DenLite Illuminated
Dental Mirror
Directions for Use

DenLite Illuminated Dental Mirror

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Printed in USA

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## Contents

### Introduction
- Intended Use .............................................. 4
- Contraindications ......................................... 4
- Unpacking Checklist ....................................... 4
- Symbol Descriptions ..................................... 4
- Warnings ...................................................... 5
- Cautions ....................................................... 5

### Equipment Setup and Use
- Charging the Batteries .................................. 6
- Assembling the DenLite Illuminated Dental Mirror 6
- Using the DenLite Illuminated Dental Mirror ...... 7

### Maintenance
- Handle Assembly ......................................... 7
- Battery Replacement ..................................... 7
- LED Light Cartridge ...................................... 7
- I-C3 Battery Charger ..................................... 8
- Cleaning ...................................................... 8
- Disinfection ................................................ 8
- Sterilization ............................................... 8
- Disposal ...................................................... 9
- Problem Solving .......................................... 9
- Specifications ............................................ 9-10
- Classification ............................................. 10
- Approvals .................................................. 10
- Guidance and Manufacturer's Declarations ........ 10-12
- Replacement Parts ...................................... 12

### Miltex Warranty
- Instruments and Products .............................. 13
- Repairs ..................................................... 13
- Warranty Exceptions .................................... 13
Introduction

This manual describes the setup and use of the DenLite Illuminated Dental Mirror, REF DP5000.

Intended Use

The DenLite Illuminated Dental Mirror is intended to provide additional illumination in a dental cavity during dental examinations. Only trained dental clinical professionals should use this device.

Contraindications

The LED DenLite light output is in a range that may cause premature polymerization of composite materials.

Unpacking Checklist

Use the following checklist to verify the shipment contents. Please use the contact information on page 2 if there are any items damaged or missing.

- LED Light Cartridge
- Autoclavable Handle Assemblies (quantity 3)
- AAA I-C3 Rechargeable Batteries (quantity 4)
- I-C3 15-Minute Battery Charger
- Single-Use Mirror Heads (quantity 6)
- Directions For Use CD
- Instrument Tray

Symbol Descriptions

- Dispose of Properly
- Caution: Consult manual for more information
- High Temperature
- Toxic If Inhaled
- Relative Humidity
- Recyclable
- Protected against spraying of water
Warnings

A warning statement in this manual identifies a condition or practice which, if not corrected or discontinued immediately, could lead to patient injury, illness, or death.

WARNING Do not re-use or sterilize the Single-Use mirrors.

WARNING The LED DenLite light output is in a range that may cause premature polymerization of composite materials.

WARNING Do not look directly at an illuminated LED Light Cartridge. Temporary blinding may result.

WARNING Do not use the I-C3 Battery Charger in the patient area.

WARNING To reduce risk of injury, charge only I-C3, NiMH, and NiCd rechargeable batteries. Other types of batteries may burst, causing personal injury and damage.

WARNING To reduce the risk of electric shock, unplug the charger from the outlet before cleaning. Never immerse the charger in water or any other liquid. Do not expose the charger to rain or snow.

WARNING Never disassemble the charger or alter the plug. This may cause electric shock.

WARNING To reduce the risk of injury, charge only I-C3, NiMH or NiCd rechargeable batteries. Other types of batteries may burst, causing personal injury or damage.

WARNING To reduce risk of battery explosion, follow the instructions and cautionary markings on the battery charger, battery, and DenLite Illuminated dental Mirror.

WARNING The batteries may become warm during charging. Use caution when handling.

WARNING The LED Light Cartridge may get hot during extended use. Allow the instrument to cool before removing it.

WARNING Do not use the DenLite Illuminated Dental Mirror continuously for more than 45 minutes.

Cautions

A caution statement in this manual identifies a condition or practice which, if not corrected or discontinued immediately, could lead to equipment failure, equipment damage, or data loss.

Caution Never attempt to charge single-use alkaline or zinc carbon batteries in the charger.

Caution Do not charge Rechargeable Alkaline (Renewal) batteries in the battery charger.

Caution Do not immerse or soak the handle, collet assembly, LED light cartridge, or batteries of the DenLite in any liquid.

Caution Do not autoclave the batteries or the LED Light Cartridge. Damage to the batteries and LED Light Cartridge will occur.
Equipment Setup and Use

Charging the Batteries

The battery charger will charge 2 I-C3 AAA batteries in 15 minutes. A fully charged set of new batteries will last 45 minutes in the DenLite Illuminator Dental Mirror.

1. Place the battery into the charging pocket.
   a. Push the positive (+) terminal of the battery against the sliding contact.
   b. Press the negative (-) end of the battery to seat it securely into the charging pocket.
2. Flip the prongs from the back of the charger and plug the charger into a standard 110V wall outlet. You will hear the cooling fan when the charger is operating.
3. A green LED light indicates the charging status and will turn off when charging is complete. Upon completing the charge, unplug the charger and remove the batteries. It is safe to leave the batteries into a plugged-in I-C3 battery charger. However, do not leave the batteries in an unplugged I-C3 battery charger.

Assembling the DenLite Illuminated Dental Mirror
1. Place the batteries inside the handle base with the positive (+) terminal facing upward.
2. Insert the LED Light Cartridge into the handle base.
3. Screw the collet onto the handle base to the off position (first click).
4. Attach the collet ring (1 turn) onto the collet.
5. Insert the Single-use Mirror inside the collet ring and tighten.

Using the DenLite Illuminated Dental Mirror

1. Fully tighten the collet assembly and the LED Light Cartridge will illuminate.
2. Loosen the collet assembly to the detent position and the LED Light Cartridge will extinguish.
3. Remove and properly dispose of the Single-Use Mirror after each use.
4. Sterilize the DenLite handle, collet and collet ring after each use, page 11. If the DenLite instrument is dropped at anytime:
   - Use a new handle assembly and a new mirror.
   - Properly dispose of the dropped mirror.
   - Re-sterilize the handle assembly.

Maintenance

Handle Assembly

Before each use, check the handle assembly for cracks and/or other imperfections. Replace the handle assembly as necessary (part number DP5200).

Battery Replacement

If the lamp does not illuminate or is dim, replace the batteries.
1. Remove the collet assembly.
2. Remove the LED Light Cartridge.
3. Remove the batteries from the handle assembly and replace with fully charged batteries. Only use I-C3, NiMH, or NiCd as replacement battery types.

In the USA, call 1-800-SAV-LEAD for instructions on how to recycle batteries. This device is subject to EU Directive 2002/96/EC (WEEE). It is not registered for use in private households, and may not be disposed of at municipal collection points for waste electrical and electronic equipment. For users outside the United States, contact your local authorities on recycling procedures.

Dispose of Properly
LED Light Cartridge

**Caution** The LED Light Cartridge may get hot during extended use. Allow the LED Light Cartridge to cool before removing it.

If the LED Light Cartridge no longer illuminates and you have replaced the batteries, discontinue use and replace the LED Light Cartridge.

1. Remove the collet assembly.
2. Remove the LED Light Cartridge and replace with a new LED Light Cartridge (part number DP5150).

I-C3 Battery Charger

**WARNING** To reduce the risk of injury, charge only I-C3, NiMH or NiCd rechargeable batteries. Other battery types may burst, causing personal injury or damage.

Do not leave batteries in an unplugged charger.

Cleaning

**WARNING** Do not re-use or sterilize the Single-Use mirrors.

**Caution** Do not immerse or soak the handle, collet assembly, LED light cartridge, or batteries of the DenLite in any liquid.

You can wipe the handle, and collet assembly with cold sterilants and disinfectants.

You can wipe the LED Light Cartridge clean with a cotton swab and warm water.

You can wipe the surface of the I-C3 Battery Charger with a damp cloth.

Disinfection

**WARNING** Do not re-use or sterilize the Single-Use mirrors.

**Caution** Do not immerse or soak the handle, collet assembly, LED light cartridge, or batteries of the DenLite in any liquid.

Use the following solutions to disinfect the DenLite handle and collet assembly.

- Dual synergized quaternary solution (17.2% isopropanol, 0.28% Diisobutylphenoxyethyethyl, dimethyl benzyl ammonium chloride) such as CaviCide® brand surface disinfectant
- O-phenylphenol solution (0.12%) such as Citrace® brand hospital germicidal deodorizer
- Isopropanol Alcohol 70%
• Mild soap and water solution such as Joy® soap and water solution

Sterilization

⚠️ **WARNING** Do not re-use or sterilize the Single-Use mirrors.

⚠️ **Caution** Do not immerse or soak the handle, collet assembly, LED light cartridge, or batteries of the DenLite Illuminated Dental Mirror in any liquid.

Do not autoclave the LED Light Cartridge or batteries.

The handle and collet assembly are the only steam autoclavable parts (249.8° F / 121° C for 15 minutes).

Disposal

<table>
<thead>
<tr>
<th>Handle Assembly</th>
<th>Perform a final sterilization and throw the handle assembly into the trash.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single-Use Mirror</td>
<td>The mirror is considered medical waste. Dispose of in accordance with local, state, and federal regulations.</td>
</tr>
<tr>
<td>Batteries</td>
<td>In the USA, call 1-800-SAV-LEAD for instructions on how to recycle batteries. For users outside the United States, contact your local authorities on recycling procedures or go to <a href="http://www.rbrc.org/">http://www.rbrc.org/</a> for recycling information. In Canada, please go to <a href="http://www.rawmaterials.com/rmcmain.htm">http://www.rawmaterials.com/rmcmain.htm</a>.</td>
</tr>
</tbody>
</table>

Problem Solving

<table>
<thead>
<tr>
<th>Problem</th>
<th>Cause</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is low light output or no light output</td>
<td>The batteries are inserted in the handle incorrectly.</td>
<td>Disassemble the light handle, insert the batteries with the positive (+) nubbin facing upward, and reassemble the light handle, page 5.</td>
</tr>
<tr>
<td></td>
<td>The batteries are not charged.</td>
<td>Follow charging instructions, page 5.</td>
</tr>
<tr>
<td></td>
<td>The LED Light Cartridge is defective.</td>
<td>Remove the collet cap and the collet. Replace the LED Light Cartridge and reassemble.</td>
</tr>
<tr>
<td></td>
<td>The mirror is not fully inserted into the collet</td>
<td>Loosen the collet ring and then firmly push the mirror out of the collet. Retighten the collet ring.</td>
</tr>
<tr>
<td>Mirror doesn’t slide into the collet cap</td>
<td>The collet cap is screwed too tightly on the collet.</td>
<td>Loosen the collet ring and then firmly push the mirror into the collet. Retighten the collet ring.</td>
</tr>
</tbody>
</table>
The batteries are not loaded properly. | Reload the batteries (page 5) and firmly press each battery down to the bottom of the charging pocket.
---|---
Charging is complete. | Remove the batteries from the I-Cs Battery Charger and use.
The batteries are damaged. | Discontinue use of these batteries.
The charger is outside of its operating temperature. | Allow the charger to adjust to room temperature and re-start the charging process.

## Specifications

<table>
<thead>
<tr>
<th>Length</th>
<th>7.25” (18.4 cm) (without mirror and in the off/detent position)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Diameter</td>
<td>0.875” (2.2 cm)</td>
</tr>
<tr>
<td>Weight</td>
<td>2.50 oz (71.1 grams) (without mirror)</td>
</tr>
</tbody>
</table>
| Operating Conditions | 60° F to 77° F  
16° C to 25° C  
900 hPa to 1060 hPa  
50 to 95% RH |
| Storage Conditions | -4° F at 50% RH to 120° F at 95% RH  
-20° C at 50% RH to 50° C at 95% RH  
500 hPa to 1060 hPa |
| Performance | 45 minutes nominal On |
| Electrical | 1.2 V NiMh batteries (qty 2 AAA)  
Maximum Rating 800 mAh |

## Classification

<table>
<thead>
<tr>
<th>Type of protection against electric shock</th>
<th>Internally Powered Device @ 2 x 1.2V dc 800 mA hr maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Degree of protection against electric shock</td>
<td>Type BF</td>
</tr>
<tr>
<td>Degree of protection against ingress of water</td>
<td>IPX3</td>
</tr>
<tr>
<td>Degree of safety of application in the presence of a flammable anesthetic mixture with air, oxygen, nitrous oxide</td>
<td>Device not suitable for use in flammable environment.</td>
</tr>
<tr>
<td>Mode of Operation</td>
<td>Continuous</td>
</tr>
<tr>
<td>LED Product</td>
<td>Class 1</td>
</tr>
</tbody>
</table>

## Approvals

CERTIFIED TO: CAN/CSA C22.2 No. 601.1-M90, including amendments 1 and 2; EN/IEC 60825-1; UL 60601-1

The CE mark on this product indicates that it has been tested to and conforms with the provisions noted within the 93/42/EEC Medical Device Directive.  
EN60601-1-2:2001  
EN60601-1:1990
Guidance and Manufacturer’s Declarations

Emissions for all EQUIPMENT and SYSTEMS
The REF DP5000 DenLite Illuminated Dental Mirror is intended for use in the electromagnetic environment specified below. The customer or user of the DP5000 DenLite Illuminated Dental Mirror should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>Compliance</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF Emissions CISPR 11</td>
<td>Group 1</td>
<td>The DP5000 DenLite Illuminated Dental Mirror 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.</td>
</tr>
<tr>
<td>RF Emissions CISPR 11</td>
<td>Class B</td>
<td>The DP5000 DenLite Illuminated Dental Mirror are suitable for use in all establishments other than domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>Harmonics IEC 61000-3-2</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Flicker IEC 61000-3-3</td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

Immunity for all EQUIPMENT and SYSTEMS
The REF DP5000 DenLite Illuminated Dental Mirror is intended for use in the electromagnetic environment specified below. The customer or user of the REF DP5000 DenLite Illuminated Dental Mirror should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>ESD IEC 61000-4-2</td>
<td>± 6kV Contact ± 8kV Air</td>
<td>± 6kV Contact ± 8kV Air</td>
<td>Floors should be wood, concrete, or ceramic tile. If floors are synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>EFT IEC 61000-4-4</td>
<td>±2kV Mains ±1kV I/O</td>
<td>N/A</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Surge IEC 61000-4-5</td>
<td>±1kV Differential ±2kV Common</td>
<td>N/A</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Voltage Dips, short interruptions, and voltage variations on power supply input lines. IEC 61000-4-11</td>
<td>&gt;95% Dip in 0.5 Cycle 60% Dip in 5 Cycles 30% Dip for 25 Cycles &gt;95% Dip in 5 Seconds</td>
<td>N/A</td>
<td>Mains power quality should be that of a typical commercial or hospital environment. If the user of the REF DP5000 DenLite Illuminated Dental Mirror requires continued operation during power mains interruptions, it is recommended that the REF DP5000 DenLite Illuminated Dental Mirror be powered from an uninterruptible power supply or battery.</td>
</tr>
<tr>
<td>Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8</td>
<td>3 A/m</td>
<td>N/A</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>
Guidance and Manufacturer's Declaration - Emissions

The REF DP5000 DenLite Illuminated Dental Mirror is intended for use in the electromagnetic environment specified below. The customer or user of the REF DP5000 DenLite Illuminated Dental Mirror should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>IEC 61000-4-6</td>
<td>3 Vrms 150 kHz to 80 MHz (outside ISM bands)</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the REF DP5000 DenLite Illuminated Dental Mirror, including cables, than the recommended separation distances calculated/listed below:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>N/A</td>
<td>d = (1.17)√P</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>d = (1.17)√P 80 to 800 MHz</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>d = (2.33)√P 800 MHz to 2.5 GHz</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>IEC 61000-4-3</td>
<td>3 V/m 80 MHz to 2.5 GHz</td>
<td>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 meters (m).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 V/m</td>
<td>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Interference may occur in the vicinity of equipment marked with the following symbol:</td>
</tr>
</tbody>
</table>

Recommended Separations Distances between portable and mobile RF Communications equipment and the REF DP5000 Dental Illuminated Mirror Handle

The REF DP5000 Dental Illuminated Mirror Handle is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the REF DP5000 Dental Illuminated Mirror Handle can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment (transmitters) and the REF DP5000 Dental Illuminated Mirror Handle as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Max Output Power (watts)</th>
<th>Separation (m) 150kHz to 800MHz</th>
<th>Separation (m) 80 to 800MHz</th>
<th>Separation (m) 800MHz to 2.5GHz</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>d 1.1= ( 7)√P</td>
<td>d= (1.17)√P</td>
<td>d= (2.33)√P</td>
</tr>
<tr>
<td>0.01</td>
<td>N/A</td>
<td>0.117</td>
<td>0.233</td>
</tr>
<tr>
<td>0.1</td>
<td>N/A</td>
<td>0.37</td>
<td>0.74</td>
</tr>
<tr>
<td>1</td>
<td>N/A</td>
<td>1.17</td>
<td>2.33</td>
</tr>
<tr>
<td>10</td>
<td>N/A</td>
<td>3.70</td>
<td>7.37</td>
</tr>
<tr>
<td>100</td>
<td>N/A</td>
<td>11.70</td>
<td>23.30</td>
</tr>
</tbody>
</table>
Replacement Parts

<table>
<thead>
<tr>
<th>Part No.</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>DP5000</td>
<td>Complete DenLite Illuminated Dental Mirror Kit</td>
</tr>
<tr>
<td>DP5070</td>
<td>Illuminator Tip</td>
</tr>
<tr>
<td>DP5200</td>
<td>DenLite Handle Assemblies (quantity 1)</td>
</tr>
<tr>
<td>DP5410</td>
<td>AAA I-C3 Batteries (quantity 4)</td>
</tr>
<tr>
<td>DP5030</td>
<td>Single-Use Mirror Heads (box of 50)</td>
</tr>
<tr>
<td>DP5150</td>
<td>LED Light Cartridge</td>
</tr>
<tr>
<td>DP5400</td>
<td>DenLite AAA Battery Charger Set</td>
</tr>
<tr>
<td>DP5005</td>
<td>Quick Reference Card / Directions for Use CD</td>
</tr>
</tbody>
</table>

Miltex Warranty

Instruments and Products

Miltex hereby warrants all Miltex product purchased directly from Miltex or an Authorized Dealer in accordance with the following terms and conditions:

All Miltex instruments and products are guaranteed to be free from defects in material and workmanship when used for their intended surgical or dental purpose. Any Miltex product that proves defective in workmanship or material will either be repaired or replaced, at Miltex’s discretion, without charge. Products not purchased from an authorized source may not be authentic or meet Miltex’s quality standards and may have been tampered with.

Other Instrument and Product Warranties:

- DenLite – 90 days
- Union Broach Chiropractic Mallet – 90 days
- Union Broach Electrical Devices – 1 year except for Sprint TCM – 2 years
- Cassettes – 4-year warranty on all moving parts and lifetime guarantee against corrosion
Repairs

Instruments and products repaired by the Miltex Instrument Repair Service are guaranteed to be free from defects in material and workmanship for 90 days when used for their intended surgical or dental purpose. Any Miltex repair that proves defective in workmanship or material within this 90-day period will either be repaired again or replaced, at Miltex’s discretion, without charge. Instruments must be cleaned and sterilized prior to returning to Miltex for repair.

Warranty Exceptions

This warranty is void for Miltex instruments and products serviced by any person or facility other than the Miltex Instrument Repair Services. Any custom made, custom etched or neutralized products are not returnable. Warranties are not valid for Miltex instruments and products that prove defective as a result of improper care and cleaning or misuse. Instruments or products that are damaged by fire, flood or other acts or disasters are also excluded from warranty. Except as set forth in these Terms and Conditions, Miltex makes no other representations and warranties regarding its instruments or products, either expressed or implied. In addition, in no event will Miltex be liable for any incidental, special or exemplary damages or loss of profits in connection with the use of Miltex instruments and products.

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