



# CarieScan PRO User Manual

## Declaration of Conformity

We herewith declare that the generic family of devices, Hand Held Caries Detection Devices, meet the provisions of the Council Directive 93/42/EEC for medical devices and the UK Medical Devices Regulations SI 1994/3017.

The Technical File is retained in the premises of the manufacturer.

### Primary Product Safety Standards Fulfilled

IEC / UL 60601-1 General Requirements for Safety  
CSA-C22.2 No.601.1-M90 Part 1 General Requirements for Safety



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The CarieScan PRO is protected by UK Patent 2385136B and Registered Community Designs EC000680467-0002. Equivalent patent and design applications are pending in other countries.

# CONTENTS

|           |                                                                |           |
|-----------|----------------------------------------------------------------|-----------|
| <b>1</b>  | <b>Getting Started</b> .....                                   | <b>1</b>  |
| 1.1       | The CarieScan PRO™.....                                        | 1         |
| 1.2       | Taking a measurement on Occlusal and Free Smooth Surfaces..... | 2         |
| <b>2</b>  | <b>Product Overview</b> .....                                  | <b>5</b>  |
| 2.1       | Box Contents List.....                                         | 6         |
| 2.2       | CarieScan PRO.....                                             | 7         |
| 2.3       | Soft Tissue Cable.....                                         | 8         |
| 2.4       | Charging Cradle and Stand.....                                 | 8         |
| 2.5       | Power Supply Unit.....                                         | 8         |
| 2.6       | Cable Test Adaptor.....                                        | 8         |
| 2.7       | Sensor Pack.....                                               | 8         |
| <b>3</b>  | <b>INSTALLATION / ASSEMBLY</b> .....                           | <b>9</b>  |
| 3.1       | Charging the CarieScan PRO.....                                | 9         |
| 3.2       | Connections to Compatible Accessories via Bluetooth®.....      | 9         |
| <b>4</b>  | <b>DEVICE START UP</b> .....                                   | <b>9</b>  |
| 4.1       | Start Up.....                                                  | 9         |
| 4.2       | Initialisation.....                                            | 9         |
| 4.3       | Standby.....                                                   | 10        |
| 4.4       | Measurement mode.....                                          | 10        |
| 4.5       | Navigation Mode.....                                           | 10        |
| 4.6       | System Health Check.....                                       | 11        |
| <b>5</b>  | <b>CARIES DETECTION PROTOCOL</b> .....                         | <b>12</b> |
| 5.1       | Caries Detection Evaluation Scale.....                         | 12        |
| 5.2       | Setting up the device.....                                     | 13        |
| 5.3       | Preparing the patient.....                                     | 13        |
| 5.4       | Taking a measurement on Occlusal and Free Smooth Surfaces..... | 13        |
| <b>6</b>  | <b>CLEANING AND MAINTENANCE</b> .....                          | <b>15</b> |
| 6.1       | General.....                                                   | 15        |
| 6.2       | Service.....                                                   | 15        |
| 6.3       | Storage conditions.....                                        | 15        |
| <b>7</b>  | <b>Important Information</b> .....                             | <b>16</b> |
| 7.1       | Intended Use.....                                              | 16        |
| 7.2       | Indications for use.....                                       | 16        |
| 7.3       | Restrictions on Use.....                                       | 16        |
| 7.4       | Contraindications.....                                         | 16        |
| 7.5       | Warnings.....                                                  | 16        |
| 7.6       | Precautions.....                                               | 16        |
| 7.7       | Infection control.....                                         | 16        |
| <b>8</b>  | <b>CERTIFICATIONS</b> .....                                    | <b>17</b> |
| <b>9</b>  | <b>WARNINGS &amp; PRECAUTIONS</b> .....                        | <b>18</b> |
| 9.1       | General.....                                                   | 18        |
| 9.2       | Label Glossary.....                                            | 18        |
| 9.3       | Classification.....                                            | 19        |
| <b>10</b> | <b>FURTHER INFORMATION</b> .....                               | <b>19</b> |
| 10.1      | Product support.....                                           | 19        |
| 10.2      | Battery information.....                                       | 19        |
| 10.3      | LCD Glossary.....                                              | 20        |
| 10.4      | Troubleshooting.....                                           | 20        |

# 1 Getting Started

## 1.1 The CarieScan PRO™

The CarieScan PRO™ enables dentists to evaluate posterior (molar and premolar) teeth using AC Impedance Spectroscopy (ACIST) by providing information about whether the tooth is healthy, in the early stages of decay or already significantly decayed (see also [Section 7](#)). The PRO assesses the occlusal surfaces and the free-smooth surfaces of teeth.

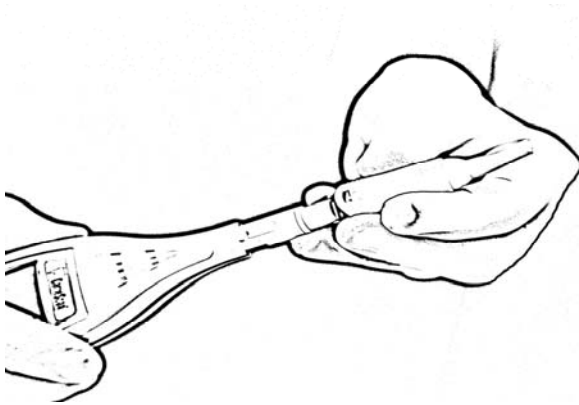
The system consists of the CarieScan PRO handpiece, a Soft Tissue Cable for attaching the soft tissue contact (lip clip) to the PRO, and a Sensor. The PRO uses a disposable sensor that resembles a small toothbrush. The sensor is held against the tooth to be examined and the measurement takes about four seconds to complete then the result is displayed.

**Note:**  
For full details see [Section 2](#)



**The CarieScan PRO**

## 1.2 Taking a measurement on Occlusal and Free Smooth Surfaces



**Placing the sensor on to the CarieScan PRO**

### *Prepare the CarieScan PRO*

1. After taking suitable cross-infection precautions (see our website at [www.cariescan.com](http://www.cariescan.com) for our recommendation of barriers) hold the CarieScan PRO with the display facing you and push the Tufted Sensor onto the CarieScan PRO with the tuft facing away from you, locating it with a click.
2. Switch on the PRO by holding down the 'Power' button until the device starts up.

*Note: Use the Tufted Sensor for measurement of occlusal and accessible smooth surfaces only.*

3. Open the sensor blister pack by peeling off the Tyvek lid.

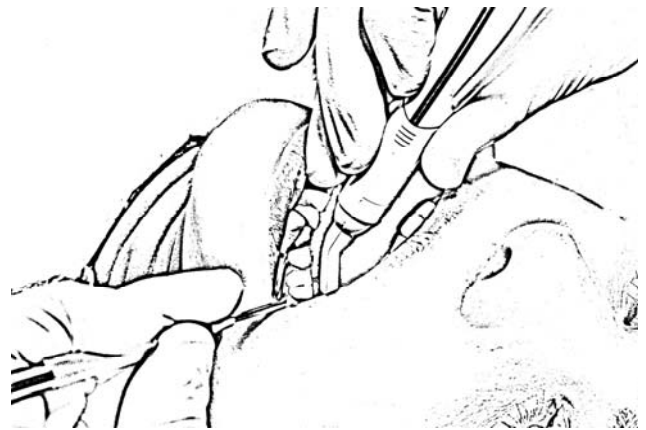
### **Note:**

*Care must be taken if any plastic sheathing is used for cross-infection control purposes. Ensure that it does not prevent electrical contact between the end of the CarieScan PRO and the contacts inside the sensors.*

4. The LCD will show 'RdY' (ready), the Occlusal  and Smooth surface  icons will be shown.

### *Prepare the patient*

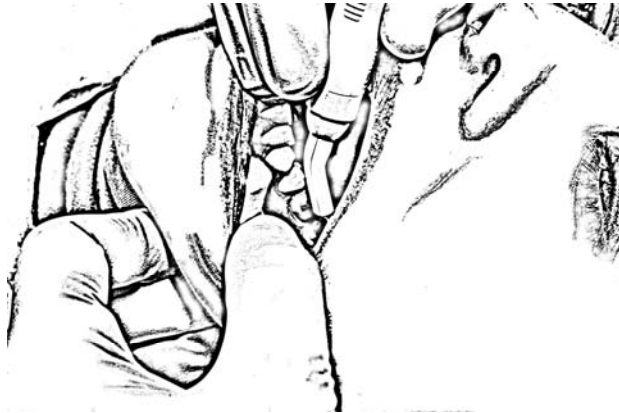
5. Place the PRO in its stand while you ensure the surface of the tooth to be measured is free from any plaque and debris.
6. Connect the Soft Tissue Contact (lip clip) to the socket of the cable.
7. Firmly connect the plug of the soft tissue cable into the socket at the side of the CarieScan PRO.
8. Gently place the curled end of the Soft Tissue Contact over the lower lip of the patient.
9. Dry the tooth site to be measured for 5 seconds with a 3-in-1 syringe to remove any pooled fluid.



**Measurement of occlusal surface**


*Note: that drying time is based on standard air pressure of 40psi.*

*Record the result and move on to another site*



**Measurement of smooth surface**

*Measure the site*

10. Press the 'Enter' button  to start measuring.
11. The blue LED on the pyramid will flash indicating that the CarieScan PRO is in measurement mode.
12. Place the sensor firmly onto the chosen occlusal or smooth surface and a measurement will automatically be taken. During the measurement 4 audible tones will be heard before the result is displayed.
13. On completion of the measurement the result is presented by a further sequence of beeps and the colour pyramid classification will light displaying the caries detection level ([Section 5.1](#)).

**Note:**

*If there is a bad connection or improper site preparation the PRO may not provide a measurement value.*

14. With the measurement complete the sensor can be removed from the tooth surface, the result will remain visible on the displays until the next tooth site is detected. Record the last result as required and select another site to measure.
15. Record the last result as required and select another site to measure.
16. Should the sensor become contaminated or waterlogged, you should replace the sensor with a new one before continuing.

*Finishing up*

17. The Measurement mode (indicated by the blue flashing LED) automatically restarts after 3 seconds, and subsequent measurement will begin when the CarieScan PRO detects when the sensor is on a tooth.
18. Take a new measurement by returning to step 9. (Further drying may not be necessary if repeating measurements on the same site.)
19. Terminate the measurement process by pressing any button on the Keypad for about 1s.
20. When measurements on the patient are complete:
  - to remove the sensor from the CarieScan PRO, squeeze the sensor on the side grips to release the catch and remove from the device.

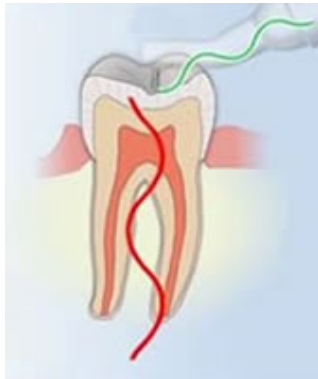
- all sensors must be disposed as sharp contaminated waste. All such waste must be placed in a suitable receptacle marked as biohazard, conforming to the required regulations.
- the CarieScan PRO and Soft Tissue Cable should be wiped down with alcohol-based wipes.

## 2 Product Overview

The CarieScan PRO has a number of advantages over other measuring / visualisation systems. The absence of X-rays has safety advantages and allows increased frequency of monitoring. Most importantly the accuracy of results sets the system apart from other diagnostic methods. CarieScan PRO is 92.5% accurate at detecting both sound and carious teeth, minimising false positive or false negative results.

The PRO enables earlier and more accurate detection of “early” caries lesions which are not clearly visible to the human eye enabling remedial (preventive) treatment to be initiated. It also enables detection of the more extensive “hidden” lesions extending into dentine which can be missed by even the most careful examiner. Unlike competitors, the PRO is not affected by optical factors such as staining or discoloration of the tooth. The CarieScan PRO provides a qualitative value based directly on the disease state, rather than the indirect optical properties of the tooth or surrogate markers such as bacterial breakdown products.

The impedance of a healthy tooth is very high due to relatively low ionic conduction. However, as a tooth demineralises it starts to lose some of its regular structure from beneath the tooth’s surface zone and increasingly larger pores are formed as minerals are eluted out. If the lesion progresses, the pores can connect with each other and the tooth becomes a mix of highly conductive parts (the fluid filled pores) and the low conductive enamel, so impedance decreases. As the decay progresses, dentine becomes involved and cavities are formed, the impedance falls further.







The key to evaluating dental tissue in this way has been to pass a very low current (undetectable to the patient) through a tooth and to measure the impedance of the flow of charge passing through it.

The variance in signals between the different stages of decay is significant. The impedance measured in a healthy tooth is significantly greater than that of a tooth that is demineralising which is itself significantly greater than that of a tooth with a cavity. As a result the sensitivity (ability to find caries when it is present) and specificity (ability to detect healthy tissue, or lack of false positives) of the ACIST system in distinguishing these different stages is very high.



## 2.1 Box Contents List

Please review the contents below and ensure all the components are present. If there are any missing components please refer to Product Support ([Section 10.1](#)).

| Part Number | Figure                                                                              | Item                 | See Section         |
|-------------|-------------------------------------------------------------------------------------|----------------------|---------------------|
| CP-SYS-01   |    | CarieScan PRO system | <a href="#">2.1</a> |
| CP-STC-01   |    | Soft Tissue Cable    | <a href="#">2.3</a> |
| CP-STD-01   |                                                                                     | Display Stand        | <a href="#">2.4</a> |
| CP-CHG-01   |  | Charging Cradle      | <a href="#">2.4</a> |
| CP-PSU-01   |  | Power Supply Unit    | <a href="#">2.5</a> |
| CP-TSN-01   |  | Cable Test Adaptor   | <a href="#">2.6</a> |

## 2.2 CarieScan PRO

### 2.2.1 General

The CarieScan PRO has a keypad, LCD symbol display, colour LEDs and a soft tissue cable socket. The PRO includes Bluetooth® for future connectivity. Battery charging is achieved via the charging cradle.



### 2.2.2 Audio response

The CarieScan PRO provides audio feedback. Sounds are used to indicate:

- completion of internal test at startup
  - 2 short beeps for OK
  - 2 long beeps for fail
- the completion of a measurement:
  - Green: Single beep
  - 1-99: 3 beeps
  - Red: 6 rapid beeps
- the completion of System Health Check
  - 2 short beeps for OK
  - 2 long beeps for fail

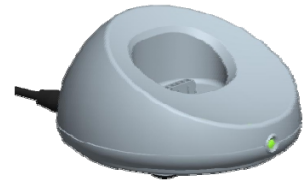
### 2.3 Soft Tissue Cable

The soft tissue cable is for attaching the soft tissue contact (lip clip) to the CarieScan PRO.



### 2.4 Charging Cradle and Stand

The charging cradle is used to charge the CarieScan PRO and has a DC Jack for connection to CP-PSU-01 only.



#### **CAUTION:**

**The charging cradle must NOT be placed inside the patient environment.**

The display stand is a non-electrical unit and should be used to hold the CarieScan PRO within the patient environment.

### 2.5 Power Supply Unit



The CarieScan PRO has been certified for use via the charging cradle with only the supplied power charger, part code CP-PSU-01.

Input: 100V-240V ac, 47Hz-63Hz  
Output: 6V dc, 0A – 1.7A

Any attempt to charge or power the CarieScan PRO from any other source will render the system's warranty permanently invalid. In order to disconnect the CarieScan PRO from the mains power, remove the PSU plug from the wall socket.

### 2.6 Cable Test Adaptor

The Cable Test Adaptor is a non-disposable component which allows the cable to be connected directly to the PRO and is used to test that the cable is undamaged. The Adaptor is placed onto the PRO in the same way as the disposable sensors. We recommend that a test is performed on a daily basis to ensure the cable is undamaged.



**CAUTION: The Cable Test Adaptor MUST NOT be used in a patient's mouth.**

### 2.7 Sensor Pack



The sensor packs are sold separately – reorder code CS-OCC-50. Each pack contains a tufted Sensor for occlusal and free smooth surfaces and a Soft Tissue Contact that is attached to the soft tissue cable which is, in turn, connected to the CarieScan PRO. It is placed over the lip in the corner of the patient's mouth.


The contents of the pack are supplied clinically clean and are disposable, single use only. These are each single use items and MUST NOT be sterilised for re-use.

**CAUTION: A NEW sensor pack must be used for EACH patient at each visit.**

## 3 INSTALLATION / ASSEMBLY

### 3.1 Charging the CarieScan PRO

The mains plug from the Power Supply Unit (CP-PSU-01) should be plugged into an ac mains socket. The dc jack from the PSU must be inserted into the power socket at the rear of the Charging Cradle.

The Low battery status indicator  will show when the CarieScan PRO has less than about 1½ hours of charge remaining. To charge the CarieScan PRO, place it into the Charging Cradle. The blue LED on the CarieScan PRO will illuminate until it is removed from the Cradle or until the CarieScan PRO is fully charged. The product is disabled from use during charging.

**Note:**


*Before using the CarieScan PRO for the first time, charge the battery for a minimum of 8 hours (overnight). Please see notes regarding battery life and charging in Further Information ([Section 10.2](#))*

### 3.2 Connections to Compatible Accessories via Bluetooth®


Compatible accessories can be connected wirelessly to the CarieScan PRO using the integrated Bluetooth® capability. Please refer to the Bluetooth Setup Section in your relevant Instruction Manual for further details.


## 4 DEVICE START UP

### 4.1 Start Up

The 'Power' On / Off key  powers the CarieScan PRO On and Off. A single press of the 'Power' key switches the CarieScan PRO on. The CarieScan PRO then begins its initialisation. Note that the Power key must be held down for more than 2 seconds then released to switch the CarieScan PRO off.

### 4.2 Initialisation

During initialisation, the Busy symbol  on the LCD is shown and an automatic self-test will be performed showing 'Ok' on the display when complete. If the measurement circuit is not operating within specification, the CarieScan PRO will prevent measurements from being made and the LCD will show 'CFL'. If this occurs you should refer to System Health Check (see [Section 4.6](#)).





A check is performed to determine if a Bluetooth® link is within range and the Wireless Connectivity symbol  will flash. If an existing pairing is established, the Wireless Connectivity symbol remains on. If a pairing is not found, the Bluetooth search switches OFF and the Wireless Connectivity symbol is OFF. A Bluetooth search can be switched on again using Navigation (see [Section 4.5](#)).

**Note:**


*A Bluetooth® pairing is only initiated by the CarieScan Plus unit for remote control, or by a CarieScan approved device.*

### 4.3 Standby

After initialisation, the CarieScan PRO waits for user input in Standby mode.

| <b>Keys</b> |                                                                                   | <b>Action</b>                                  |
|-------------|-----------------------------------------------------------------------------------|------------------------------------------------|
| Enter       |  | Start Measurement mode                         |
| Up          |  | Enter Navigate mode                            |
| Down        |  | Enter Navigate mode                            |
| Power       |  | Press and hold for more than 2s to switch off. |

### 4.4 Measurement mode



After fitting a sensor (see [Section 5.4](#)) to the CarieScan PRO pressing Enter  will start measurement mode in ReadyScan. This ReadyScan feature sets up the device to 'look' for sensor contact with a tooth surface and The blue LED will flash indicating that the CarieScan PRO is ready for measuring.


See [Section 5](#) for details on the Caries Detection Protocol including measurement setup and results.



**Note:**





*Without a sensor on the CarieScan PRO, the LCD shows 'NOS' and a measurement cannot start.*

### 4.5 Navigation Mode

If an Up  or Down  key is pressed when in Standby, the device enters Navigation Mode. Presently, only the Bluetooth on/off control is available.

The Bluetooth symbol  appears on the LCD indicating that Bluetooth® can be manually enabled or disabled.

Press Enter  to toggle Bluetooth® On or Off. When enabled, the Wireless Connectivity icon  will appear in the status bar at the bottom of the LCD. The CarieScan PLUS, or other approved device, can now connect with the CarieScan PRO.

| <b>Keys</b> |                                                                                     | <b>Action</b>                                                                               |
|-------------|-------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|
| Enter       |  | Toggles Bluetooth on or off                                                                 |
| Up          |  | Exit Navigation mode                                                                        |
| Down        |  | Exit Navigation mode                                                                        |
| Power       |  | Press and release to exit Navigation mode<br>Press and hold for more than 2s to switch off. |

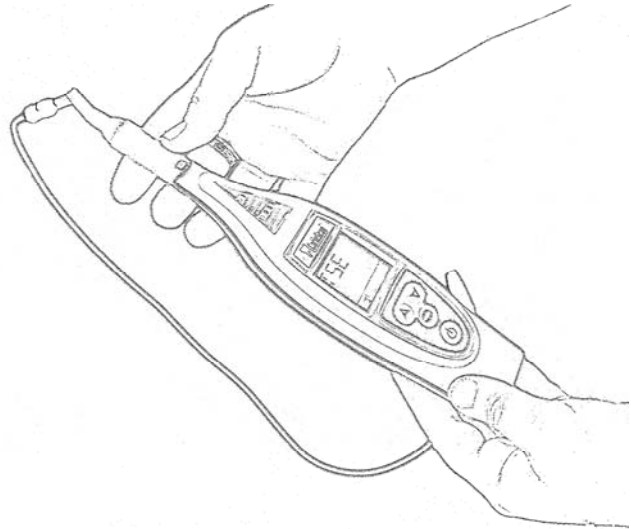
#### 4.6 System Health Check

The Cable Test Adaptor enables an external system test to be performed.

**IMPORTANT:** It is advised that this external test is performed on a daily basis.

Please refer to the LCD Glossary ([Section 10.3](#)) for an explanation of the abbreviated terms.








1. With the LCD facing you connect the Cable Test Adaptor to the PRO with the pin facing away from you, locating it with a click.
2. 'TSE' is shown on the LCD indicating the device has detected the adaptor.
3. Push the angled plug of the Soft Tissue Cable into the socket at the side of the CarieScan PRO.
4. Connect the Soft Tissue Cable socket onto the pin of the adaptor.
5. Press 'Enter' to start the test. The result of the health check is assessed.
6. If the health check passes the LCD shows 'Ok', otherwise an error is reported by displaying 'CFL'. If 'CFL' is observed, then it is likely that the soft tissue cable is damaged. In this case replace or contact your supplier for advice.
7. The PRO will return to the 'TSE' state until the Cable Test Adaptor is removed.



**Checking the system with the Test Adaptor**

## 5 CARIES DETECTION PROTOCOL

### 5.1 Caries Detection Evaluation Scale

|                                                                                     |                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|    | <p>LCD: G</p> <p>LED: 1 green</p> <p>AUDIO: 1 beep</p>                   | <p>OBSERVATION:<br/>Sound tooth surface</p> <p>ADVICE:<br/>No treatment required beyond continuing surveillance, with Reassessment and Review at intervals appropriate to the particular caries risk characteristics of the patient.</p>                                                                                                                                                                                                                                                                                                                                                                                                |
|    | <p>LCD: 1 – 20</p> <p>LED: 1 green, 1 yellow</p> <p>AUDIO: 3 beeps</p>   | <p>OBSERVATION:<br/>Possibility of first indications of initial carious change beneath the enamel surface.</p> <p>ADVICE: <i>Preventive Care Advised (PCA)</i><br/>Consider localised oral hygiene advice with use of fluoride toothpaste and review with monitoring over time.</p>                                                                                                                                                                                                                                                                                                                                                     |
|    | <p>LCD: 21 – 30</p> <p>LED: 1 green, 2 yellows</p> <p>AUDIO: 3 beeps</p> | <p>OBSERVATION:<br/>Probability of first indications of initial carious change beneath the enamel surface.</p> <p>ADVICE: <i>Preventive Care Advised (PCA)</i><br/>Consider localised oral hygiene advice, diet advice, with use of fluoride toothpaste and review with monitoring over time.</p>                                                                                                                                                                                                                                                                                                                                       |
|   | <p>LCD: 31 – 50</p> <p>LED: 3 yellows</p> <p>AUDIO: 3 beeps</p>          | <p>OBSERVATION:<br/>Possibility of significant carious change beneath the enamel surface warranting specific preventive care.</p> <p>ADVICE: <i>Preventive Care Advised (PCA)</i><br/>Consider fluoride varnish or (on pit &amp; fissure sites) pit &amp; fissure sealants, with localised oral hygiene, diet advice and personalised review with monitoring over time.</p>                                                                                                                                                                                                                                                             |
|  | <p>LCD: 51 – 90</p> <p>LED: 3 yellows</p> <p>AUDIO: 3 beeps</p>          | <p>OBSERVATION:<br/>Probability of significant carious change beneath the enamel surface warranting specific preventive care.</p> <p>ADVICE: <i>Preventive Care Advised (PCA)</i><br/>Strongly consider fluoride varnish or (on pit &amp; fissure sites) pit &amp; fissure sealants, with localised oral hygiene, diet advice and personalised review with monitoring at shorter intervals.</p>                                                                                                                                                                                                                                         |
|  | <p>LCD: 91 – 99</p> <p>LED: 4 yellows</p> <p>AUDIO: 3 beeps</p>          | <p>OBSERVATION:<br/>Possibility of established decay equating to carious change extending through the enamel and into superficial dentine warranting specific preventive, or possibly operative, care.</p> <p>ADVICE: <i>Preventive Care Advised (PCA)</i><br/>Strongly consider either fluoride varnish or (on pit &amp; fissure sites) pit &amp; fissure sealants, with or without a sealant restoration technique. In addition, localised oral hygiene and diet advice should be given with personalised review and monitoring over short intervals. Operative intervention may be appropriate for the high caries risk patient.</p> |
|  | <p>LCD: R</p> <p>LED: 1 red</p> <p>AUDIO: 6 rapid beeps</p>              | <p>OBSERVATION:<br/>Established caries. The likelihood that significant dentine caries involvement is present indicates that, subject to patient profile, Operative Care is Advised for this lesion.</p> <p>ADVICE: <i>Operative Care Advised (OCA)</i><br/>Minimally Invasive Dentistry means that the restoration should be as small as possible. (examples: amalgam, composite, glass ionomer).</p>                                                                                                                                                                                                                                  |

## 5.2 Setting up the device

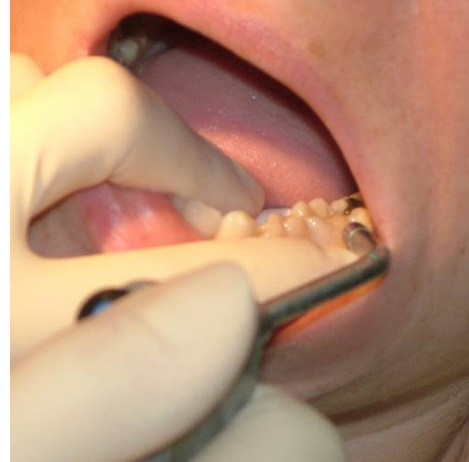
1. Ensure the CarieScan PRO is charged in accordance with the instructions given in *Charging the CarieScan PRO* ([Section 3.1](#)).
2. Remove the CarieScan PRO from the Charging Cradle and place it on the Stand.
3. Switch on the CarieScan PRO by depressing the power button on the keypad.

## 5.3 Preparing the patient

Perform any cross-infection precautions normally taken in your clinic. See our website at [www.cariescan.com](http://www.cariescan.com) for our recommendation of barriers.

To ensure the accuracy of the detection of dental caries, the following steps **must** be taken prior to any measurements:

1. Remove any intra-oral removable appliances.
2. Clean all tooth surfaces to remove any plaque: Occlusal and free smooth surfaces should ideally be cleaned with a tooth brush or a prophylaxis brush and water. If toothpaste or prophylaxis paste is used care must be taken to ensure it is all removed prior to making a measurement in order to avoid false readings.
3. Isolate the tooth to be measured and those in the immediate vicinity using cotton-wool rolls and a saliva ejector.





**Isolation of tooth to be measured**

## 5.4 Taking a measurement on Occlusal and Free Smooth Surfaces



**Attaching the sensor**

*Note: Use the Tufted Sensor for measurement of occlusal and accessible smooth surfaces only.*

1. Open the blister pack by peeling off the Tyvek lid.
2. After taking suitable cross-infection precautions hold the CarieScan PRO with the display facing you and push the Tufted Sensor onto the CarieScan PRO with the tuft facing away from you, locating it with a click.
3. The LCD will show 'RdY' (ready), the Occlusal icon  and Smooth surface icon  will both be shown.

*Note: Care must be taken if any plastic sheathing is used for cross-infection control purposes. Ensure that it does not prevent electrical contact between the end of the CarieScan PRO and the contacts inside the sensors.*



*Prepare the Patient*

4. Ensure the surface of the tooth to be measured is free from any plaque and debris, as described in [Section 5.3](#).
5. Connect the Soft Tissue Contact (lip clip) to the socket of the cable.
6. Firmly connect the plug of the soft tissue cable into the socket at the side of the CarieScan PRO.
7. Gently place the curled end of the Soft Tissue Contact over the lower lip of the patient.
8. Dry the site to be measured for 5 seconds with a 3-in-1 syringe to remove any pooled fluid.




**Measurement of occlusal surface**

**Note**

*Drying time is based on standard air pressure of 40psi.*

*Take a measurement*

9. Press the 'Enter' button  to start measuring.
10. The blue LED on the pyramid will flash indicating that the CarieScan PRO is in measurement mode.
11. Place the sensor firmly onto the chosen occlusal or smooth surface and a measurement will automatically be taken. During the measurement 4 audible tones will be heard before the result is displayed.



**Sensor placement on occlusal surface**



**Sensor placement on smooth surface**

12. On completion of the measurement the result is presented by a further sequence of beeps and the colour pyramid classification will light displaying the caries detection level, as described in [Section 5.1](#).

*Record the result and move on to another site*

13. With the measurement complete the sensor can be removed from the tooth surface, the result will remain visible on the displays until the next tooth site is detected. Record the last result as required and select another site to measure.

**Note:**

*If there is a bad connection or improper site preparation the CarieScan PRO may not provide a measurement value.*

14. The measurement mode (indicated by blue flashing LED) will automatically restart after 3 seconds, and subsequent measurement will begin when the CarieScan PRO detects when the sensor is on a tooth.
15. Take a new measurement by returning to step 11.

*Note: Further drying may not be necessary if repeating measurements on the same site.*

**Finishing up**

16. Terminate the measurement process by pressing any button on the Keypad for about 1s.
17. When measurements on the patient are complete:
  - To remove the sensor from the CarieScan PRO, squeeze the sensor on the side grips to release the catch and remove from the device.
  - All sensors must be disposed as sharp contaminated waste. All such waste must be placed in a suitable receptacle marked as biohazard, conforming to the required regulations.
  - the CarieScan PRO and Soft Tissue Cable should be wiped down with alcohol-based wipes.

**Note:**

*During a measurement, ReadyScan can be aborted by pressing any of the buttons on the keypad to escape the sequence. The CarieScan PRO will then return to Standby mode.*

*If the blue LED stops flashing, ReadyScan can be restarted by returning to step 9.*

*The device automatically switches off after 15 minutes on idle without any measurements taken or key presses.*

## 6 CLEANING AND MAINTENANCE

### 6.1 General

The CarieScan PRO contains no user replaceable parts.

Inspect the device regularly for significant damage and/or wear and tear. If any damage is found then your supplier should be contacted. The CarieScan PRO and Soft Tissue Cable should be wiped down with alcohol-based wipes after each use. They must not be subjected to sterilisation procedures. Keep this system away from wet locations as functionality may be compromised.

**A new sensor pack must be used for each patient at each new visit.**

**IMPORTANT:** All sensors must be disposed of as sharp contaminated waste. All such waste must be placed in a suitable receptacle marked as biohazard, conforming to the required regulations.

### 6.2 Service

CarieScan PRO contains no user serviceable parts. If any problems arise, please contact your supplier ([Section 10.1](#)).

### 6.3 Storage conditions

Temperature range: -20°C to +60°C.

Normal operating temperature range of the product is 0°C to +50°C at non-condensing relative humidity of 10% to 90% RH.

## 7 Important Information

### 7.1 Intended Use

The CarieScan PRO is intended for use by dental professionals as an aid in the diagnosis and monitoring of dental caries.

### 7.2 Indications for use

The CarieScan PRO is indicated for the detection and monitoring of primary coronal dental caries.

### 7.3 Restrictions on Use

The CarieScan PRO is a prescription only use device. The sensors are single use devices and must not be sterilised. A NEW sensor pack must be used for EACH patient at each visit.

If using on patients with a fixed orthodontic appliance avoid contacting any metal parts of the appliance to ensure reliable measurement.

Care should be taken when using the device on teeth up to 3 years after their eruption – do not rely solely on a single CarieScan PRO measurement result for making a treatment decision on a tooth surface on such teeth Use the device to monitor the tooth surface over time to help determine the treatment decision.

With deciduous teeth care should be taken to cross-reference CarieScan PRO readings with the results of conventional clinical examinations and the clinician's judgement.

**CAUTION:** US Federal Law restricts the sale or use of this device to qualified dental professionals.

### 7.4 Contraindications

The CarieScan PRO cannot be used to assess:

- secondary caries
- the integrity of a restoration
- dental root caries
- the depth of an excavation within a cavity preparation

Further, the CarieScan PRO should not be used when tooth surfaces are covered with an excess of plaque and / or other debris. Ensure the teeth are cleaned and excess plaque removed.

### 7.5 Warnings

It is the responsibility of the Dental Healthcare Professional to understand:

- i. the appropriate use of this product
- ii. the health of each patient
- iii. the dental procedures being undertaken
- iv. industry and governmental agency recommendations, requirements, and regulations for the safe practice of dentistry.

### 7.6 Precautions

Do not place the system on or next to a radiator or other heat source as excessive heat may damage the system's electronics. The system is portable, but must be handled with care.

### 7.7 Infection control

As with all dental procedures, universal cross-infection precautions should be observed. Please visit [www.cariescan.com](http://www.cariescan.com) for recommended infection control barriers.

## 8 CERTIFICATIONS

The product is manufactured by CarieScan Ltd in accordance with ISO 13485:2003.  
The device is CE marked in accordance with Medical Device Directive 93/42/EEC.

This product is certified to comply with:  
IEC60601-1, UL 60601-1/UL 2601-1, CSA 22.2 No.601-1, EN60601-1-2, FCC 47CFR Part 15

| <b>Guidance and manufacturer's declaration – electromagnetic emissions</b>                                                                                                                    |                   |                                                                                                                                                                                                                                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The CarieScan PRO is intended for use in the electromagnetic environment specified below. The customer or the user of the CarieScan PRO 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 CarieScan PRO 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 CarieScan PRO 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 IEC 61000-3-2                                                                                                                                                              | Class A           |                                                                                                                                                                                                                                |
| Voltage fluctuations/flicker emissions IEC 61000-3-3                                                                                                                                          | Complies          |                                                                                                                                                                                                                                |

These limits are designed to provide reasonable protection against harmful interference in a typical dental installation. This equipment generates, uses and may radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- i. Reorient or relocate the receiving device.
- ii. Increase the separation between the equipment.
- iii. Connect the equipment into an outlet on a circuit different from that to which the other devices are connected.
- iv. Consult the manufacturer or field service technician for help.

We hereby declare the product CarieScan PRO FCC ID:TTZ0002 is a class 2 BT device (max 1mW Transmit power) and for typical product usage the antenna distance from a person is 15cm. The product is not subject to the routine RF exposure evaluation as per Section 2.1093 of the FCC rules.


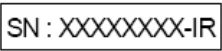
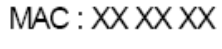



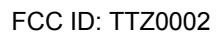

## 9 WARNINGS & PRECAUTIONS

### 9.1 General

Only the CarieScan PRO and Display Stand should be taken inside the patient environment, which is defined as a radius of 2m from the patient. For the avoidance of doubt, the Charging cradle and all other accessories MUST remain outside the patient environment.

Use only the separately available CarieScan sensor packs (CS-OCC-50) with the CarieScan PRO. Avoid direct contact with water, wet surfaces or condensing humidity.

### 9.2 Label Glossary

|                                                                                     |                                                                                                                                                                                                                                                                                                                                                      |
|-------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|    | <p>Type B applied part<br/>May be connected to earth and can be immediately released from the patient</p>                                                                                                                                                                                                                                            |
|    | <p>Serial number with hardware I) Issue and R) Revision.</p>                                                                                                                                                                                                                                                                                         |
|    | <p>Last 6 digits of the Bluetooth MAC address used as a unique identifier.</p>                                                                                                                                                                                                                                                                       |
|   | <p>Year and month of manufacture.</p>                                                                                                                                                                                                                                                                                                                |
|  | <p>See Accompanying Documents for further information (this User Manual)<br/>Electrical Device certified to comply with the stated Medical Device Directives</p>                                                                                                                                                                                     |
|  | <p>Waste Electrical and Electronic Equipment (WEEE) Directive<br/>This product cannot be discarded as unsorted municipal waste. Separate collection of such waste is necessary.</p>                                                                                                                                                                  |
|  | <p>This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:</p> <ul style="list-style-type: none"> <li>i. this device may not cause harmful interference, and</li> <li>ii. this device must accept any interference received, including interference that may cause undesired operation.</li> </ul> |
|  | <p><b>MEDICAL EQUIPMENT</b><br/>WITH RESPECT TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL60601-1, CAN/ CSA C22.2 No. 601.1.</p> <p><b>31TZ</b></p>                                                                                                                                                                    |

### 9.3 Classification

#### 9.3.1 CarieScan PRO

- i. Internally powered equipment
- ii. Type B applied part
- iii. Not intended to be sterilised.
- iv. Not suitable for use in the presence of flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
- v. Intended for continuous operation

#### 9.3.2 Charging Cradle

- i. Not intended to be sterilised.
- ii. Not suitable for use in the presence of flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
- iii. Intended for continuous operation.

#### 9.3.3 Display Stand

- i. Not intended to be sterilised.

## 10 FURTHER INFORMATION

### 10.1 Product support

If there are any missing components or service / maintenance required, please contact:

CarieScan Ltd  
Prospect Business Centre  
The Technology Park  
Dundee  
DD2 1SW  
UK

Tel. +44 (0)1382 598628

Email: [support@cariescan.com](mailto:support@cariescan.com)







Web: [www.cariescan.com](http://www.cariescan.com)

### 10.2 Battery information


Self discharge within approximately 90 days at 20°C.

Storage at higher or lower temperatures can significantly reduce / increase this stated discharge time. It is strongly recommended that each unit is recharged fully at least once per month.

### 10.3 LCD Glossary

|                                                                                   |                                        |
|-----------------------------------------------------------------------------------|----------------------------------------|
|  | Wireless connectivity indicator        |
|  | Busy / wait                            |
|  | Low battery status indicator           |
|  | Smooth surface measurement available   |
|  | Occlusal surface measurement available |
|  | Three character display                |

The following messages may be seen in the three character display over the course of the normal operation of the CarieScan PRO:

|                                                                                     | <b>See Section</b>                                  |
|-------------------------------------------------------------------------------------|-----------------------------------------------------|
| <b>Measurement</b>                                                                  | <a href="#">4.4</a>                                 |
| Ok                                                                                  | Startup tests ok                                    |
| NOS                                                                                 | No sensor attached                                  |
| RdY                                                                                 | Ready to start measurement                          |
| bYE                                                                                 | Powering off                                        |
| TSI                                                                                 | Testing internal Load                               |
| TSE                                                                                 | Waiting for external System Health Check            |
| CFL                                                                                 | System Health Check failure                         |
| <b>Result</b>                                                                       | <a href="#">5.1</a>                                 |
| G                                                                                   | Sound tooth                                         |
| 1 - 99                                                                              | Intermediate scale between G and R                  |
| R                                                                                   | Established caries                                  |
| <b>Navigation</b>                                                                   | <a href="#">4.5</a>                                 |
|  | Indicates that Bluetooth can be enabled or disabled |

### 10.4 Troubleshooting

Please visit Frequently Asked Questions on our website ([www.cariescan.com/faqs.php](http://www.cariescan.com/faqs.php)) for up-to-date frequently asked questions and troubleshooting tips.



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