



**Humeca cordless dermatomes**  
**type D42 and D80**

***Instructions for use and maintenance***



IFU 14/01



**CE** 0344

## Contents

	Page
<b>SECTION I Instructions for use</b>	<b>3-27</b>
1. Application	3
2. The main parts of the dermatome	3
3. Operation	3
4. Charging the batteries	3
4.1 <i>Precautions</i>	4
4.2 <i>The charging procedure</i>	4
5. Placing motor/battery cartridge in the dermatome	5
6. Inserting and removing the blade	6
7. Cutting skin or other tissue with the dermatome	7
7.1 <i>Regular lubrication</i>	7
7.2 <i>Adjusting graft thickness</i>	7
7.3 <i>Adjusting graft width</i>	7
7.4 <i>Cutting</i>	7
8. Cleaning and sterilization	8
9. Atmospheric conditions during use and storage	11
10. Rules, CE–hallmark, responsibilities	12
11. Trouble shooting	13
12. Warranty	14
13. Technical datasheet	15
14. EMC data	16
15. Classifications of clause 5 of IEC 60601-1	20
16. Ordering	21
Images section I	22-32
<b>SECTION II Instructions for periodical maintenance</b>	<b>33-36</b>

**NOTE:**

**A video about use and handling of Humecca electrical dermatomes is available from the Humecca website [www.humecca.com](http://www.humecca.com) (section ‘electrical dermatomes’), or scan this code:**



## SECTION I

### Instructions for use

#### 1. Application

The dermatome has been designed for (split) skin harvesting and debridement of open wounds.

#### 2. The main parts of the dermatome

The dermatome and accessories are shown in pictures 1, 2 and 3. Reference is made to the following parts:

- |   |                                 |    |                      |
|---|---------------------------------|----|----------------------|
| 1 | Power shaft                     | 10 | Battery cartridge    |
| 2 | Cutting head                    | 11 | Disposable blades    |
| 3 | Power switch                    | 12 | Battery charger      |
| 4 | Graft thickness adjusting lever | 13 | Charger support unit |
| 5 | Locking pin                     | 14 | Sterile clamp        |
| 6 | Locking cap                     | 15 | Width reducing clamp |
| 7 | Button rings for opening cover  | 16 | Autoclave case       |
| 8 | Blade compartment cover         | 17 | Sterile funnel       |
| 9 | Motor cartridge                 | 18 | Lock-unlock switch   |

#### 3. Operation

After the coupled motor- and battery cartridges (9 and 10) are inserted in the power shaft (1) and when the locking cap (6) has been closed, the motor can be switched on by pressing the power switch (3) at the upper side of the shaft. The motor puts a rectangular blade in a reciprocating motion. The graft thickness is adjusted by the graft thickness-adjusting lever (4). The standard graft width can be reduced by placing a width reducing clamp on the cutting head (2). A lock-unlock switch prevents accidental run of the dermatome for safety reasons.

#### 4. Charging the batteries



#### Attention! Important security advice!

Connect only Lithium-Ion or Lithium-Polymer battery packs with 2 cells. Never connect other battery types. **Danger of explosion!**

#### **4.1 Precautions**

- Do not attempt to open or disassemble charger or batteries.
- Keep the charger in a dry place (indoor use only).
- For 1200 mAh battery use charger marked 9C94142/03 only.
- For 2400 mAh battery use charger marked 9C94142/01 only.
- Must not be operated under adverse circumstances (for example: inflammable gas, solvents, vapours, dust, humidity over 80% or temperatures under 0°C or above 40°C)
- In order to avoid risk of fire and/or electric shock, the charger must be protected against high humidity and condensation.
- Don't short-circuit. Avoid contact of terminals with metal objects.
- Keep out of reach of children and read instructions before use.
- Charge only rechargeable Li-Ion or Li-Po batteries with an end of charge voltage of 4.2C per cell.
- To shut off the charger, disconnect it from the mains socket.

Failure to comply with the safety instructions may lead to damage to the charger and/or batteries and may cause serious injury to the user.

#### **4.2 The charging procedure**

A battery cartridge (10) is coupled to the motor cartridge (9), as shown in fig. 4, steps 1, 2 and 3. Charging the batteries requires uncoupling of both cartridges. This is done by turning one of the cartridges a quarter turn, while holding the other one in position (fig. 4, steps 3, 2 and 1).

For charging the batteries you proceed as follows:

- Attach the right primary mains adapter to the charger (there is a slide on the charger that allows change of the adapters, see fig. 7a)
- Connect the charger to the mains socket. The green LED "Power" indicates the right connection and the yellow LED shortly lights up.
- Insert the round power plug (12e) of the charger (12) into the female connector of the charger support unit (13), as shown in fig. 5.
- Put the battery cartridge in the round opening of the charger support unit (note that it only fits one way). Secure with a quarter turn (fig. 6).

When connecting the battery, the yellow "Charge" LED lights to indicate the charging process. When the battery is fully charged, the charger switches off automatically and the yellow "Charge" LED is extinguished. If the yellow LED flashes for a period of time, the charger is checking if the battery was deeply discharged. After checking, the charger switches to

the charge process and the yellow “CHARGE” LED lights continuously until the battery is fully charged. If the yellow LED keeps flashing and does not switch to the charge process, the battery pack may be defective.

To prevent its loss, you can place the motor cartridge in the groove of the charger support unit during charging the battery, as shown in fig. 8.

NOTE: The only way to shut off the charger is to disconnect it from the mains socket.

## 5. Placing the motor-/battery cartridge in the dermatome

The motor- and battery cartridges should not be sterilized, at no time !!

- Couple the motor cartridge (9) to the battery cartridge (10) by sliding them into each other, followed by a quarter turn. The marking lines on the two cartridges should be in the same position (fig. 4).
- A circulating nurse now holds the non-sterile motor-/battery cartridge with the marked line (10a) showing upwards. Then the clamp (14) is inserted into the back of the cartridge and lifted up a little, as shown in fig. 9.

**Attention: never hold the cartridge with the marking line downwards: it might fall off from the sterile clamp!**

- Push the sterile funnel (17) over the backside of the dermatome, after having removed the locking cap (6 in fig. 2). The circulating nurse now pushes the motor-/battery cartridge in the dermatome in such a way that the marking lines on the cartridges are in line with the marking line 1a on the power shaft of the dermatome (see fig. 10).
- Remove the funnel (fig. 10 picture 4).
- Finally place the sterile cap at the end of the power shaft with one of the locking balls in line with the line on the power shaft and fix it with a quarter turn until it clicks (see fig. 11).
- Press the power switch 3, with the lock-unlock switch 18 in the unlock position to check proper run of the motor (fig. 12).

## 6. Inserting and removing the blade

### Warnings:

- Do not use other than Humeca blades in the D42 and D80 dermatome and do not use Humeca blades in other dermatomes.
- Always pay attention to the presence of a very sharp blade in the dermatome. Remove it before cleaning and maintenance and always handle it with care to prevent cutting accidents!
- The Humeca dermatome blades are single-use products. According to the amendment 2007/47/EC of the Medical Device Directive we want to point out that there are risks in using blades more than once. Persons involved in re-sterilizing the blades and others might cut themselves when handling and packaging the blades. Also packaging of the blades might be inappropriate to prevent accidental cutting by user and/or damage of the sealed pouch that assures sterility. Therefore Humeca will not accept any responsibility for second use of its dermatome blades.

### *Inserting the blade:*

Hold the dermatome in one hand, the blade compartment cover (8) upwards. Press the round buttons (7) at both sides of the cutting head, using the thumb and index finger of the same hand and open the cover with the other hand (fig. 13).

Carefully put the blade (11) in the dermatome, the cutting edge to the front, taking care that the three pins (2a) interlock with the slots in the blade, as shown in fig. 14. Close the cover.

### *Removing the blade:*

First open the blade compartment cover (see fig. 13) and then remove the blade by lifting the backside with a scalpel or forceps (see fig. 15). To facilitate lifting of the blade, a cavity has been made at the backside for easy access.

**Attention: Never try to lift the front (sharp) side of the blade (as shown in fig. 16) as this might seriously damage the instrument! Always lift it at the backside.**

## **7. Cutting skin or other tissue with the dermatome**

### **7.1 Regular lubrication**

Before sterilization (after cleaning) put a drop of oil (Humeca supplies Aesculap STERILIT<sup>®</sup> oil for this purpose) in the hole (1b) at the bottom of the shaft, situated closely behind the cutting head (Fig. 17). For smooth run, spread a drop of sterile water or salt solution (PBS) over the surface of the blade (fig.16). For periodical maintenance, cleaning and lubrication, please read the instructions in section II of this booklet.

### **7.2 Adjusting graft thickness**

Pull the disk at the locking pin (5) of the lever (4) and adjust the lever to the desired graft thickness (Fig. 19). After releasing the locking pin the lever is fixed. Cutting thickness is indicated in mm and inches (Fig. 19)

### **7.3 Adjusting graft width**

The standard graft width of the dermatome can be reduced by placing a width-reducing clamp on the head of the dermatome. For that purpose take the dermatome upside down in your hand (blade compartment cover upwards). Fig. 20 shows how the width-reducing clamp (15) is put into position. Push the upright hooks (15a) of the clamp behind the cover (8). Now move the clamp little by little forward, until its front closes round about the cover hinge (Fig. 21).

### **7.4 Cutting**

Switch the motor on by pressing switch (3). When cutting, push the cutting head evenly forward under slight pressure over the tissue or skin, while keeping the switch pressed (Fig. 22).

For optimum cutting results and minimum resistance it is recommended to keep the skin slightly tightened on the spot and moistened with water or (paraffin) oil. The cut off skin flap is gripped on the sloping side of the cutting head by hand or using forceps. Do not use force to grip skin with forceps, as it might damage the instrument.

### **Attention:**

**It is strongly recommended to use the re-usable plastic forceps, supplied with the dermatome, to take the skin out of the dermatome as a metal forceps might damage the front of the instrument. After use you can put this forceps in the sterilization case of the dermatome and autoclave it repeated use.**

To cut the strip straight off from the body, move the cutting head upwards, while the motor is still switched on.

**Remark:**

If the Humeca MEEK technique is applied for skin grafting on burns or other large skin defects, ***never - during cutting - use oil or any other fatty substance as lubricant on the skin of the patient.*** This would stand in the way of a good tack of the adhesive used in the MEEK technique. You can use water instead of oil.

## **8. Cleaning and sterilization**

### ***8.1 Preparing the dermatome for cleaning and sterilization***

Immediately after use, when the blade has been taken out, remove the motor- and battery cartridge from the instrument (these are not to be cleaned) and clean from blood and tissue remnants with hot water and soap by hand. Afterwards, the instrument is to be cleaned by conventional procedures for cleaning surgical instruments.

### **!! Never sterilize the motor-/battery cartridge !!**

***Accidental sterilization of motor and/or battery is prevented when the Humeca autoclave case is used, because the dermatome does not fit in this case when the motor-/ battery cartridge is still inside the instrument. Therefore we strongly recommend the use of the Humeca autoclave case!***

For sterilization, proceed as follows (see the pictures of fig. 25):

- Remove and discard the disposable blade.
- Open the locking cap (6) (turn it a quarter and remove it) and take out the motor-/battery cartridge from the dermatome. Put this cartridge aside; it is not to be sterilized.
- Open the autoclave case 16. Inside this case there are some cams, as indicated in Fig. 25A.
- Put the cap (6) between the two cams 16b and place the funnel (17) over the four cams 16d, as shown in Fig. 25B.
- Put the dermatome, with the blade compartment cover (8) opened, in the case in such a way that the security cam 16c comes in the

backside of the power shaft. The two cams 16b interlock with the slots, indicated as 2f in Fig. 25. For good cleaning we advise to put the thickness adjustment lever (4) at maximum thickness position.

- Put the width reduction clamps and the sterile clamp in the case.
- All parts, except for the motor-/battery cartridge can be sterilized with saturated steam using common and accepted procedures for surgical instruments in the hospital.
- Close the cover of the autoclave case and sterilize it at the common temperature of 134 °C (usually 5-10 minutes) or 121°C (prolonged exposure time of approx. 20 minutes).

Note: If by accident the battery cartridge was sterilized, replacement of only the battery pack inside (not the cartridge housing) is possible. If the motor cartridge was sterilized, replacement of only the motor (not the cartridge housing) is possible. See chapter 15 “Ordering” for the ordering numbers.

## **8.2 Cleaning and sterilization procedure**

Parts of Humecca surgical instruments are made out of anodised aluminium. This material is corrosion resistant to a large range of chemicals that are in use as cleaning and disinfection agents for surgical instruments. However, before cleaning and sterilizing the products, we ask you to pay attention to the following (please consult your Central Sterile Services Department (CSSD):

- The instructions for use of the cleaning agent should indicate whether or not the product is suitable for cleaning and disinfecting anodised aluminium. Please find out if this is the case and if necessary contact the supplier for this information.
- We recommend using neutral cleaning agents in combination with demineralised water. Strong alkaline cleaning agents (pH>10) cause clearly visible changes, such as marks and colour fading after only a few cleaning cycles. The intermediate acidic rinse used in an alkaline cleaning process also may attack the anodised aluminium surface. Don't use H<sub>2</sub>O<sub>2</sub> in the washing process.
- Do not use softened water in the rinsing and disinfection stages. After only a few cycles the anodised surface will show clear signs of deterioration.

- After intensive use you will see fading of the coloured parts of the instrument. This however is considered as a normal process and it doesn't harm the instrument.

**The following tables detail the cleaning, disinfecting and sterilization process.**

<b>CLEANING</b>				
<b>Step</b>	<b>Description</b>	<b>Instruction</b>	<b>Accessories</b>	<b>Duration</b>
1	Removal of tissue and body fluids	Rinse with warm water and use soft brush	Soft brush and tap water	Until all visible pollution is removed
2	Pre-soak (optional)	Immerse device into water and liquid cleaner	- Tap water - Neutral pH disinfectant/cleaner	Minimum 15 minutes
3	Pre-soak rinse	Rinse product under warm tap water and clean with soft brush	- Tap water - Neutral pH disinfectant/cleaner	Minimum 30 seconds
4	Drying	Dry with wipe and/or air	- Wipe - Dry air	Until product is visually dry.
5	Automated washer	Place device and brush in washer	- Washer - Cleaning solution - Washer neutralizing solution (if applicable)	Minimum total cycle time 34 minutes when including all steps below
<b>AUTOMATIC WASHER CYCLE</b>				
	<b>Step</b>	<b>Minimum time</b>	<b>Recommended temperature °C</b>	
	Pre-wash	3 minutes	65	
	Cleaning I	3 minutes	85	
	Cleaning II or neutralizing	1 minute	20	
	Rinse I	1 minute	20	
	Final rinse	1 minute	80	
	Thermal disinfection and drying	25 minutes	110	
<ul style="list-style-type: none"> <li>- Pre-soak cleaner may be surfactant or protease/enzymatic based cleaning solution compatible with aluminium</li> <li>- Washer cleaning solution should be a neutral pH or solution compatible with aluminium</li> <li>- Neutralizing solution should be appropriate for the utilized cleaning solution, based upon the manufacturer's recommendation.</li> </ul>				

<b>RECOMMENDED STEAM STERILIZATION PARAMETERS</b>				
<b>Cycle type</b>	<b>Minimum temperature</b>	<b>Minimum exposure time <sup>6</sup></b>		<b>Minimum dry time <sup>3,10</sup></b>
		<b>wrapped <sup>7,8</sup></b>	<b>unwrapped <sup>9</sup></b>	
Prevacuum / Pulsating vacuum <sup>1,3</sup>	134 °C 273 °F	3 min	3 min	8 minutes
Prevacuum / Pulsating vacuum <sup>2,3</sup>	132 °C 270 °F	4 min	4 min	
Prevacuum / Pulsating vacuum <sup>3,4</sup>	134 °C 273 °F	18 min	18 min	
Prevacuum / Pulsating vacuum <sup>5</sup>	132 °C 270 °F	8 min	8 min	

1. Minimum validated steam sterilization time required to achieve a 10<sup>-6</sup> assurance level (SAL).
2. Minimum validated steam sterilization temperature required to achieve a 10<sup>-6</sup> assurance level (SAL).
3. Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed here.
4. Disinfection / steam sterilization parameters recommended by the World Health Organization (WHO) for reprocessing instruments where there is concern regarding TSE/CJD contamination.
5. For universal instrument cases without defined load configurations.
6. AAM/AORN steam sterilization cycles with longer times than those listed are also acceptable.
7. Medical grade steam sterilization compatible wrap equivalent to four thicknesses of 140-thread-count muslin
8. Rigid sterilization container that complies with ANSI/AAMI ST 46.
9. Flash (unwrapped) sterilization by exposure at 132 °C (270 °F) should only be used as an emergency procedure. Instruments should be cleaned.
10. Drying times vary according to load size and should be increased for larger loads.

**Note: The sterilizer Manufacturer's Instructions for operation and load configuration should be followed explicitly.**

In case cleaning and disinfecting products of Diversey are used, a suitable procedure is presented in a joint publication of Humeca and Diversey. It is available on request. You can also download it from [www.humeca.com](http://www.humeca.com)

In cases of doubt, please contact Humeca or your local distributor before using the instrument.

## 9. Atmospheric conditions during use and storage

For use, transport and storage of the instrument, please mind the following conditions:

- Ambient temperature      15 - 40 °C
- Relative humidity          35 - 80%
- Atmospheric pressure      850 - 1070 kPa (640 - 800 mm Hg)

## **10. Rules, CE–hallmark, responsibilities**

- The management system of Humeca for design, production and sales has been certified according to EN ISO 13485:2003.
- EMC data of the Humeca dermatomes are included in a rational of the technical dossier. This record (Rational D003) may be seen at the office of Humeca. The device is electromagnetic compatible, which means that it does not interfere with other equipment in its environment.
- According to the European Medical Device Directive 93/42/ EEC, amended by Council Directive 2007/47/EC, the dermatome and blades come under the head of Class IIa products.
- According to IEC 601-1:1998, the Humeca dermatomes are classified as “Type BF Applied Part”.
- The CE-hallmark is indicated on the dermatome and on the package of the blade.
- Do not use other than Humeca blades in the D42 and D80 dermatome and do not use Humeca blades in other dermatomes.
- Do not use a dermatome blade in case the package is damaged.
- Humeca D42 and D80 dermatomes are not for use in the presence of flammable anaesthetics (AP/APG classification).
- The manufacturer considers being only responsible for the safety and performance of the dermatome and the battery charger, if these are used in the way as described in this manual. For replacements only original spare parts have to be used. Replacements have to be carried out by the manufacturer or by his authorized local representative. Repairs are only carried out if the product is carrying the users official repair form. All repairs carried out will be specified on a delivery note. In connection with safety and performance it is only allowed to charge the battery using the original charger.

## 11. Trouble shooting

Problem	Possible cause	Solution
Dermatome doesn't run and motor axis doesn't run when outside the dermatome the button of the microswitch at the coupled cartridge is pressed	Battery not charged	Charge battery and try again
	Battery out of order	Check battery cartridge. See section 7. Repair or replace if necessary
	Problem with charging	Check charger and battery support. See section 9. Repair or replace if necessary
	Motor cartridge out of order	Check motor cartridge. See section 8. Repair or replace if necessary
	Microswitch broken	Send dermatome to dealer
Dermatome doesn't run, but you can hear the motor running in the power shaft	Motor axis cross pin broken or lost or cylinder on axis loose	Send motor cartridge to dealer
Dermatome doesn't run and motor doesn't run, but motor runs when outside the dermatome the button of the microswitch at the coupled cartridge is pressed	Some moving part is mechanically blocked, probably caused by dirt or inferior lubrication	Clean and lubricate all parts of the cutting head. If this did not help, send dermatome to dealer
Dermatome runs, but the blade doesn't move at all	Pins on the lever broken or lever worn out	Replace the lever
Dermatome runs, but the blade hardly moves	Slot-shaped hole in the lever worn out	Replace the lever
Button rings for opening the cover are stuck	Persistent dirt on the button rings	Clean button rings with fine-grain sandpaper
Dermatome doesn't cut at low position of thickness adjusting lever.	Thickness not correctly adjusted or initial adjustment changed	Send dermatome to manufacturer
Blade compartment cover cannot be closed	Locking mechanism stuck by dirt	Clean locking mechanism inside cutting had
Motor/battery cartridge doesn't fit in the power shaft	One of the screws at the outside of the motor- or battery cartridge is loose	Fix screws
	Some other part of the cartridge stands out	Carefully try to bend back. If not succeeded, replace cartridge housing (consult dealer)
	Marking line on the cartridge not in line with the mark on the dermatome	Take out cartridge and reposition corresponding lines and mark

## Trouble shooting (cont'd)

Battery pack is connected properly but the charge LED "CHARGE" doesn't light yellow	Batteries fully charged	Do not charge batteries
	Battery not connected properly	Check all connections
	Contacts are dirty	Clean contacts
	Faulty battery	Replace battery
Charger is connected but green LED doesn't light	No current on mains	Check mains power supply
	Faulty charger	Replace charger
Yellow charge LED remains flashing and it doesn't switch to light continuously	Wrong polarity of battery pack	Consult dealer
	Battery cartridge not correctly connected to the charger support	Connect correctly
	Faulty battery pack	Replace battery pack

## 12. Warranty

There is a two years guarantee on all parts of the dermatome. The batteries are under a one-year warranty.

This guarantee does not include repairs or replacements if:

- the batteries were charged using a different type of charger,
- the motor- and/or battery cartridge was sterilized,
- other than original spare parts were used for repair by user,
- the dermatome was used for other applications than the ones mentioned in this manual.

Guarantee includes free of charge repairs, if these are necessary as a result of trouble / defects that occurred during normal use of dermatome and charger. In case of problems please contact your local dealer.

### 13. Technical datasheet

#### Dermatome

Total weight D42, small / large grip	985 / 1.115 g (35 / 39 oz)
Total weight D80, large grip	1.330 g (47 oz)
Weight motor cartridge	325 g (11.5 oz)
Weight battery cartr. 1200 / 2400 mAh	149 / 240 g (5.3 / 8.5 oz)
Length dermatome with small / large grip	272 / 295 mm (10.7 / 11.5")
Width head type D42 / D80	64 / 104 mm (2.5 / 4.1")
Maximum diameter small / large grip	40 / 45 mm (1.6 / 1.8")
Cutting width D42 / D80	42 / 80 mm (1.65 / 3.15")
Cutting width using clamps D42	36 and 30 mm (1.42 / 1.18")
Cutting width using clamps D80	65, 50 and 35 mm (2.56, 1.97 and 1.38")
Graft thickness / increments (mm)	0.1-1.2 / 0.1 mm
Graft thickness / increments (inches)	0.004 – 0.048 / 0.004 "
Stroke of blade	3,0 mm (0.12")
Motor capacity / rpm	15 W / 7.030 min <sup>-1</sup>

#### Battery

Voltage / capacity battery pack, small	7.4V / 1200 mAh
Voltage / capacity battery pack, large	7.4V / 2400 mAh
Battery chemistry	Li-Ion (no memory effect)

#### Charger for 2400 mAh battery

Power supply primary	100-240V / 50-60Hz
Nominal output voltage	7,4 VDC
Charge current	1200 mA
Time to charge empty battery	2,0 h
Charger is supplied with international adapters	

#### Charger for 1200 mAh battery

Power supply primary	100-240V / 50-60Hz
Nominal output voltage	7,4 VDC
Charge current	400 mA
Time to charge empty battery	3.0 h
Charger is supplied with international adapters	

#### Disposable blades

Type	Double facet grinded
Width / Thickness	19 / 0,38 mm (0.75 / 0.015")
Length D42 / D80	50 / 90 mm (1.97 / 3.15")

#### Autoclave case

Dimensions for D80 (lxwxh)	375x130x52 mm (14.8x5.1x2.05")
Dimensions for D42 (lxwxh)	375x90x52 mm (14.8x3.5x2.05")
Weight of case for D42 / D80	717 / 910 g (25 / 32 oz)

**Note:** Details on electromagnetic immunity and emission (EMC) are given in the declaration 'Guidance and manufacturer's declaration EMC (electromagnetic immunity) for dermatomes', supplied separately with each dermatome.

## 14. EMC data

### Guidance and manufacturer's declaration EMC (electromagnetic immunity) for Humeca dermatomes

The dermatome is intended to be used in de electromagnetic environment specified below. Customer or user of the dermatome should assure that it is used in such an environment.			
Immunity test	IEC60601-1-2 test level	Compliance level	Electromagnetic environment guidance
Electromagnetic 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	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<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	<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 the user of the dermatome requires continued operations during power mains interruptions, it is recommended that the dermatome be powered from an uninterruptible power supply or a backup battery system.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE:  $U_T$  is the a.c. mains voltage prior to application of the test level.

<p>Conducted RF IEC61000-4-6</p> <p>Radiated RF IEC61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>3 Vrms</p> <p>3 V/m</p>	<p>Portable and mobile RF communications equipment should not be used no closer to any part of the dermatome, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance  <math>d = 1.2 \sqrt{P}</math>  <math>d = 1.2 \sqrt{P}</math> 80 MHz to 800 MHz  <math>d = 2.3 \sqrt{P}</math> 800 MHz to 2.5 GHz  where <math>P</math> is the maximum output power rating of the transmitter in watts (<math>W</math>) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in meters.</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey<sup>a</sup>, should be less than the compliance level in each frequency range<sup>b</sup>.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
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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.

<sup>a</sup> 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 assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the dermatome is used exceeds the applicable RF compliance level above, the dermatome should be observed to verify normal operations. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the dermatome.

<sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m

### S. 23.2 Electromagnetic Emissions

<b>Guidance and manufacture's declaration – electromagnetic emissions</b>		
The dermatome is intended to use in de electromagnetic environment specified below. The customer or the user of the dermatome should assure that it is used in such an environment.		
<b>Emissions Test</b>	<b>Compliance</b>	<b>Electromagnetic environment – guidance</b>
RF emissions CISPR 11	Group 1	The dermatome 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 dermatome is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC61000-3-3	Complies	

### S. 23.3 Recommended Separations Distances

<b>Recommended separation distances between portable and mobile RF communications equipment and the dermatome</b>			
The dermatome is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the dermatome can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the dermatome as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 G
	$d = \left[ \frac{3,5}{V_1} \right] \sqrt{P}$	$d = \left[ \frac{3,5}{E_1} \right] \sqrt{P}$	$d = \left[ \frac{7}{E_1} \right] \sqrt{P}$
0,01	0,12	0,12	0,24
0,1	0,37	0,37	0,74
1	1,17	1,17	2,34
10	3,69	3,69	7,38
100	11,67	11,67	23,34
For transmitters rated at a maximum output power not listed above, the recommended separation distance $d$ in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 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.			

**Statement:**

**Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT.**

**Warning:**

**The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the equipment or system as replacement parts for internal components, may result in increase emissions or decreased immunity of the equipment or system.**

## 15. Classifications of clause 5 of IEC 60601-1

5	CLASSIFICATION		
5.1	Type of protection against electric shock		
	Class I equipment	Dermatome is battery operated	N/A
	Class II equipment	Battery charger	P
	Internally powered equipment		P
5.2	Degree of protection against electric shock		
	Type B applied part		N/A
	Type BF applied part		P
	Type CF applied part		N/A
	Not classified - no applied parts		N/A
5.3	Classification according to the degree of protection against ingress of water as detailed in the current edition of IEC 529 (see 6.1.1).....	Not classified, not relevant	N/A
5.4	Methods of sterilization or disinfection	See instructions for details	P
5.5	Equipment not suitable for use in the presence of flammable mixtures	Not classified as such	N/A
	Category AP equipment		N/A
	Category APG equipment		N/A
5.6	Mode of operation:		
	-continuous operation	However limited by the capacity of the batteries and the operation time removing the tissue. See also table 42	P
	-short-time operation, specified operation; period		—
	-intermittent operation, specified operation; rest period		—
	-continuous operation with short-time, stated permissible loading time		—
	-continuous operation with intermittent, stated permissible loading/rest time		—

## 16. Ordering

### Equipment

4.D42STS	D42 dermatome, complete set, 1200mAh Li-Ion battery (standard)
4.D42STSx	D42 dermatome, complete set, 2400mAh Li-Ion battery
4.D80STS	D80 dermatome, complete set, 2400mAh Li-Ion battery (standard)
4.D42	D42 dermatome without battery- and motor with small grip for 1200mAh battery
4.D42x	D42 dermatome without battery- and motor with large grip for 2400mAh battery
4.D80	D80 dermatome without battery- and motor with large grip for 2400mAh battery
4.ANS-HC	Charger for Li-Ion battery 2400 mAh
4.ANS-LC	Charger for Li-Ion battery 1200 mAh
4.SU01	Dermatome charger support unit
4.BC7.4V2400	Dermatome battery cartridge 7.4V, 2400 mAh
4.BC7.4V1200	Dermatome battery cartridge 7.4V, 1200 mAh
4.BF7.4V2400	Dermatome battery pack 7.4V, 2400 mAh (only pack, not cartridge)
4.BF7.4V1200	Dermatome battery pack 7.4V, 1200 mAh (only pack, not cartridge)
4.MCX15	Dermatome motor cartridge
4.D42CL30	D42 width reducing clamp 30 mm (1.18")
4.D42CL36	D42 width reducing clamp 36 mm (1.42")
4.D80CL35	D80 width reducing clamp 35 mm (1.38")
4.D80CL50	D80 width reducing clamp 50 mm (1.97")
4.D80CL65	D80 width reducing clamp 65 mm (2.56")
4.D42AC1	D42 sterilization case
4.D80AC1	D80 sterilization case
4.SCL	Sterile clamp
4.SF01	Sterile funnel for small diameter grip
4.SF02	Sterile funnel for large diameter grip

### Disposables

5.D42BL10	D42 dermatome blades, box 10 pcs.
5.D80BL10	D80 dermatome blades, box 10 pcs.
2.JG598	STERILIT <sup>®</sup> oil for surgical instruments, bottle 50 ml (1.7 fl.oz)

For more information, please contact your local Humeca representative or:

Humeca BV  
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7544 DB Enschede  
The Netherlands

phone: +31 53 4762619  
fax: +31 53 4771905

e-mail: [info@humeca.com](mailto:info@humeca.com)  
web: [www.humeca.com](http://www.humeca.com)

Humeca is an EN ISO 13485:2003 certified company.

**Humeca cordless dermatomes  
type D42 and D80**

*Images*

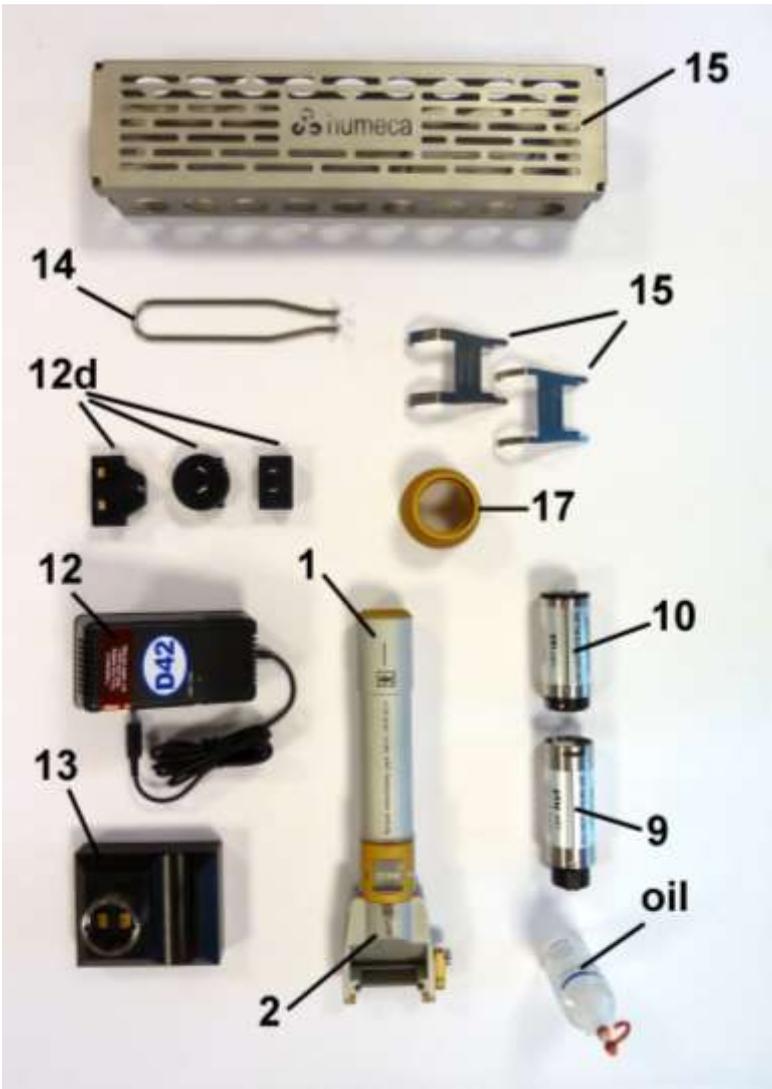


Fig. 1 The dermatome with accessories

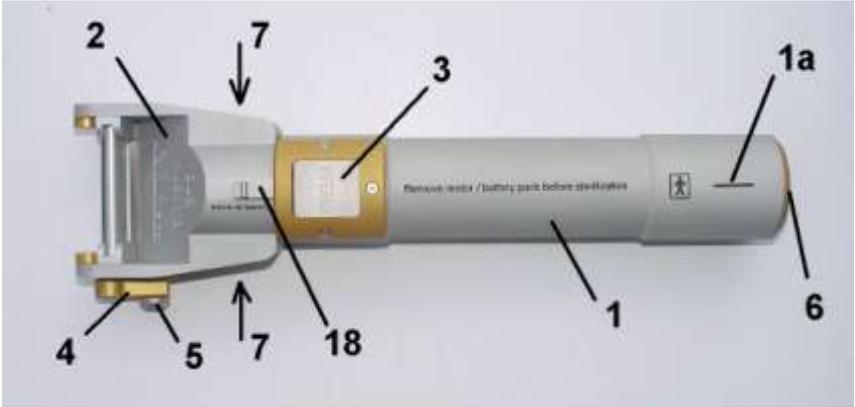


Fig. 2 Upper side

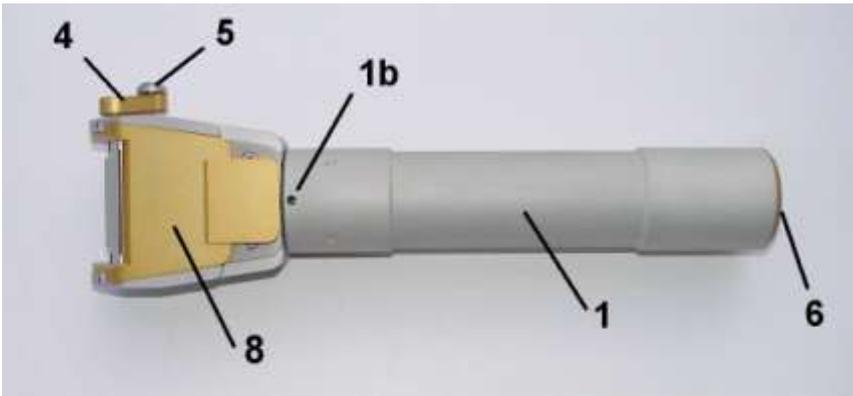


Fig. 3 Dermatome under side

1



2



3



Fig. 4 Coupling of motor- and battery pack of a D42 dermatome



Fig. 5

Connect charger to support unit



Fig. 6 Putting the battery cartridge in the charger support unit



Fig. 7 Charger

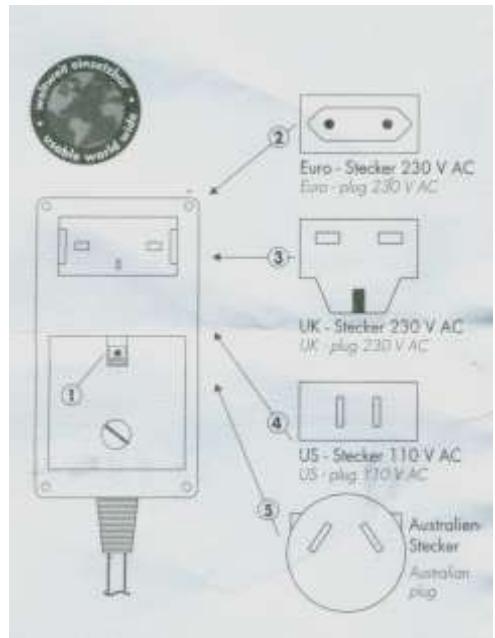
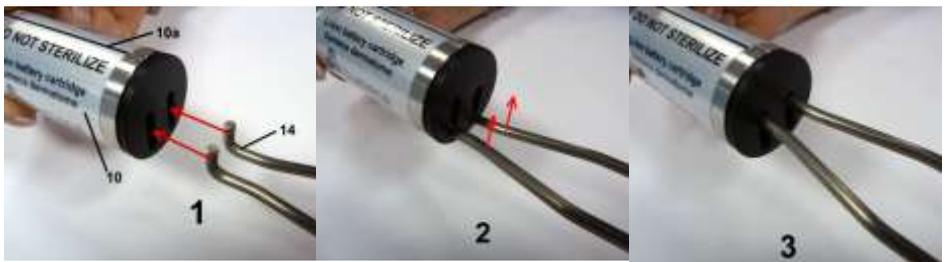


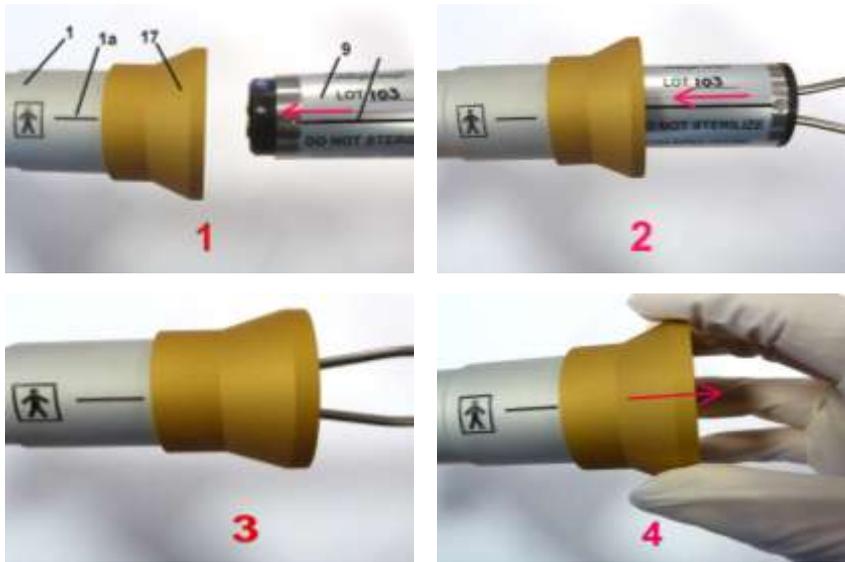
Fig. 7a Change of the power adapter of the charger



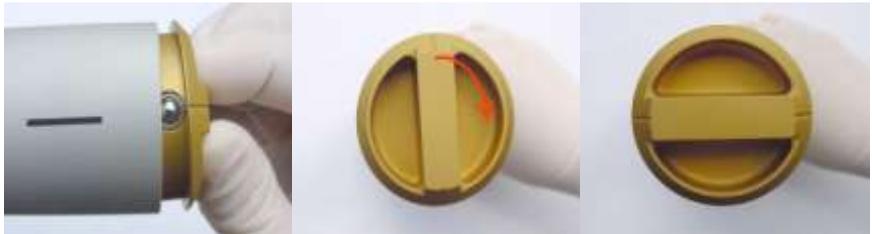
**Fig. 8** Charger connected to support unit for charging process  
(motor nearby to prevent loss)



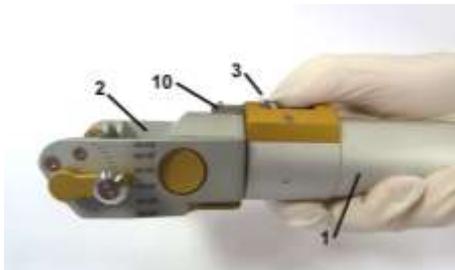
**Fig. 9** The use of the sterile clamp to handle the motor-/battery cartridge



**Fig. 10** Placing the motor-/battery cartridge in the dermatome, using the sterile funnel



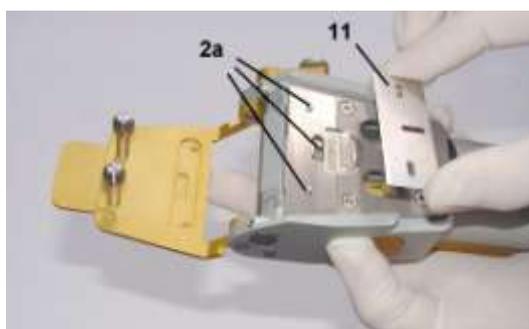
**Fig. 11** Placing the sterile cap to close the shaft of the dermatome



**Fig. 12**  
Switching on the dermatome



**Fig. 13** Opening the cover for access to the blade compartment



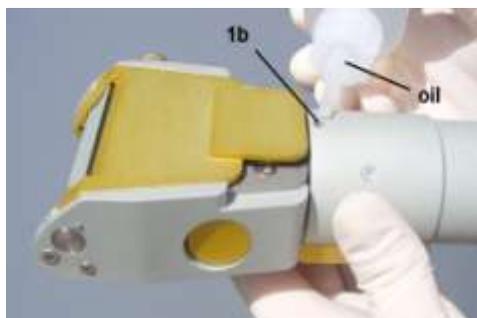
**Fig. 14.** Inserting blade



**Fig. 15** Right way to remove blade



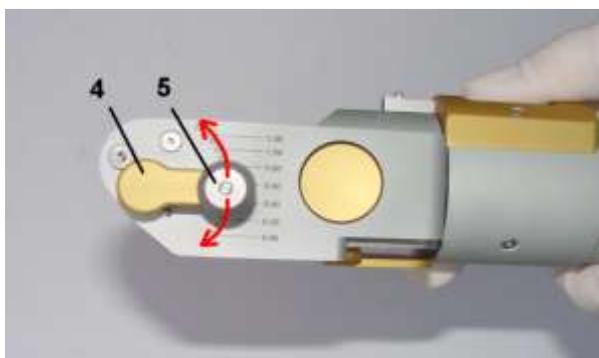
**Fig. 16** Wrong way to remove blade



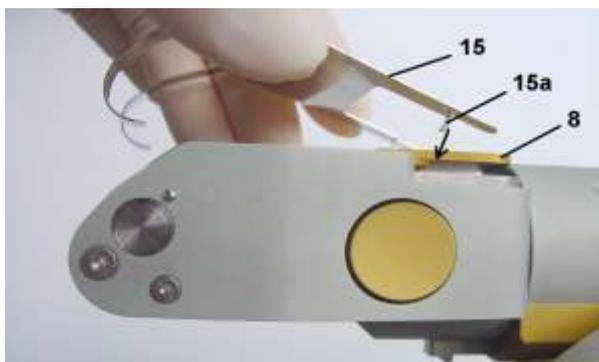
**Fig. 17 External lubrication**



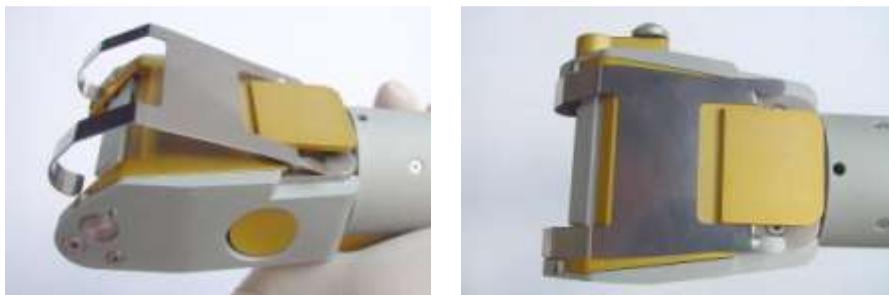
**Fig. 18 Smoothing the blade**



**Fig. 19 Adjusting the graft thickness**



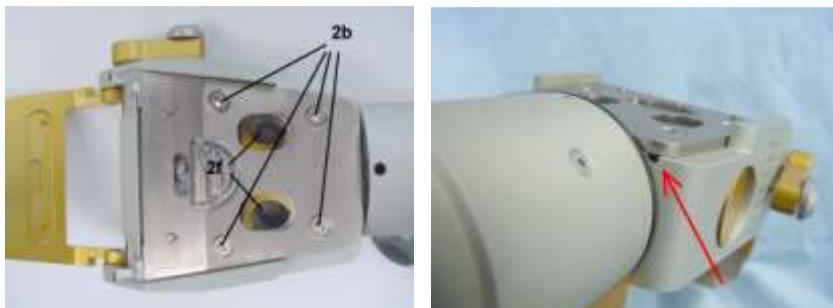
**Fig. 20 Placing width reducing clamp (1)**



**Fig. 21 Placing width reducing clamp (2)**



**Fig. 22 Skin harvesting**



**Fig. 23 Removing the covering plate**

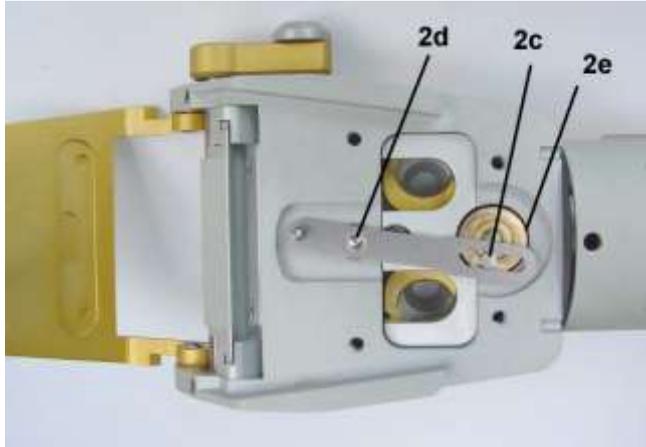


Fig. 24 internal lubrication and cleaning of the dermatome

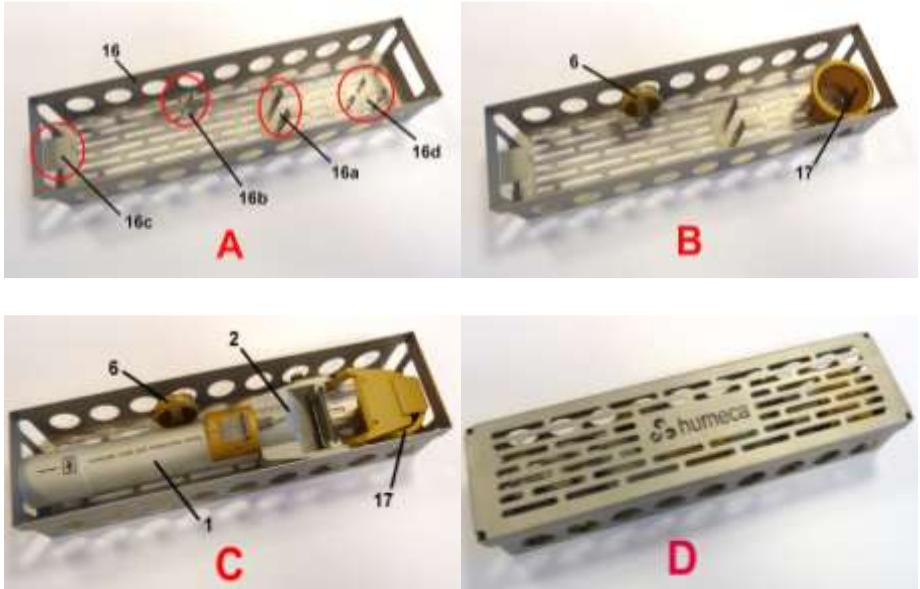


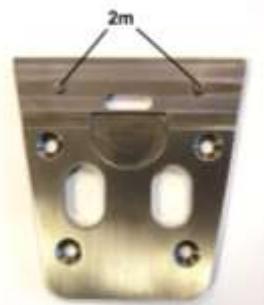
Fig. 25. The use of the autoclave case for sterilization of the dermatome and its accessories

## SECTION II

### Instructions for periodical maintenance

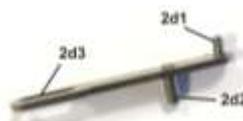
Twice a year, or after about 25 cuttings, it is advised to clean and lubricate the internal of the cutting head to assure good operation and long service life of the dermatome. The pictures below refer to the D42 dermatome. There are some differences with the D80 dermatome, but the procedure is similar. Tools are in the suitcase of the dermatome.

- Remove the covering plate by loosening the four screws, indicated as 2b in fig. 3a, with a Torx 10 driver or L-key and clean it with a dry cloth. If the plate sticks to the underground, it can be lifted by putting a screw driver in the cavity shown in fig. 3b. Clean the plate with a cloth and water. There should be no dirt in the area between the plate and the cutting head. Check the guiding pins (2m in fig. 1). If they are worn out, the covering plate has to be replaced. For ordering, please refer to order no. P801501 for a D80 dermatome and P421501 for a D42 dermatome.



**Fig. 1** Covering plate of a D42 dermatome

- Take out the lever (2d), see fig. 3c and fig. 2. Clean it and check the pins 2d1 and 2d2 on wear. Also check the slot-shaped hole 2d3. If this holes has become bigger due to wear, the movement of the blade ("stroke") becomes less and finally the lever has to be replaced. If necessary replace the lever by a new one. Refer to ordering no. P421301.



**Fig. 2** Lever

- If possible take out the bearing 2g (fig. 3d) and clean it. If the bearing cannot be removed, clean the hole in it while the bearing remains in position. Attention: the bearing consists of two parts, a stainless steel cylinder and a small brass plate. Be careful not to lose them.

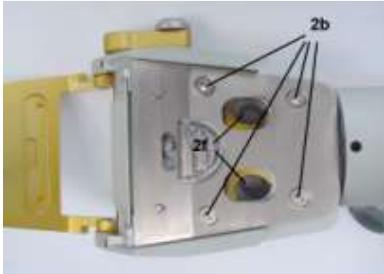


Fig. 3a Removing covering plate



Fig. 3b Cavity for lifting covering plate



Fig. 3c Removing the lever



Fig. 3d Removing bearing



Fig. 3e Removing horn



Fig. 3f Removing locking buttons



Fig. 3g Cavity to be cleaned



Fig. 3h Gearwheel to be cleaned

- Remove the horn (2i in fig. 3e) by lifting it after having removed the screw, indicated by a red arrow in fig. 3e and clean it. In the D80 dermatome the horn consists of two separated parts.
- Take out the button rings (7) for opening the cover and the spring 2k (see fig. 3f) and clean them. In the D80 dermatome there are two springs. Please refer to order number P421405 for replacing springs.
- Clean the interior of the cutting head (fig. 3g).
- Clean the gearwheel 2l, shown in fig. 3h and check if the little pin on the gearwheel and the gearwheel itself on wear. If it has to be replaced, please consult Humeca or your dealer.

### ***Assembling after cleaning***

After cleaning, please use the following sequence for assembling:

- Put some oil on the underside of the gearwheel 2l (fig. 3h) and turn the wheel round a couple of times. The wheel should run smoothly. If it doesn't, you are advised to consult your supplier.
- Replace the two button rings 7 and the spring 2k in the cavity (in case of the D80 dermatome there are 2 springs). Please note that the spring should come over the cams on the rings (see fig. 4 below).



**Fig. 4 Correct orientation of the button rings and spring**

- Replace the horn (2i in fig. 3e) while gently pressing the button rings 7 and fix it with the screw. In the D80 dermatome the horn consists of two parts that are fixed with two screws.
- Check the smooth run of the locking mechanism. You may put some oil on the button rings if necessary.
- Replace the bearing 2g (fig. 3d). First place the brass ring and then the cylinder in the hole and afterwards put some oil in it.
- Replace the lever 2d (fig.3c). Lubricate the driving mechanism. Check smooth run of the mechanism by turning it by hand.
- Replace the covering plate (fig. 3a), after having cleaned the underside of it (very important!). Fix it with the four screws.
- After assembling check the dermatome for smooth run.

In case of loss or damage of screws, please refer to the order numbers listed below:

- ISO 14581 M3x10 – A2-70 (Torx): screws in the covering plate.
- DIN 912 M3 x16: Screw(s) in the horn.

For any assistance please contact your local dealer or:

Humeca BV  
 Het Bijvank 251-a  
 7544 DB Enschede  
 The Netherlands

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 F: +31 53 4771905  
 Email: [info@humeca.com](mailto:info@humeca.com)  
 Web: [www.humeca.com](http://www.humeca.com)

**NOTE:** A video about the use and handling of Humeca electrical dermatomes is available from our website [www.humeca.com](http://www.humeca.com) (section 'electrical dermatomes' sub 'video'). You can also scan this code:

