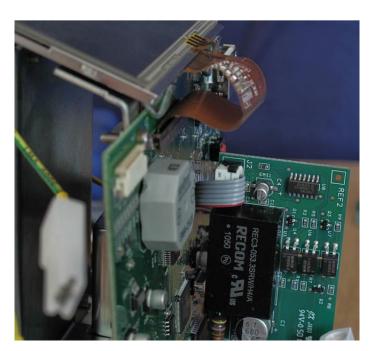
KANMED[°]BABYWARMER

Technical Service Manual KANMED BabyWarmer BW3™

Manual no BW3-079 2018-10-16 version 5 // MW/PS



((0413

Caution

Incorrect use of heating equipment may cause serious injury. Read this manual carefully.

Manufactured by:

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This manual is valid for KANMED Babywarmer BW3 system serial number 0001-10 and above, with Software version 1.0 (or higher)

Subject to changes.

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TECHNICAL SERVICE MANUAL

1 INTENDED USE

Intended use

The intended use of the KANMED BabyWarmer BW3 is to keep newborn and premature babies normo-thermic. KANMED BabyWarmer BW3 is designed for hospital use only. It must be used according to the instructions in the operator manual and according to established clinical routines and by qualified personnel.

Essential Performance

The automatic system supervision will safeguard any malfunction that may have influence on the performance of the system. If used according to this instruction manual, and if the warning information is taken into account, no unacceptable patient risks should occur. However, always monitor the patient's vital signs and adapt the use after the patient's actual requirements.

Only KanMed original parts can be used with this system. All other use will jeopardise the system function and the safety of the patient.

Latest version of the user manual and information about accessories can be found at www.kanmed.se

2 EXPLANATION OF SYMBOLS USED

Symbols

Move highlighted selection in MENU. Display the graph screen during operation.



Move highlighted selection in MENU. Also part of the keyboard lock. Display the status screen during operation.

 (\mathbf{A})

Decrease temperature, or change highlighted selection in MENU

Increase temperature, or change highlighted selection in MENU.



OK, ENTER, select highlighted item in MENU.

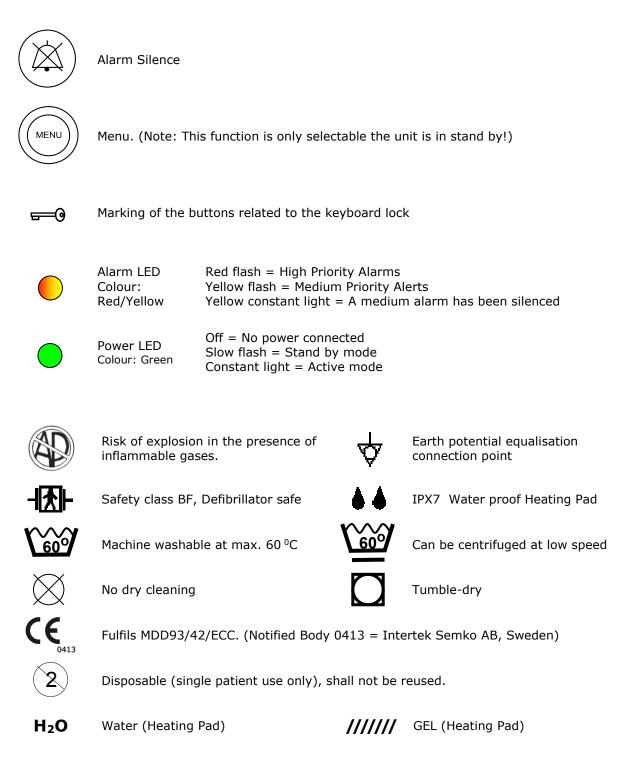


High Temperature Alarm Limit for the temperature monitor. When pushed, the display changes to "adjust high alarm level screen" (*Note: This function is only selectable when an external temperature probe is connected*).

Low Temperature Alarm Limit for the temperature monitor. When pushed, the display changes to "adjust low alarm level screen". (*Note: This function is only selectable when an external temperature probe is connected*).

ON/OFF

Information symbol (Read the Manual) The push button is part of the keyboard lock.



3 SAFETY INFORMATION

Pls refer to the safety information found in the User Manual for hazards related to normal operation of the system.

Warnings

- **System Malfunction.** If the Babywarmer BW3 self test does not perform correctly or the function supervision has displayed an alarm or error message or the Control Unit has received mechanical damage, it must be examined by a qualified technician before being used. If the Babywarmer BW3 is suspected to not operating properly, immediately consult a qualified technician for advice.
- **Electrical Hazard** The system must always be connected to a mains power outlet with proper protective grounding. Always remove the mains power cable before cleaning the Control Unit. **NOTE**: The BW3 may not be interfaced with any other electrical system. If this is done a new "system" is created per definition, and the safety classification of the BW3 may be effected. Do not position the Control Unit so it will be difficult to disconnect the mains power cable!
- Dropped or otherwise possibly damaged. If the BabyWarmer BW3 Control Unit had fallen to the floor or has been subjected to other possible damage it must be examined by a technician before being used.
- Always remove mains power if the control unit is opened!
- Always perform internal work with the system in an ESD-protected environment.
- **Modifications.** Un-authorised personnel are not allowed to open the Control Unit. No modifications of the system, of any kind, are allowed since it will void the safety certification of the system and may seriously endanger patient safety. Only original parts may be used. The Heating Pad cable may not be altered in length or repaired in any way. If damaged, the complete Heating Pad must be replaced.

Caution

- Check the Water Mattress daily for leaks.
- **Compatibility.** Only KANMED BW3 series Heating Pads can be used with Babywarmer BW3 Control Unit. The Babywarmer BW3 system is <u>NOT</u> compatible with KANMED BW50 series Heating Pads.
- **EMC.** Babywarmer BW3 needs to be installed and put into service according to the EMC information provided. (Detailed EMC information can be downloaded from <u>www.Kanmed.se</u>)
- **DIATHERMY equipment and Defibrillators.** Under normal circumstances the Babywarmer BW3 is not disturbed by this type of equipment. However, if the diathermy or defibrillation is set at very high output levels, the Babywarmer BW3 might go into alarm state. In such a case, restart the system and observe that the self test is being performed correctly. Note that the Control Unit housing is electrically connected to earth.
- ECG disturbance. Under unfavourable conditions there is a risk that interference may occur on ECG
- traces. This may occur if the ECG electrodes are not being applied strictly to the manufactures instructions.MRI cameras. The system is not designed for use with MRI cameras.
- Heating Pad storage. Do not bend or fold the Heating Pad in a way that sharp crease arises.
- **Cleaning**. Users should not use cleaning or decontamination methods different from those recommended by Kanmed without first checking with Kanmed that the proposed methods will not damage the equipment.

4 CLEANING, CHECKS BEFORE USE AND MAINTENANCE

Cleaning / Disinfecting

Always unplug mains power cord before any cleaning procedure. Wipe off the Control Unit with a moist cloth and if necessary use normal hospital cleaning agent.

Clean the watertight Heating Pad with soap or your usual cleaning agent. Disinfect the Pad with alcohol or any other commonly used disinfectant.

NOTE: Do not autoclave the Pad. Do not submerge the connector in any liquid.

Checks before use

• Check that all parts are clean and in god condition. Check that the unit performs a correct self test at start. If error codes appear and cannot be eliminated with the suggestions given in the trouble shooting section of this document, then it should be notified to Technical staff. Note: If any part of the system has received mechanical damage, it should always be checked and correct system function verified by technical staff. Check the Water Mattress daily for leaks.

Maintenance

Kanmed Babywarmer BW3 does not require any special maintenance apart from what is described in the technical section of the user manual.

5 ACCESSORIES AND SPARE PARTS

| Article number | Description | Quantity | |
|---|--|--------------|--|
| BW3-001 | Complete Kanmed Baby Warmer kit with Water Mattress | 1 | |
| | Control Unit BW3 | | |
| BW3-020 | | 1 | |
| BW3-003 BW-50-003 | Heating Pad Water Mattrees 4 5 litre (standard) 600 x 270 mm | 1 | |
| BW-50-010 | Water Mattress 4,5 litre (standard) 600 x 270 mm Water Mattress 10 litre. For the Kanmed Single beds. 60 x 40 cm. | 1 | |
| BW-50-015 | Water Mattress for Twins. 60 x 58 cm | 1 | |
| | Kanmed Water Conditioner 118 ml | 20 | |
| BW-50-029 | Kanmed Clean Water Tablets. 10 pcs. | 20 | |
| BW3-029 | | 1 | |
| GE-602815 | Gel Pad with pocket 600 x 280 x 15 mm | L | |
| GE3-003 | Gel pad with integrated heating pad | | |
| BW-50-025 | Baby Nest blue (re-usable) 650/400 x 350 mm | 1 | |
| BW-50-025-P | Baby Nest pink (re-usable) 650/400 x 350 mm | 1 | |
| BW-50-025-Y | Baby Nest yellow (re-usable) 650/400 x 350 mm | 1 | |
| BW-50-25XL | Baby Nest Extra Large | 10 | |
| BW-50-200 | Baby Nest white disposable (single patient) 650 x 350 mm | 10 | |
| BW-50-200S | Disposable nest small | | |
| BW3-070 | Instruction manual, English | 1 | |
| BW3-079 Service manual, English | | 1 | |
| BW3-007 Battery Cable (power adapter) for 12 V batteries | | 1 | |
| BW3-0837 Pole Clamp. Standard on all Control Units since May 2017 | | 1 | |
| | BB-112 Holder for Pole Clamp. Mounted under Kanmed Beds. | | |
| 800-0527 | Bracket for 25 mm drip poles. To optimize view angle. | | |
| 3W3-099 YSI Temperature Sensor | | 1 | |
| BW3-100 Test box for easy test of the temperature | | | |
| Spare parts | local distributor will provide a spare part price list as well as a service m | anual that | |
| contains all infor permitted by Kar | mation necessary to perform diagnostics, maintenance and repairs to th nmed. | | |
| | epairs of the PCBs are permitted, exchange units only. | | |
| 699-1171 | Mains Cord 230V (Swedish plug) | 1 | |
| 400-009 | Power supply unit | 1 | |
| 400-005 | Heating Pad and Power interface board | 1 | |
| 400-003 | YSI-sensor interface board | 1 | |
| 400-001 | Main PCB | 1 | |
| 400-020 | Top assembly, including the display panel | 1 | |
| 400-0152 | Plastic bottom part | 1 | |
| 400-017 | Label set | 1 | |
| 400-0194 Back cover plate | | | |
| 400-0194 | | | |
| 400-0194 400-007 | LED-Display | 1 | |





PAD and Power interface board

Main PCB





YSI-probe interface board

Power supply unit

6 Technical Information

General

The Control Unit contains a microprocessor based heating control system that regulates the temperature of the Heating Pad element.

The safety system in the Control Unit is continuously monitoring internal voltages, running parameters, the pad condition and the behaviour of the heating pad.

An autonomous high temperature safety circuit, totally independent of the microprocessor based operating system, can at any time stop the heating.

If a fault is detected, the Control Unit will alarm visually and acoustically and switch off the heating. The type of error is indicated on the alarm display. A description of the error codes are found under the chapter "Trouble Shooting".

Detailed system description.

The Babywarmer BW3 system is designed with multiple level of protection against any foreseeable errors that may cause potentially harmful conditions for the patient. The system is computer controlled, with a failsafe (twin state) watch-dog, monitoring the correct operation of the main process and will cause a safety relay to break the power to the pad if a computer error occurs. The computer constantly monitors the running state of all vital parts of the system, and will immediately report an error if any parameter runs outside its stated boundaries.

Two separate microprocessors are used, one is running the main program the other is an independent alarm processor.

The temperatures of the heating pad element are measured by four separate thermistor sensors. Two of the sensors (T2 and T4) are in thermic connection with the heating element, and two are isolated from the heating element (T1 and T3). Sensors T2 and T4 are constantly monitoring the actual temperature of the heating element. The computer will use the highest of the two sensor readings to regulate the temperature of the heating element. The isolated sensors (T1 and T3) are in thermic contact with the mattress (water or gel), and will thereby provide a feedback temperature, making it possible to regulate the water mattress temperature with a very high accuracy in H2O mode. In GEL-mode, the sensors will detect if an aluminium plate is present, and if not - render an alarm.

The measuring circuits are separated into two completely independent electronics circuits. The constant measuring current of these two circuits are constantly monitored, and displayed as R1 and R2 in the Technical Status display.

One measuring circuit is totally computer independent and will cause the safety relay to activate if the measured temperature of any of the thermistors T3 or T4 will reach a safety threshold value, hence causing the heating to stop.

Apart from a constant on-line supervision of the systems vital safety functions, the system will automatically turn into a cyclic self test mode for a couple of seconds every 15 min. and perform an full off-line test of the safety circuits, among other thing turning the safety relay on and off, in order to verify its integrity.

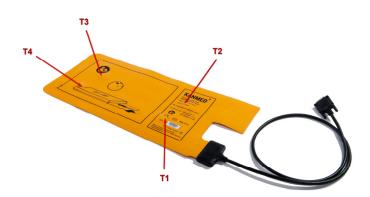
The control unit will automatically log events and running parameters into memory when operated, enabling post-analyses to be made of suspected system malfunctions.

The heating pad consists of an electric element with four integrated temperature sensors. The design and construction of the Heating Pad has reduced the magnetic field (by full bifilarity of the element), and the electrical fields (by shielding) to normal background levels and thereby making them harmless. The element feeding voltage is 24V DC.

Location of the integrated temperature sensors.

T1 and T3: temperature of the mattress (feedback sensors)

T2 and T4: temperature of the element



7 TECHNICAL DATA

Heating Pad, BW3-003

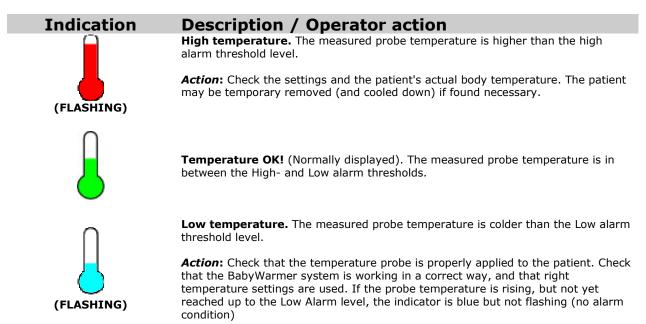
| Heating Pad, BW3-003 | |
|---|--|
| Voltage | 24 Volt DC from Control Unit BW3 when powered from mains power, or 12/24 V DC |
| | when powering from 12/24V battery source |
| Power consumption | 50 Watt, 10 Watt when the Control Unit is powered from a 12 Volt battery. |
| Dimensions and Weight | 580 x 250 mm / 0,5 kg |
| Length of connection cable | 1,2 m |
| Material cover | PVC |
| Watertight | Yes |
| Conductivity - surface | Not electrically conductive |
| Radiation | No measurable magnetic and electrical fields |
| Life expectancy | The lifetime for the BW3 Heating Pad is expected to be more than 2 years from first day of use. This is under the condition that the pad has been handled and maintained according to the user manual. |
| | |
| Control Unit, BW3-020 | |
| Mains power / Frequency | 100 - 240V AC / 50/60 Hz |
| Battery power | 24V DC 12V DC (with limited warming capacity). |
| Power consumption | Max 100 VA (peak value). Average consumption, approximately 15 VA |
| Temperature settings | $25 {}^{\mathrm{o}}\mathrm{C}$ - $35 {}^{\mathrm{o}}\mathrm{C}$ in steps of 0,5 ${}^{\mathrm{o}}\mathrm{C}$ |
| available | 35 °C - 38 °C in steps of 0,1 °C |
| Regulating accuracy | better than ±1.0 °C |
| Display resolution | 0.1 °C |
| Auditory Alarm | 55 dBA normal, 45 dBA reduced sound level at 1 m horizontally |
| | Note : Sound level adapted to a quiet environment, delivery- or maternity ward etc. |
| Over temperature alarm | At a water temperature of 39.5 \pm 0,5 °C, in GEL mode 40,0 \pm 1 °C |
| Dimensions and Weight | Height 200 mm, Width 140 mm, Diameter 150 mm. Weight 1400 g |
| Fuses | Primary fuses; built in to the power supply |
| 1 4505 | Secondary fuses; built in to the PAD interface board |
| Mode of operation | Designed for continuous use |
| Water protection | Drip proof when installed according to instructions |
| Life expectancy | Kanmed warrants a safe lifetime for the BW3 Control unit of 10 years from first day |
| | of use. This is under the condition that the unit has been serviced according to the user and or service manual and that the unit has not been modified or changed in |
| | any way or for any reason. |
| Water Protection Water Mattress, BW50-00 | IP20 , if mounted according to this user manual. |
| Dimensions and Weight | Length 600 mm, With 270 mm, Height 30 mm, |
| | Other sizes might be available. Please contact your local supplier. |
| | Weight about 0.5 kg (not filled), about 5.0 kg (filled with water) |
| Material | Medical grade PVC |
| Kanmed Clean Water Tablets | Bottle of 10 tablets. Turns slightly unclean tap water into drinkable water. Contact Kanmed for product data safety sheet |
| Life expectancy | The safe lifetime for the Water Mattress is at least 1 year from first day of use. This i under the condition that the mattress has been handled and maintained according to the user manual. |
| Other sizes are available. Please | 1 |
| | and GE3-003 integrated heating pad |
| Dimensions and Weight | GE-602815:. Length 600 mm, With 280 mm, Height 15 mm, Weight about 2,3 kg GE3-003: Length 600 mm, With 280 mm, Height 15 mm, Weight about 3 kg |
| Material | AKTON viscoelastic polymer sealed in a polyether urethane (PU) film. |
| Life expectancy | The safe lifetime for the GEL Mattress is several years from first day of use. This is under the condition that the mattress has been handled and maintained according to |

| KANMED Baby Nest I | 3W50-025 (re-usable type) | | |
|----------------------------|--|--|--|
| Dimensions | Length 650 mm, Width 450 mm Height 50 mm flattened | | |
| Material | Cover: High quality ÖKOTEX grade cotton and polyester | | |
| | Filling of collar: Polyester fibre. Always tumble dry | | |
| Washing | Recommended temperature 60°C, Can tolerate 90°C but this may shorten lifetime | | |
| Various colours, sizes and | materials are available. Please contact your local supplier. | | |
| KANMED Baby Nort | 3W50-200 (disposable type) | | |
| | | | |
| Dimensions Material | Length 650 mm, Width 450 mm Height 50 mm Cover: Non woven spunbond polypropylene, 40 g / m ² | | |
| Material | Filling of collar: Thermoloft DW, Libeltex AB, Bredaryd. | | |
| Washing | Must not be washed. Single patient use only. | | |
| Various sizes and types m | ay be available. Please contact your local supplier. | | |
| Warming Capacity | Note: Fill Water Mattress with warm water to reduce warming up time) | | |
| Std. Water Mattress | About 4-6 °C per hour. | | |
| | (Room temperature about 22 °C and filled with 4,5 litres of water and placed on the | | |
| | mattress of a baby bed and covered with the nest and a sheet. Connected to mains AC-power, or directly to a 24V battery, or with the BW3-007 Battery Cable (12 to 24 V DC power adapter)). | | |
| Gel Mattress | About 8-10 °C per hour. | | |
| | (Room temperature about 22 $^{\circ}$ C and placed on the mattress of a baby bed and | | |
| | covered with the nest and a sheet. Connected to mains AC-power, or to a 24V battery, or with the BW3-007 Battery Cable (12 to 24 V DC power adapter)). | | |
| Safety Standards | | | |
| Standards | EN 60 601-1, EN 60 601-1-2, EN 60 601-2-35 | | |
| Protection type | BF, Defibrillator safe Class I | | |
| CE marking | Fulfils MDD 93/42 EEC. MDD class IIB. (EC 0413= Intertec SEMKO, Sweden) | | |
| Environmental Condi | tions, normal use | | |
| Temperature / Humidity | +10 to + 34 °C / 10 - 90%, non condensing | | |
| - · · · · | | | |
| Environmental Condi | tions, storage and transport | | |
| Temperature / Humidity | -25 to + 50 °C / 10 - 100%, non condensing | | |
| EMC Guidelines | | | |
| | The BW3 Baby Warming system should not be used adjacent to, or stacked with othe equipment. If adjacent or stacked use is necessary, the BW3 Baby warming system should be observed to verify normal operation in the configuration in which it is used. Additional EMC information is found in the user manual and in the service manual | | |
| Connection to batter | y | | |
| | If the Control Unit is to be connected to a battery (12V DC, from a vehicle etc.) use the Battery Cable BW3-007. Connect the battery cable to the Battery inlet below the PAD connector on the Control Unit. Connect the other end (fitted with a DIN 4165 plug) to the vehicles cigarette lighter socket or similar outlet. If the Control Unit is powered directly from a 24 V battery source, then note that the center pin of the DC power inlet is + (positive). Make sure that the power outlet is able to supply minimum of 3 A DC. (The 2,5/5,5 mm power inlet of the BW3 Control Unit is internally fuse-, and polarity protected.) | | |
| Modifications | Any modifications on the central wait besting and CEL convertes matters with the | | |
| | Any modifications on the control unit, heating pad, GEL- or water mattress will void KANMED's responsibilities totally and are not allowed without the written consent of KANMED. | | |

TROUBLE SHOOTING 8

Temperature monitor alerts

These alerts relates to the built in temperature monitor, and does not effect the function of the baby warmer. The temperature monitor is only activated when a YSI400 compatible temperature probe is connected. If a temperature monitor alert condition is detected, the alarm is activated, indicated on the display by a flashing thermometer icon, audio signal and the yellow LED. After pressing the Alarm button, the alarm will be silenced for 2 minutes. If the alert condition remains, the alarm will return.

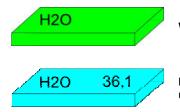


Quick indications

Informative system messages only, the system will continue operation as normal. The colour of the face icon depends on a combination of the mattress temperature and the YSI400 temperature sensor (if fitted).

| Indication | Description / Operator action |
|------------|--|
| | Excess heat / Slow cooling / High temp alarm. The mattress has a higher temperature than the set value OR the temperature monitor YSI400 sensor is warmer than the Hi temp alarm level (if a probe is connected). Action: Will normally occur after the set value has been reduced from a higher value. The settings should always be checked, and if found necessary, the patient may be temporary removed (and cooled down). |
| •• | Within limits! Set temperature has been reached and the temperature monitor is within the alarm levels (if a probe is connected). The system is ready for use provided that a correct set temperature has been chosen. |
| | Low heat / Slow heating / Low temp alarm. The mattress has not reached the set temperature OR the temperature monitor YSI400 sensor is colder than the Lo temp alarm level (if a probe is connected). Will normally occur when a cold start is being performed. Action: Check the temperature monitor probe. All settings should be checked. If a cold start has been performed, the patient should not be placed on the mattress before the indication has turned green. |
| H2O 37,6 | High mattress temperature. The calculated temperature is more than 0,8°C warmer than the set value. The mattress temperature is displayed in the icon. |

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Within limits! The calculated temperature is within ± 0.8 °C of the set value.

Low mattress temperature. The calculated temperature is lower than 0,8°C under the set value. The mattress temperature is displayed in the icon.

Medium priority alarms

When a medium priority error is detected, the alarm is activated (error code display, audio signal and the error LED). After pressing the Alarm button, the unit will continue to operate normally for 2 minutes. If the error condition remains, the alarm will return.

| Code | Description | Action | Note |
|----------|---|--|---|
| 20 | Low H₂O Temp alarm . The calculated water mattress temperature is more than 1°C below the set value. | Reset the alarm. Check the actual mattress temperature. If there is a logical explanation (e.g. a heavy thermal load on the Pad, an extra large water mattress being used etc), then make necessary corrections. Restart the system. If the alarm re-occurs, the system should be analyzed and/or replaced. | This alarm is only activated in H2O- mode 4 hours after system start or after any set temp adjustment. |
| 21 | Low GEL Temp alarm . The calculated GEL- mattress temperature is more than 1°C below the set value. | Reset the alarm. Check the actual mattress temperature. If there is a logical explanation (e.g. a heavy thermal load on the Pad, the system operating on 12 V DC etc), then make necessary corrections. Restart the system. If the alarm re- occurs, the system should be analyzed and/or replaced. | This alarm is only activated in GEL- mode 4 hours after system start or after any set temp adjustment. |
| 22 | High Temp alarm. The calculated GEL- or water mattress temperature exceeds the set value by 1°C or more. | If there is a logical explanation (e.g. the set value lower than the room temperature, the mattress effected by a radiant warming light or similar), then make the necessary corrections. Restart the system. If the alarm re-occurs, the system should be analyzed and/or replaced. | This alarm is only activated 4 hours after system start or after any set temp adjustment. |
| 23 | Error in the temperature monitor interface. | The system should be analyzed and/or replaced. | |
| 24 25 | Defect YSI400 temperature probe Temperature probe disconnected | The external temperature probe needs to be replaced. Reconnect the probe or silence the alarm | |

High priority alarms If a high priority error is detected, the heating is switched off and the alarm is activated (the error code is displayed, audio signal emitted and the red LED flashing). After pressing the Alarm button, the unit goes to stand by. If a restart is performed, please carefully observe that a correct self test is being performed.

| Code | Description | Action |
|------|---|---|
| 01 | Power loss has occurred during normal operation. | The power alarm can be silenced by the operator by pressing the alarm button for about 2 seconds. Reset the alarm and restart the unit when the power has been restored. |
| 02 | High H ₂ O temp alarm: The calculated H ₂ O- mattress temperature (thermistor T1 or T3) has exceeded 41°C for more than 30 sec. | Reset the alarm. Check the actual mattress temperature. If there is a logical explanation (e.g. a external heat source affecting the heating pad), then make necessary corrections. Reset the alarm and restart the unit. Check that the self test performs OK. If the alarm re-occurs, the system should be analyzed and/or replaced. |
| 03 | Measuring error : The independent HW safety circuit has detected that the H2O thermistor T3 render a higher reading than 42°C or the element thermistor T4 more than 43°C, or the internal reference deviates more than 1 %. | Reset the alarm. Check the actual mattress temperature. If there is a logical explanation (e.g. an external heat source affecting the heating pad), then make necessary corrections. Reset the alarm and restart the unit. Check that the self test performs OK. If the alarm re-occurs, the system should be analyzed and/or replaced. |
| 04 | High GEL temp alarm: The calculated GEL- mattress temperature (thermistor T2 or T4) has exceeded 45°C (peak reading). | Reset the alarm. Check the actual mattress temperature. If there is a logical explanation (e.g. an external heat source affecting the heating pad), then make necessary corrections. Reset the alarm and restart the unit. Check that the self test performs OK. If the alarm re-occurs, the system should be analyzed and/or replaced. |
| 05 | Sensor error A: Thermistor T3 or T4, or the measuring circuit is faulty (open loop). | Reset the alarm. Replace the Heating PAD. Restart the system. Check that the self test performs OK. If the alarm re-occurs, the system should be analyzed and/or replaced. |
| 06 | Sensor error B : Thermistor T1 or T2, or the measuring circuit is faulty (open loop). | Reset the alarm. Replace the Heating PAD. Restart the system. Check that the self test performs OK. If the alarm re-occurs, the system should be analyzed and/or replaced. |
| 07 | Sensor error C : Thermistor T1, T2, T3 or T4, or the measuring circuit is faulty (short circuited or rendering a value grater than 49°C). | Reset the alarm. Replace the Heating PAD. Restart the system. Check that the self test performs OK. If the alarm re-occurs, the system should be analyzed and/or replaced. |
| 08 | Regulator error : The heating PAD output has been active for more than 120 consecutive sec, indicating an error in the output circuit. | The Control Unit should be replaced and the faulty unit analyzed by an authorized technician. Note: This error can also occur as a secondary alarm when alarms for other primary errors have been silenced. |
| 09 | High internal temperature: The Control Unit's internal temperature has exceeded 60°C. | Reset the alarm. If there is a logical explanation (e.g. an external heat source affecting the Control Unit), then make necessary corrections. Reset the alarm and restart the unit. Check that the self test performs OK. If the alarm re-occurs, the system should be analyzed and/or replaced. |
| 10 | Safety relay malfunction : The safety relay does not operate properly - or there is something wrong with the PAD-current. | The Control Unit must be replaced and the faulty unit analyzed by an authorized technician. Note: This error will also occur if the heating PAD element is faulty (open loop). |
| 11 | Short circuit in the Heating Pad: Internal short circuit detected in the PAD. | Caution: If this alarm occurs, the PAD interface board (part no 400-005) needs to be replaced! If the short circuited PAD (that caused this error) is connected to another Control Unit, it will most likely damage the PAD interface board on that unit as well. |
| | | The Control Unit and the PAD must be replaced and the faulty system analyzed by an authorized technician. |
| 12 | Uneven Heating Pad temp in H_2O mode: Unnatural temperature differences (> 1,4° C) measured between the two H2O thermistors T1 and T3. | Reset the alarm. If there is a logical explanation (e.g. a heavily tilted bed during warming up phase, low water level in the H_2O mattress, external heat source or high thermal load affecting one of the thermistors), then make necessary corrections. Reset the alarm and restart the unit. Check that the self test performs OK. If the alarm re-occurs, the system should be analyzed and/or replaced. |
| 13 | DC power error. The PAD voltage is either lower than 9 V, or higher than 28 V. | If the control unit is fed by external DC source or a 12 V power adapter, check the external supply voltage and the adapter. If the unit is fed by mains AC Power and this alarm occurs, the control unit should be analyzed and/or replaced. |
| 14 | Uneven Heating Pad temp in GEL mode : Un- natural temperature differences measured between the two H2O thermistors T1 and T2, OR between T3 and T4. During the first two hours after a cold start, the maximum allowed temperature difference is 8° C, thereafter 4° C. | Reset the alarm. If there is a logical explanation (e.g. a GEL mattress without aluminium plate is used, external heat source or high thermal load affecting the Pad), then make necessary corrections. Reset the alarm and restart the unit. Check that the self test performs OK. If the alarm re-occurs, the system should be analyzed and/or replaced. |

9 ANNUAL CHECK OF THE SYSTEM

The system must be checked annually by a qualified technician. The following shall be tested:

- Visual control of the Control Unit and Heating Pad as well as cables.
- Check the Water Mattress for leaks.
- Complete electrical safety test (as per hospital regulation).
- Check of the safety functions, as per 9.1 below.
- For a optional check of the Control Unit calibration, also perform 9.2 below.

9.1 Check of the safety functions

a) Mains Power failure alarm

This test is performed on a system with Mattress and a Heating Pad.

- 1. Start the warming
- 2. After about one minute, select a temperature different from 37°C and make a note of it.
- 3. Wait about 2 minutes and then disconnect the supply voltage by pulling out the mains plug.
- 4. Check that the Control unit alarm indicator starts to blink and that the acoustic alarm beeps intermittently for at least 10 minutes
- 5. Switch on supply voltage again and check that the Power alarm is displayed and that the warming starts at the set temperature selected before the power interruption.

b) Testing the uneven pad temperature alarm (H₂O mode).

Start the system in H2O-mode, at 37°C <u>without</u> any mattress placed on the heating Pad. The **Alarm 12** should be received within 15 minutes. (Note: Alarm 08 can sometimes occur as a consequence of the first alarm).

c) Testing the uneven pad temperature alarm (GEL mode).

Start the system in GEL-mode, at 37°C <u>without</u> any mattress placed on the heating Pad (no aluminium plate under the heating pad). The **Alarm 14** should be received within 15 minutes. (Note: Alarm 08 can sometimes occur as a consequence of the first alarm).

9.2 Optional test of the calibration and over temperature alarm functions, using the optional test/calibration adapter.

a) Check of system calibration. Connect the optional test/calibration adapter to the Control Unit (to the Pad connector).

Press MENU and select the status screen. Sensor T1 to T4 should display 37,0 \pm 0,4 deg C. Connect the YSI reference cable. The YSI temperature should display 37,0 \pm 0,3 deg C.

Instruction for setting (adjusting) the temp levels on the test adapter..

b) Check of over temperature alarm. Connect the optional test/calibration adapter to the Control Unit (to the Pad connector). Connect the Heating Pad to the test/calibration adapter.

1. Run the system with a water mattress at 37°C till it is in normal thermal balance (green smiley). Check the system status by pressing the down arrow. The T3 should read $37,0 \pm 0,5$ deg. Press and hold the T3 (high H2O temp) button on the test/calibration adapter. A red smiley should be displayed and **alarm 02** should be received within 40 sec..

2. Run the system with a GEL mattress at 37°C till it is in normal thermal balance (green smiley). Check the system status by pressing the down arrow. The T4 should read $38,5 \pm 0,5$ deg. Press and hold the T4 (high GEL temp) button on the test/calibration adapter. **Alarm 04** should be received immediately

3. Connect a 15-pin D-sub cable between the reference connector, and the pad connector on the test box. Connect the test box to the Control unit. Press MENU on the CU, select the status screen. Sensor T1 to T4 should display 37,0 \pm 0,4 deg C.

a) Press and hold the **T3** button on the test/calibration adapter. The **T3** temperature should display 41,5 - 42,5 deg. Make a note of this value. Continue to hold the test button and adjust the trim potentiometer TR3 so that the displayed temperature exceeds 43,0 deg. The safety relay in the CU should now trip (a distinct klick) and the display start to flash. Re-adjust the trim potentiometer TR3 so that the displayed temperature returns to the original (previously noted) value between 41,5 - 42,5 deg.

b) Press and hold the **T4** button on the test/calibration adapter. The **T4** temperature should display 41,5 - 42,5 deg. Make a note of this value. Continue to hold the test button and adjust the trim potentiometer TR4 so that the displayed temperature exceeds 43,0 deg. The safety relay in the CU should now trip (a distinct klick) and the display start to flash. Re-adjust the trim potentiometer TR4 so that the displayed temperature returns to the original (previously noted) value between 41,5 - 42,5 deg.

NOTE: If the PAD is reconnected before the TR3 or TR4 trim potentiometers are re-adjusted (as described above), and the T3 or T3 test button is pressed during normal operation, the **alarm 03** will be received.

Should any of the tests in 9.1 or 9.2 fail, pls contact the authorized Kanmed Distributor for a comprehensive control of the system.

10 REPAIR INSTRUCTIONS BW3 Control Unit

Repairs of the BW3 control unit are limited to replacement of circuit boards and sub-units. The PAD and Power interface board contains non replaceable fuses. Only Kanmed factory may perform repairs of the boards itself.

Pre requirements:

- Disconnect the cable from the power inlet and from the control unit.
- Make sure that you have proper **ESD-protection** as you are handling ESD sensitive circuit boards. Always work in an anti-static environment. Use an ESD-protection bracelet attached to the earth pin on the control unit.

Tools required:



- Torx key, Size T10
- Torx key, Size T20
- 5 mm socket wrench
- 15 mm socket wrench
- small flat screwdriver
- ESD-protection bracelet

CU Disassembling instructions:



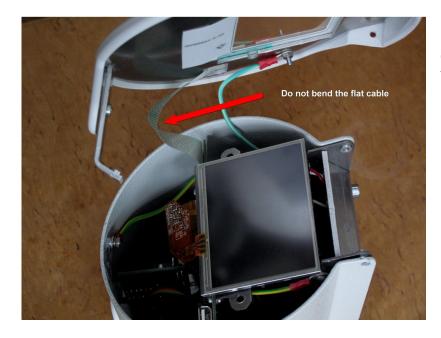
Remove the hanger - if fitted (4 or 6 screws with washers).



Remove the 4 screws that hold the top assembly.



Gently press the top assembly upwards (there are sensitive cables underneath).



Careful not to damage the flat cable.



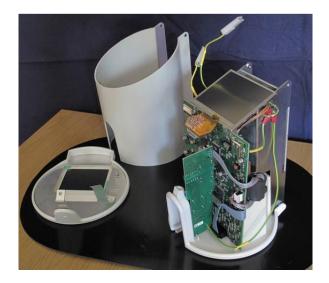
 a) Un-lock the connector by lifting the two tabs and remove the flat cable.

b) Remove the earth cable and remove the top assembly.

c) Remove the earth cable from the front of the aluminum cover.



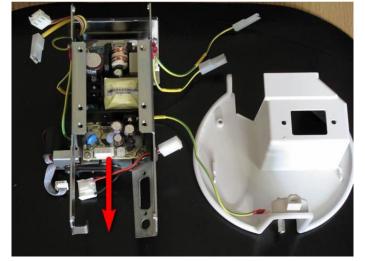
Remove the 2 screws that hold the bottom part. One on each side.



Slide/lift the aluminum housing gently right up.



The Power supply unit is accessed by removing the two screws that holds the net filter (mains power intake). Remove the back cover plate and the plastic bottom part.



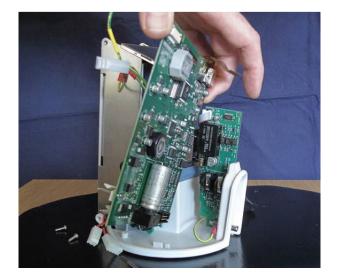
The power supply unit is fixed by 4 screws, and can be removed by sliding it out downwards (after disconnecting the cables).



PAD and Power interface board is removed using a 5 mm socket wrench (after removing the cables).



The display connector is unlocked by folding the black part forward.



The main board is removed by removing the two screws below the display. Disconnect all cable connectors (and make sure to note how they are fitted). Bend the YSI board slightly forward and slide the main board out.

Re-assembly.

Pls. NOTE the following points.

Always use an ESD-protection bracelet and perform work in a ESD-safe environment. Make sure all cables are routed correctly before fitting the aluminium housing.

Before fitting the top:



1. Loosen the two screws that are holding the net filter (power intake) 4-5 turns.

(*Note*: remember to tighten them again after the top assembly has been refitted!)



2. Pay attention to the flat cable. It gets easily pinched when putting the parts back in place. Make sure that the display is in correct position as it easy to break



3. <u>Do not over-tighten the long front-</u> <u>bottom screw</u> (Important!)

11 WARRANTY

KANMED AB warrants the BabyWarmer BW3 Control Unit and Heating Pads for a period of 12 month from the purchase date. In case of a warranty matter KANMED may on its own judgement decide to:

- Repair the unit with new or exchanged parts
- Change the equipment
- Take the unit back against a refund

This warranty is not valid if:

• The product has been modified, adjusted or repaired without the written consent of KANMED.

- The product has been modified, adjusted or repaired without following the written KANMED guidelines.
- The unit has been used for other purposes than the intended use, misused, dropped or in any other way been abused.

Warranty claims must be confirmed in writing.

KANMED is not responsible in any way for any damages arising from deviation from the intended use, neglect of safety instructions, neglect of alarms, neglect of annual service etc.

12 DISPOSAL



When the Babywarmer BW3 have reached end of life, it should be returned to the distributor for recycling in accordance with the EU 2002/96/EC (WEEE) directive if applicable.

13 EMC COMPATIBILITY STATEMENT

EMC Guidelines for the Babywarmer BW3 system

- Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT.
- The KANMED Babywarmer BW3 system should not be used adjacent to, or stacked with other equipment. If adjacent or stacked use is necessary, the KANMED Babywarmer BW3 system should be observed to verify normal operation in the configuration in which it is used.

Guidance and manufacturer's declaration - electromagnetic emissions

The KANMED Babywarmer BW3 system is intended for use in the electromagnetic environment specified below. The customer or the user of the KANMED Babywarmer BW3 should assure that it is used in such an environment.

| Emission test | Compliance | Electromagnetic environment - guidance | |
|---|------------|--|--|
| RF emissions CISPR 11 | Group 1 | KANMED Babywarmer BW3 system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. | |
| RF emissions CISPR 11 | Class B | The KANMED Babywarmer BW3 system is suitable for use in | |
| Harmonic emissions IEC 61000-3-2 | Class B | all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Complies | purposes. | |

Recommended separation distances between portable and mobile RF communications equipment and the KANMED Babywarmer BW3 system.

The KANMED Babywarmer BW3 system is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the KANMED Babywarmer BW3 system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the KANMED Babywarmer BW3 system as recommended below, according to the maximum output power of the communications equipment.

| Rated maximum | Separation distance according to frequency of transmitter m | | | |
|-------------------------------------|--|--------------------------------------|---|--|
| output power of transmitter W | 150 kHz to 80 MHz <i>d</i> = 1,17 √ <i>P</i> | 80 MHz to 800 MHz d = 1,17 √ P | 800 MHz to 2,5 GHz <i>d</i> = 2,33 √ <i>P</i> | |
| 0,01 | 0,2 m | 0,2 m | 0,3 m | |
| 0,1 | 0,4 m | 0,4 m | 1,6 m | |
| 1 | 1,2 m | 1,2 m | 2,3 m | |
| 10 | 3,7 m | 3,7 m | 7,4 m | |
| 100 | 11,7 m | 11,7 m | 23,3 m | |

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

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. *Note 2*: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and manufacturer's declaration - electromagnetic immunity

The KANMED Babywarmer BW3 system is intended for use in the electromagnetic environment specified below. The customer or the user of the KANMED Babywarmer BW3 system assures that it is used in such an environment.

| immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment - guidance | | |
|---|---|---|--|--|--|
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±6 kV contact ±8 kV air | ±6 kV contact ±8 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30% | | |
| Electrical fast transient/burst IEC 61000-4-4 Surge IEC 61000-4-5 | +2 kV for power supply lines +1 kV for input/output lines +1 kV differential mode +2 kV common mode | ±2 kV for power supply lines ±1 kV for input/output lines ±1 kV differential mode ±2 kV common mode | Mains power quality should be that of a typical commercial or hospital environment | | |
| Voltage dips, short interruptions and voltage variations on the power supply input lines IEC 61000-4-11 | <5% UT (>95% dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec | <5% U _T (>95% dip in U _T) for 0,5 cycle 40% U _T (60% dip in U _T) for 5 cycles 70% U _T (30% dip in U _T) for 25 cycles <5% U _T (>95% dip in U _T) for 5 sec | Mains power quality should be that of a typical commercial or hospital environment. If continued operation during power mains interruptions, it is recommended that the KANMED Babywarmer BW3 system be powered from an uninterruptible power supply unit (UPS) | | |
| Power frequency (50 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment | | |
| <i>Note:</i> U_T is the AC mains voltage prior to application of the test level | | | | | |

| Guidance and manufacturer's declaration - electromagnetic immunity | | | | |
|---|--|--------|--|--|
| The KANMED Babywarmer BW3 system is intended for use in the electromagnetic environment specified below. The customer or the user of the KANMED Babywarmer BW3 system should assure that it is used in such an environment. | | | | |
| Immunity test | Immunity test IEC 60601 test level Compliance level Electromagnetic environment - guidance | | | |
| | | | Portable and mobile RF communications equipment should be used no closer to any part of the KANMED Babywarmer BW3 system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. | |
| | | | Recommended separation distance | |
| Conducted RF IEC 61000-4-6 | 3 Vrms 150 kHz to 80 MHz | 3 Vrms | $d = 1,17 \sqrt{P}$ $d = 1,17 \sqrt{P} \qquad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2,33 \sqrt{P} \qquad 800 \text{ MHz to } 2,5 \text{ GHz}$ | |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2,5 GHz | 3 V/m | Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). | |
| | | | Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey*, should be less than the compliance level in each frequency range** | |
| | | | Interference may occur in the vicinity of equipment marked with the following symbol: | |
| | | | (((•))) | |
| <i>Note 1</i> : At 80 MHz and 800 MHz, the higher frequency range applies. | | | | |

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

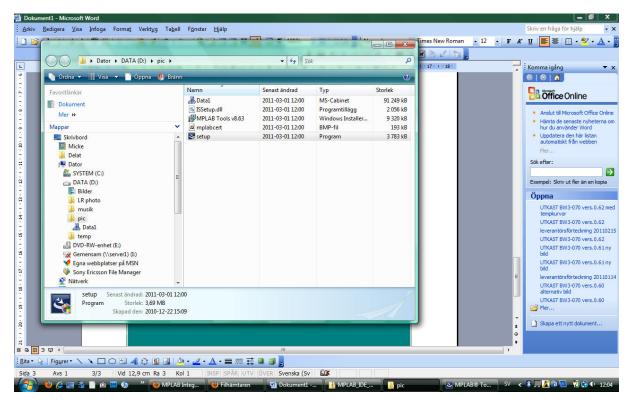
* Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the KANMED Babywarmer BW3 system is used exceeds the applicable RF compliance level above, the KANMED Babywarmer BW3 system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Babywarmer BW3. ** Over the frequency range of 150 kHz to 80 MHz, field strength should be less than 3 V/m.

14 FACTORY LEVEL PROCEDURES

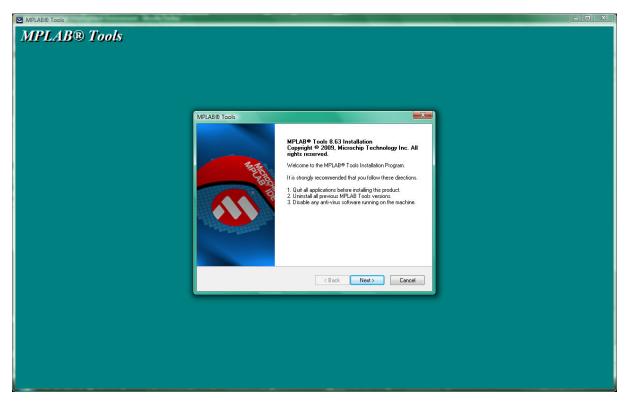
The Babywarmer BW3 firmware can be updated if a future need requires. However, this is a procedure that only should be performed by an accredited Kanmed workshop. A PC-computer running MS-XP or Vista is required, and an MPLAB ICD3 pic programmer device used.

Install the program in a PC.

1. In the enclosed CD choose explorer. Look for the Directory MPLAB_IDE_v8.50. Start the installation by dubble klick the setup icon.



2. Choose Next and answer Yes to all questions.



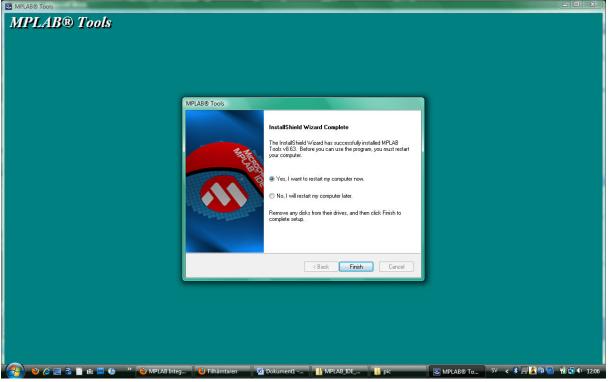
.. Except this one. Answer No (Nej)

| C MPLAB® Tools | |
|---|------------------------------------|
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OBSERVE.. At one point while MPLAB IDE is installing, Windows Vista Security dialogs will pop up saying they can't verify the driver publisher. **Click "Install this driver software anyway"** <u>each</u> <u>time (5 - 6 times!).</u> >IMPORTANT! This seems only

be related to Windows Vista only. On Windows XP or 7 it did not appear.

3. After installation completed. Restart your PC.



In some cases you will have to update the USB driver to make the program work.

Pre requirements before programming a BW3-022 Control Unit.

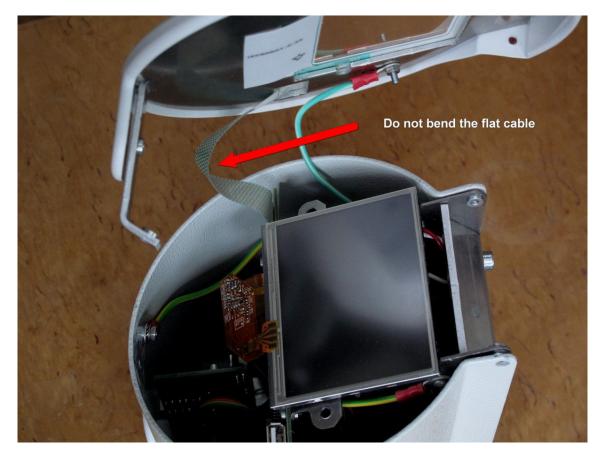
Opening the CU



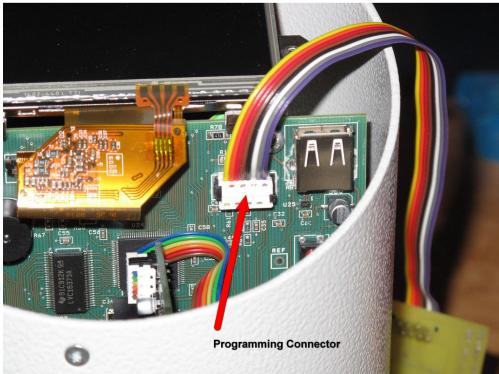
Remove the 4 screws that hold the top assembly.



Carefully slide the assembly upwards. There are sensitive cables underneath.



Careful not to damage the flat cable.



Locate the connector for the programming dongle. Next to the USB connector (not in use). Note the position of the cable to the connector.



Connect the programming adapter to the PC (USB) and carry on to the programming instruction.

Reassembly:

NOTE, before reassemble the top:

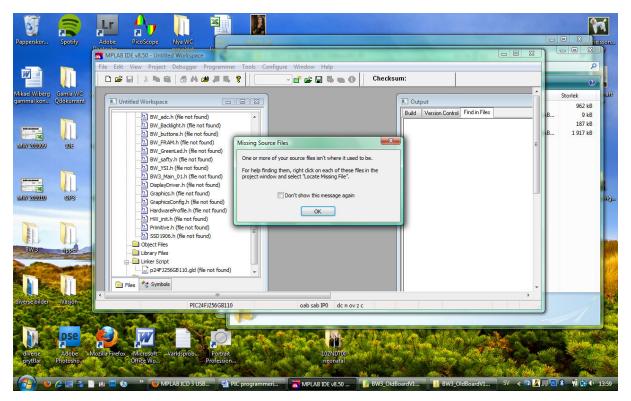
- 1. Loosen the two screws that are holding the net filter (power intake).
- 2. Make sure that the display is in correct position as it easy to break.

3. Pay attention to the flat cable. It gets easily pinched when putting the parts back in place (see picture).

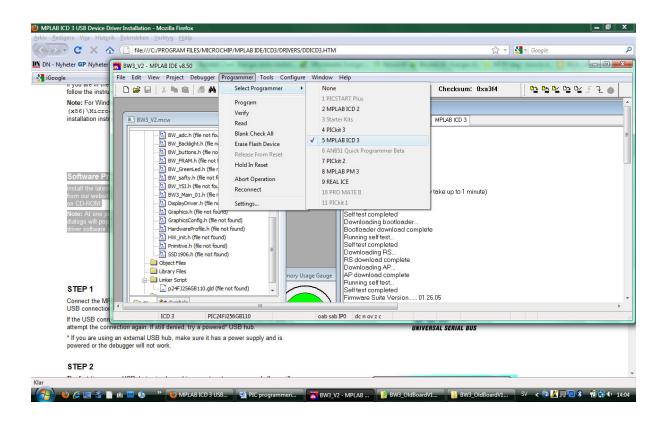
4. Do not over-tighten the front-bottom screw, (close to the YSI connector).

Programming of Main processor.

1. Connect the adapter cable to the BW3's programming connections. Connect the power cable to the BW3 control unit. Start the MPLAD program and connect the dongle to your PC USB port. You might get an error message about *missing Source Files,* just press OK.



2. Choose Programmer; MPLAB ICD3.



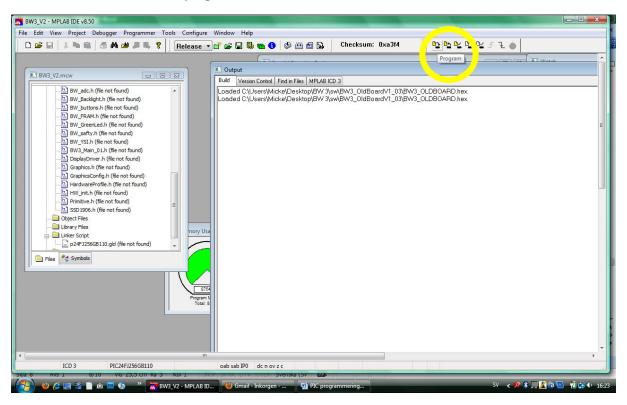
3. Choose: *Project -and Open.*. – Look for current project, mark and press open.

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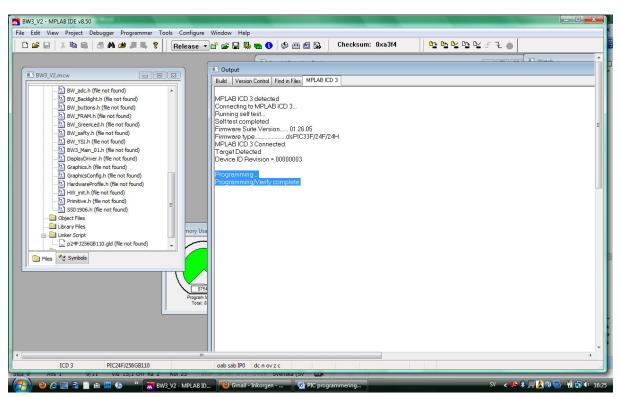
4. Choose: : File - Import... – look for current Hexfil, mark and open

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5.In the headline Press the "program icon"



6. Verify that *Programming/Verify Complete* been reported.

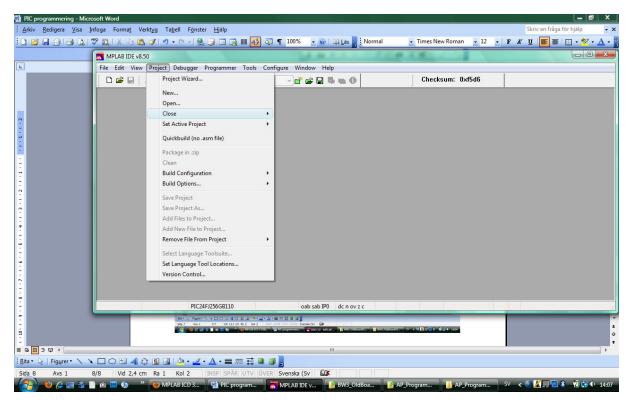


Press MENY on the BW3 control unit, Choose status and verify that correct program version shows on the display. Should more Control Units be programmed at the same time, just connect the program cable and connect the power to the unit and press the program icon.

Programming the Alarm processor.

(NOTE: It is a good idea to start with updating the alarm processor if both processors need to be updated with new program.

1. Change the RJ45-connection to the adapter to "Alarm Processor" (printed on the circuit board). If you have a project already open, this should be closed before starting a new session.



2. Open new Project (AP1 in this case)

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3. Import the Hex-file for the Alarm processor.

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4. Press the Program icon. Note! If fault is reported at the programming (seems to be normal behavior) loosen the USB connector at the PC and re connect again and try to program again.

| Main Processor |
|-----------------|
| Alarm Processor |
| |

NOTE:

Depending on application that shall be loaded you need to use the correct connection.