-lobe artifacts
- 1 – 4 transmitted foci; focus positionable with the aid of the trackball
- self-adjusting receiving focus (15 focus zones)
- TGC (time gain compensation) adjustable by 8 depth selective slide controls, range-dependent steps
- large, easy-to-handle knob for overall gain
- transmission power alterable from 1 % to 100 %
- noise suppression by means of picture correlation overlay
- dynamic range from 30 dB to 60 dB, in 5-dB steps

ECG

- amplitude infinitely variable

Storage matrix:

- 512 X 1024 pixels, 64 shades of grey
- cross-line technology for orthograde display when used with external video monitors, printers and recorders

Image display:

- high-resolution pivoting and tilting monitor with anti-dazzle filter, screen diagonal 200 mm
- positive or negative echo imaging
- left-to-right inversion
- top-to-bottom inversion
- scan rate maximum 30/second, depending on image depth and number of focus zones selected
- overlay of all image processing parameters such as gain, transmission power, dynamic range, edge enhancement, scan rate etc.
- pictogram overlay facility including scanhead symbol and scan plane.

Zoom:

- read and write zoom; magnification factor selectable in small steps

Modes of operation:

- B-mode
- dual B-mode
- full format B-mode / partial magnification
- M-mode

Programmable default settings:

- B-mode gain
- M-mode gain
- transmission power
- dynamic range B-mode
- dynamic range M-mode
- edge enhancement B-mode
- edge enhancement M-mode
- focus zones B-mode (number and position)
- focus zones M-mode (number and position)
- M-mode scroll speed
- image size
- noise suppression
- vertical inversion of the image through 180°

Measuring function:

- cursor control by means of quick-reaction trackball
- sensitivity of the trackball (degrees of angle of rotation per mm of cursor movement) adjustable
- four distance measurements independent of each other
- two circumference measurements
- two surface area measurements
- display of all measured values on the screen
- calibration of the speed of the ultrasound beams to 1540 ms

Calculation programs:

- calculation of gestational age or normal-growth assessment according to Rempen and Hansmann
- overlay of calculated values in the normal-growth curves as displayed
- calculation of foetal weight according to Merz
- three freely programmable growth tables
- calculation of alpha and beta angle for determining hip joint according to Graf
- determination of volume

Data input:

- washable standard keyboard for alphanumeric entry of patient's data, for image annotation, for entering the permanently stored name of the clinic etc.

Video outputs:

- standard video signal, 625 lines, CCIR standard
- output for connecting up a video printer, control of the printer from control panel of the unit
- output and input for recording and playback with video recorder operation

Computer interface:

- RS232

Scanheads:

- 3.5 MHz, electronic linear array, field of view 100 mm, 384 elements
- 3.5 MHz, electronic linear array, field of view 85 mm, 384 elements
- 5 MHz, electronic linear array, field of view 50.2 mm, 384 elements
- 5 MHz, electronic linear array, field of view 85 mm, 384 elements
- 7.5 MHz, electronic linear array, field of view 40.5 mm, 384 elements
- 3.5 MHz, electronic convex array, array radius 45 mm, sector angle 75.4°, 384 elements
- 3.5 MHz, electronic convex array, array radius 25 mm, sector angle 97.3°, 384 elements
- 5 MHz, electronic convex array, array radius 15 mm, sector angle 97.3°, 384 elements
- 5 MHz, electronic convex array, array radius 40 mm, sector angle 60°, 384 elements
- 7.5 MHz, electronic convex array, array radius 15 mm, sector angle 97.3°, 384 elements
- electronic intravaginal scanhead, 5 MHz, convex array, array radius 11 mm, sector angle 97.3°, 384 elements
- electronic transrectal transducer, 5 MHz, linear array, field of view 70.8 mm, 270 elements

Dimensions and weight:

- 450 mm (width) X 1150 mm (height) X 800 mm (depth), 80 kg

Mains connection:

- 220/240 V, 50/60 Hz, 0.8 A

Right to make technical alterations reserved.