# **DURAY**<sup>®</sup> Intraoral Sensor

Instruction for use





#### Content

1. Production introduction	.3
2. Product installation and function description	.5
3. Operation instructions	. 15
4. Notes	.29
5. Trouble shooting	. 30
6. Cleaning, disinfection and sterilization	.31
7. Storage, maintenance and transportation	. 32
8. Environment protection	. 33
9. After-sales service	.34
10. Electromagnetic compatibility	. 35
11. Symbol instruction	.44
12. Beyes limited warranty statement	.45

#### Preface

Thank you for purchasing the digital intraoral X-ray imaging system produced by Beyes Dental Canada Inc., is a high-tech enterprise researching, developing, producing and selling dental products. It has a thorough quality control system. To ensure that you use the equipment correctly and safely, please read the full text of the instruction manual carefully before use.

# 1. Production introduction

# **1.1 Product introduction**

The digital intraoral X-ray imaging system is applicable for oral two-dimensional image photographing, case diagnosis, and information management. Features:

a) Ultra-high image resolution can provide doctors with clearer diagnostic images.b) High-quality user interface makes photographing and reading easier.c) User-friendly design makes the photographing process more comfortable.

# 1.2 Model

Duray Sensor DS0 / Duray Sensor DS1 Duray Sensor DS1.5 / Duray Sensor DS2

# 1.3 Configuration

Equipment configuration is detailed in packing list.

# 1.4 Structure and Components

This equipment is composed of X-ray sensor, USB transmission cable, disposable protective sheath, sensor bracket, image management software system and other parts.

# 1.5 Scope of application

It is mainly applicable for oral two-dimensional image photographing, case diagnosis and information management.

# 1.6 Contraindications

Pregnant women and young children should be cautious to use the equipment. 1.7 Device safety classification

- 1.7.1 Type of operation mode: Intermittent operation
- 1.7.2 Type of protection against electric shock: Class II equipment
- 1.7.3 Degree of protection against electric shock: BF type applied part
- 1.7.4 Degree of protection against harmful ingress of water: IP68

1.7.5 Degree of safety application in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide: Equipment cannot be used in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.

## 1.8 Primary technical parameters

1.8.1 Power adapter input: 5V/USB interface 1.8.2 Sensitive surface: 30\*20mm(DS1) / 36\*26mm(DS2) 24\*18mm(DS0) / 33\*24mm(DS1.5) 1.8.3 Surface in pixels: 1000\*1500(DS1) / 1300\*1800mm(Ds2) 1200\*900(DS0) / 1650\*1200(DS1.5) 1.8.4 Physical pixel size: 20µm 1.8.5 Effective resolution: > 16lp/mm 1.8.6 Outer Dimension: 31 x 21 x 4.4mm(DS1) / 37 x 27 x 4.4mm(DS2) 25 x 19 x 4.4mm(DS0) / 34 x 25 x 4.4mm(DS1.5) 1.8.7 Weight: 118g(DS1) / 158g(DS2) / 108g(DS0) / 138g(DS1.5)

# **1.9 Operation environment**

- 1.9.1 Environment temperature: 5°C~40°C
- 1.9.2 Relative humidity: 30%~75%
- 1.9.3 Atmospheric pressure: 70kPa~106kPa

# 2. Product installation and function description

# 2.1 Schematic diagram of the whole machine



Figure 1 X-ray sensor

# 2.2 Installation of accessories

### 2.2.1 configuration requirements

It is a must to first ensure that the computer and its peripheral devices do not cause any restrictions that may cause personal safety issues when using the digital intraoral X-ray imaging system. The computer system must also meet the following configuration requirements:

Windows®:	Configuration
Operating system	Windows <sup>®</sup> 7 or above
Processor	Intel <sup>®</sup> Core 2
Memory	2 GB or above
Hard disk	320 GB or above
USB port	4 high-speed USB 2.0 ports
Display board	Nvidia chip graphics card or ATI discrete graphics card
USB chip	Intel or NEC <sup>®</sup> / RENESAS <sup>®</sup>
Display resolution	1280 x 1024

#### X-ray generator compatibility

Digital intraoral X-ray imaging system is compatible with dental X-ray machines that comply with regulatory standards on the current market.

## 2.2.2 Software installation

a) Double-click to run the "Duray-setup.exe" installation program.

Duray-Beyes Dental-V1.0.0.4-setup Figure 2

Beves'

b) After the installation program starts, click the "Browse" button to select the installation path. After the path is selected, click the "Next" button, as shown in Figure 3:

Select Destinat	ion Location				
					C
Setup will insta	ll into the following fo	lder,if you want t	o change location	click "open" button,	
C:\Duray					open
Images will be :	saved in location:				
<ul> <li>default</li> </ul>	C:\Duray-Images				
◯ custom					
At least 352.3	MB of free disk space	is required.			
				Next >	Cancel

c) Select the component. The user selects the corresponding component as needed, and then click the "Next" button, as shown in Figure 4:

Which components should be installed?	
Select the components you want to install; clear the comp when you are ready to continue.	ponents you do not want to install. Click Next
Client	171.4 M
≤ Server	389.0 M
Current selection requires at least 912.6 MB of disk space	ŧ.

d) Set whether to create a desktop shortcut and server auto start, click the "Next" button after completion, as shown in Figure 5:

Setup - Duray version V1.0.0.4		_	• ×
Select Additional Tasks Which additional tasks should be performed?			
Select the additional tasks you would like Setup to perform while	installing Duray, then	dick Next.	
Additional shortcuts:			
Create a desktop shortcut			
☑ server auto start			
	< Back Ne	ext >	Cancel
Figure 5			

e) Click the "Install" button to start the installation, as shown in Figure 6:

etup is now ready to begin installing l	Duray on your computer.		J.
lick Install to continue with the install	ation, or click Back if you want to	review or change any se	ettings.
Destination location: C:\Duray			^
Setup type: full			
Selected components: Client			
Additional tasks:			
Create a desktop shortcut server auto start			~
			>

f) After clicking the "Install" button, the program starts to install. The user can wait for the installation to complete, as shown in Figure 7:

Secup - Duray Version V1.0.0.4		
nstalling		
Please wait while Setup installs Duray on your computer.	Č.	
Extracting files		
C:\Duray\jre1.8.0_x64\bin\api-ms-win-core-console-l1-1-0.dll		
	Cancel	

g) After the database is installed, the installation completion interface is displayed. Click "Finish" to exit the installation program, and the software is successfully installed.



12

2.2.4 Installation of support frame

The sensor support frame is fixed on a flat wall by two screws. When the sensor is idle, secure it on the support frame, as shown in the following figure:



# 3. Operation instructions

# 3.1 Brief description of photographing steps

3.1.1 First, turn on the PC with the image software system installed and start the image processing software.

3.1.2 Start the matching X-ray generator and set photographing parameters. 3.1.3 Put the protective sheath on the sensor and place the sensor in the patient's mouth parallel to the long axis of the teeth, so that the effective surface of the sensor is close to the teeth.

3.1.4 Move the generator to the patient's head. Ensure that the generator cone is perpendicular to the position of the sensor. Press the generator switch.

3.1.5 After exposure, the imaging software downloads the X-ray image to the screen for display.

# 3.2 Use of sensor protective sheath

In order to ensure the maximum health and safety of the patient, the sensor must be used with a disposable sensor protective sheath. Pay attention to the following points during operation:

- 1. Wear gloves to place the sensor protective sheath.
- 2. Replace the sensor protective sheath every time finishing photographing.
- 3. Place the sensor protective sheath in a dry and clean place.
- 4. The used sensor protective sheath should be disposed of together with other organisms and potentially infectious waste.
- 5. It is better to use the sensor protective sheath specially designed for digital intraoral X-ray imaging system.
- 6. When the sensor protection device is damaged while the patient is Being examined or if the sensor is contaminated due to the removal of the protective sheath, the sensor and the front 40cm cable must be thoroughly disinfected.

# 3.3 Software operation instructions

#### 3.3.1 Login module

Double-click "Duray-Server" to start the server. After the server is started successfully (as shown in Figure 10), double-click "Duray-Client" to start the

software and enter the software login interface (as shown in Figure 11). Enter the user name and position, and click the "Login" button to log in to the main interface, as shown in Figure 12.





Figure 12

# 3.3.2 Patient module Click the "Patient" button to enter the patient module.

#### a) Add, modify and delete patients

Click the "Add Patient" button to enter the information, click "OK" and a patient can be added. If you need to modify the patient information, click the "Modify Patient" button to modify the patient information, click "OK" and the modification can be successful. If you need to delete a patient, click the "Delete Patient" button and click "OK". As is shown in Figure 13:

Beyes	Patient	Diagnosis	Report	Setting
	& &	8		
		<b>F</b> i 10		

Figure 13

#### b) Image acquisition

After entering the software interface, the WIFI name will be displayed in the software status bar. Click the "Acquisition" button, connect the Duray Sensor device to WIFI, and select the Duray Sensor device type. When the device is connected, the IP address will be displayed under the device type. Click "Open", the device will enter the acquisition state, and start to acquire images. As is shown in Figure 14:



Figure 14

#### c) Image preview

Click the "Preview" button to view acquired images. Select an image, right-click and select "Export" to export the image to the local. Select "Information" to view the information of the image. Select "Delete" to delete the image. Double-click the image to enter the diagnosis interface. As is shown in Figure 15:





### 3.3.3 Diagnostic module

Click the "Diagnosis" button to enter the diagnosis module.

Click the image on the left to select an image to be processed. There are image processing tools on the right side of the diagnosis interface, such as Display, Image Correction, Measuring, View, Enhance, Sharpening, Histogram, Annotation, etc.

Select the image processing tool and adjust the image quality to a satisfactory level. In the Enhance, click the "HD" button and the image will be enhanced. Click the "HD" button again to cancel the enhancement.

Use image processing tools to adjust image quality. Click the "Add Temporary State" button to save the image quality at this time. Select the temporary state in the drop-down box to reproduce the image.

There are delete, export, and image information functions above the processed image. These functions are similar to the corresponding functions of the patient module. When multiple images are selected for processing, click the "Clear" button to close them all.

Move the mouse wheel up and down to zoom in and out of the image. Hold down the right button and move the mouse up to increase contrast, move down to decrease contrast, move left to decrease brightness, and move right to increase brightness.

Select an image, and click the linear measurement icon (or angle measurement icon) in the Measuring. Click the left mouse button to form the starting point and move the mouse. Click the left mouse button again to form the end point and rightclick the end point to end the measurement. The measurement line will be displayed on the image, and meanwhile the corresponding annotation of the measurement line will be displayed in the Annotation. As is shown in Figure 16:



Figure 16

## 3.3.4 Report module

Click the "Report" button to enter the report module. Click the "New Report" button to create a new report template. Drag an image from the left to the image box, and enter the diagnosis result in the text box, etc. If you need more pages, click "Add

Page", and a page will be added to the report. After writing the report, click the "Save to Server" button to save the report to the server. When you want to view the report, click "Open Report", select the report you want, and click "Open" to view. Click the "Export to PDF" button to export the report to the local. As is shown in Figure 17:



#### Figure 17

3.3.5 Setting Module

Click the "Setting" button to enter the setting module.

#### a) Basic Setting

Click the "Basic Setting" button to enter the basic setting page. Click the "Sign Out" button to return to the login interface. Click the language drop-down box to select the software language. Click the tooth profile drop-down box and select the tooth profile number. As is shown in Figure 18:

Beyes	Patient	Diagnosis	Report	Setting	
			🔹 🔲 Show		
	" پر لا	* * * * * * * * W & } } } }	1 2 3 4 5 6 6 6 6 6 6 W	<b>W</b>	
	nght <b>()</b>	6 5 4 3 2 1		7 8	

Beves

### b) Clinic Management

Click the "Clinic Management" to enter the clinic management interface and enter the clinic information, as shown in Figure 19:

Beyes	Patient	Diagnosis	Report	Setting	? _ (	×
Basic Setting						
Clinic Management						
Image Processing						
Network Settings						
Device Management						
Staff Management						
	Clinic Logo					
	🔘 Text 👩	· · · · ·	Clinic Logo			

Figure 19

# c) Image Processing

Click the "Image Processing" button to enter the image processing interface. Select the HD checkbox, select "HD", and the acquired image will be initialized and HD processed automatically. Select "Fine", and the acquired image will be initialized and Ultra HD processed automatically. As is shown in Figure 20:



# d) Network Settings

Click the "Network Settings" button to enter the network setting interface. Enter the IP address and port number. Click "Test Connection" to view the test result. Click "Modify" to switch the connected server, and the software needs restarting at this time. Click "Edit" button and input the password "0000" to change "wireless" to "wired". As is shown in Figure 21:

Beyes	Patient	Diagnosis	Report	Setting	
	IP Address				
Clinic Management	Test Connection				
Image Processing Network Settings					
	Network settings				
Staff Management	<ul> <li>♥ wireless</li> <li>♥ w</li> <li>Wifi settings</li> </ul>	ired			
	🛜 🔲 Edit				
	Edit				



#### 3.3.6 Software upgrade

The software has the function of automatic upgrade. If the computer is installed with the Duray server and the software can be upgraded, a pop-up window "Upgrade or not" will appear on the computer. Click "Yes" and all clients connected to the server will receive a reminder of 10s countdown to upgrade. After 10 seconds, the software will automatically close and then start to upgrade. Click "No" and the software will not be upgraded temporarily.

#### 4. Notes

### 4.1 Notes for sensor use

4.1.1 Be sure to place the sensor carefully.

4.1.2 Be sure to use a disinfectant wipe to clean the sensor.

4.1.3 Be sure to place the sensor on the holder.

4.1.4 Do not ask the patient to bite the sensor and connecting cable.

4.1.5 Do not put the sensor in water.

4.1.6 If a malfunction occurs, do not open the sensor.

4.1.7 Our company is a professional manufacturer of medical devices. The maintenance, repair and modification of the product must be carried out by our company or our authorized distributors. We are responsible for the safety of maintenance, repair and modification only when they are replaced by the original accessories of our company and operated according to the instruction manual.

Beves

# 5. Trouble shooting

Fault	Possible cause	Solution
The software interface shows the connection timeout	<ol> <li>USB driver is not installed.</li> <li>USB driver is incorrectly installed.</li> <li>The USB port is not inserted correctly.</li> <li>The USB cable is damaged.</li> </ol>	1. Reinstall the USB driver 2. Reinstall the USB driver 3. Re-plug the USB port 4. Contact the local dis- tributor

If the above methods can not eliminate the fault, please contact the distributor to return the device to the manufacturer for handling. Do not try to open the casing of this device and repair it yourself.

# 6. Cleaning, disinfection and sterilization

# 6.1 Cleaning and disinfection of x-ray sensor and USB cable

To further eliminate the latent danger of cross infection, in addition to using disposable protective sheath, the sensor and the front 40cm cable should be cleaned and disinfected before each patient is replaced for photographing. The recommended disinfectant for cleaning and decontamination is 70% is opropanol. It's recommended to use a cloth sprayed with aldehyde-free disinfectant to wipe and disinfect the surface.

# 6.2 Unavailable cleaning and disinfection methods

a) Do not use hard tools to clean for avoiding abrasion.

b) The following disinfectants should not be used: trichloroethylene, dichloroethylene, ammonium hydrochloride, chlorinated hydrocarbons and aromatic hydrocarbons, dichloroethane, methylene chloride and methyl ketone.

c) Do not spray the disinfectant directly on the X-ray sensor.

# 7. Storage, maintenance and transportation

# 7.1 Storage

7.1.1 This device should be handled with care, not subjected to excessive shock or vibration, and should be installed or stored in a cool, dry and ventilated place.
7.1.2 Do not mix it with toxic, corrosive, flammable and explosive materials during storage.

7.1.3 The product should be stored in an environment with a relative humidity of 10%~93%, an atmospheric pressure of 70kPa~106kP, and a temperature of -20°C  $\sim$  +55°C .

# 7.2 Calibration

In some European countries-especially Germany-current laws require the quality of sensors to be checked through specially designed test cards (once a month). Even when used in other countries that do not require this type of calibration, it is recommended to perform this type of calibration regularly (once a month) to ensure that the product can still be used for diagnostic purposes. The calibration process is as follows:

Step 1: Connect the sensor and start the image management software. Step 2: Place the test phantom in the field of view of the sensor. Step 3: Set the matching X-ray generator parameters (60KV, 50mAs) and take exposure photographing. Step 4: Confirm whether the resolution is not less than 8lp/mm.

# 7.3 Transportation

7.3.1 During transportation, excessive impact and vibration should be prevented. Handle it with care and avoid inversion.7.3.2 It should not be mixed with dangerous goods during transportation.7.3.3 Avoid sunlight, rain or snow during transportation.

# 8. Environment protection

The product does not contain any harmful ingredients. It can be processed or destroyed in accordance with the relevant local regulations.

Part names	Toxic and harmful substances or elements					
	(Pb) (Hg) (Cd) (Cr6+) (PBE				(PBB)	(PBDE)
X-ray sensor	0	0	0	0	0	0
USB cable	0	0	0	0	0	0



O: Indicates that the content of the toxic substance in all homogeneous materials of the component is below the limit requirement in SJ/T-11363-2006 Limit Requirements for Toxic and Hazardous Substances in Electronic Information Products.

×: Indicates that the content of the toxic substance in at least a certain homogeneous material of the part exceeds the limit requirement of SJ/T-11363-2006. (This product complies with EU RoHS environmental protection requirements. At present, there is no mature technology in the world that can replace or reduce the lead content in electronic ceramics, optical glass, steel and copper alloys.) According to the Administrative Measures on the Restriction of the Use of Hazardous Substances in Electrical and Electronic Products, the Regulations on the Management of Recycling and Disposal of Waste Electrical and Electronic Products and related standards, please observe the safety and use precautions of the products and recycle or discard the products in accordance with local laws and regulations after use.

#### 9. After-sales service

Since the date of sale, if the device fails to work normally due to quality problems, our company will be responsible for the maintenance with the warranty card. Please refer

to the warranty card for the warranty period and scope. This product does not contain self-maintained parts, and the maintenance of this device should be carried out by designated professionals or special repair shops.

# 10. Electromagnetic compatibility

For this device, special precautions regarding electromagnetic compatibility (EMC) must be taken. The installation and use must be in accordance with the electromagnetic compatibility information specified in this manual. Portable and mobile radio frequency communication equipment may affect this device.

The following cables must be used to meet electromagnetic emission and anti-interference requirements:

Name	Cable length	Whether to block	Remark
USB cable	2.7m	No	EUT

The equipment or system should not be used close to or stacked with other equipment. If must be used in this way, it should be observed to verify that it can operate normally under the configuration used.

## 10.1 Guidance and manufacturer's declaration-electromagnetic emission

Guidance and manufacturer's declaration-electromagnetic emission

Digital intraoral X-ray imaging system is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment-guidance
RF emission GB 4824	Group 1	Digital intraoral X-ray imaging system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference to nearby electronic equipment.
RF emission GB 4824	Class 1	Digital intraoral X-ray imaging system is suitable for used 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 emission GB17625.1	Not conformable	Power is less than 75W
Voltage fluctuation/ Flicker emission GB17625.2	Conformable	

# 10.2 Guidance and manufacturer's declaration-electromagnetic immunity

Guidance and manufacturer's declaration-electromagnetic immunity

Digital intraoral X-ray imaging system is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.

Immunity test	Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge GB/T17626.	±6kV contact discharge ±8kV air discharge	±6kV contact discharge ±8kV air discharge	Floors should be wood, con- crete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Beves\*

Electrical fast Transient burst GB/T 17626.4	±2kV for power supply lines ±1kV for handpiece lines	±2kV for power supply lines Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge GB/T 17626.5	±1kV line to line ±2kV line to earth	±1kV line to line Not applicable	Mains power quality should be that of a typical commer- cial or hospital environment.
GB/T 17626.11 Voltage dips, short interruptions and voltage variations on power supply input lines GB/T 17626.11	<5 % UT (>95% dip in UT) for 0.5 cycle;w <40 % UT (60% dip in UT) for 5 cycles; 70 % UT (30% dip in UT) for 25 cycles; <5 % UT (>95% dip in UT) for 5s	5 % UT (>95% dip in UT) for 0.5 cycle; <40 % UT (60% dip in UT) for 5 cycles; 70 % UT (30% dip in UT) for 25 cycles; <5 % UT (>95% dip in UT) for 5s	Mains power quality should be that of a typical commercial or hospital environment. If the user of digital intraoral X-ray imaging system requires continued operation during power mains interruptions, it is recommended that the scanner be powered from an un interruptible power supply or a battery.

Power frequency magnetic field (50/60Hz) GB/T 17626.8	3A/m	3A/m (50Hz)	The power frequency magnetic field should have the level characteristics of that in a typical commercial or hospital environment.		
[NOTE: UT is the AC mains voltage prior to application of the test level.]					

### 10.3 Guidance and manufacturer's declaration-electromagnetic immunity

Guidance and manufacturer's declaration-electromagnetic immunity

Digital intraoral X-ray imaging system is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.

Immunity	Test	Compliance	Electromagnetic
test	level	level	environment - guidance

Conduct- ed RF GB/ T17626.6 Radiated RF GB/ T17626.	3Vrms 150kHz~ 80MHz 3V/m 80MHz~ 2.5GHz	3Vrms 3V/m	Portable and mobile RF communication equipment should be used no closer to any part of the digital intraoral X-ray imaging system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance 80 MHz to 800 MHz 800 MHz to 800 MHz 800 MHz to 2.5 GHz Here the "P" is the maximum output rated power of the transmitter provided by the transmitter manufacturer, in watts (W). "d" is the recommended separation distance, in meters (m). The field strength of the fixed RF transmitter "b" is determined by surveying the electromagnetic field "a", and "b" should be lower than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbols.
			(((:)))

NOTE1: At 80 MHz end 800 MHz, the formula of higher frequency range is applied.

NOTE 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by the absorption and emission of buildings, objects and human bodies.

a.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 of fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the digital intraoral X-ray imaging system is used exceeds the applicable RF compliance level above, the imaging system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the digital intraoral X-ray imaging system.

b. In the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

10.4 Recommended separation distances between portable and mobile RF communication equipment and the digital intraoral X-ray imaging system

Recommended separation distances between portable and mobile RF communication equipment and the digital intraoral X-ray imaging system

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

Rated maximum	Separation distance according to frequency of transmitter/m			
output power of transmitter/W	150kHz~80MHz	80MHz~800MHz	800MHz~2.5GHz	
0.01	0.12	0.12	0.23	
0.1	0.38	0.38	0.73	
1	1.2	1.2	2.3	
10	3.8	3.8	7.3	
100	12	12	23	

For the rated maximum output power of transmitters not listed in the above table, the recommended separation distance "d", in meters (m), can be determined by the formula in the corresponding transmitter frequency column. Here "P" is the maximum output rated power of the transmitter provided by the transmitter manufacturer, in watts (W).

NOTE1: At 80 MHz end 800 MHz, the formula of higher frequency range is applied.

NOTE 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by the absorption and emission of buildings, objects and human bodies.

### Notes:

Without the explicit consent of Beyes Dental Canada Inc. unauthorized changes or modifications to the equipment may cause electromagnetic compatibility problems of this equipment or other equipment.

# 11. Symbol instruction

# Manufacturer



Date of manufacture



Type BF applied part



Recovery



Humidity limitation



Class II equipment



Non-reusable

Follow Instructions for Use



Temperature limitation

Atmospheric pressure for storage

Appliance compliance WEEE directive

# 12. Beyes limited warranty statement

All rights of modifying the equipment design, product technology or accessories, manual and packaging content at any time are reserved to the manufacturer without further notice.

### **13.1 SCOPE OF WARRANTY**

BEYES Dental Canada Inc. warrants to the original retail purchaser that it will be at BEYES option to repair or replace components of the dental products manufactured by BEYES (except for components not warranted under 'Exclusions') that are defective in material or workmanship under normal use and service. BEYES' obligation under this limited warranty is limited to the repair or replacement of the applicable components. This limited warranty period and which, upon examination by Beyes, prove to be defective. This warranty extends only to the first retail purchaser of a product and is not transferable or assignable. Replacement components or products may be used and/or refurbished components or products, provided they are of like quality and specifications as new components or products.

### **13.2 APPLICABLE WARRANTY PERIOD**

The applicable warranty period, measured from the date of invoice to the original user, shall be as follows

Duray Sensor are warranted for a period of 24 months

Beves'

# 13.3 EXCLUSIONS

This limited warranty does not cover and BEYES shall not be liable for the following;

1. Defects, damage or other conditions caused, in whole or in part, by misuse, abuse, negligence, alteration, accident, freight damage, negligent storage, tampering or failure to seek and obtain repair or replacement in a timely manner;

2. Products which are not installed, used, and properly cleaned and maintained as required or recommended in the BEYES 'Installation' and/or 'Installation/Operation Manual' for the applicable product, including the specified structural and operational environment conditions and electrical power requirements;

3. Products considered to be of a consumable or sterile nature;

4. Accessories or parts not manufactured by BEYES;

5. Charges by anyone for adjustments, repairs, replacement parts, installation or other work performed upon or in connection with such products which are not expressly authorized in writing in advance by BEYES;

6. Costs and expenses of routine maintenance and cleaning;

7. Representations and warranties made by any person or entity other than BEYES;

8. Matching of color, grain or texture except to commercially acceptable standards;

9. Changes in color caused by natural or artificial light;

10. Custom manufactured products;

11. Alterations or modifications to the product by any person or entity other than BEYES;

12. Products that would otherwise by covered under Sections 1 and 2 of this limited warranty, but are acquired: (i) from a person or entity that is not BEYES or one of its

authorized dealers; or (ii) from a BEYES dealer that is not authorized to sell the product at issue in the geographic territory where the purchaser is located, or is not authorized to sell the product at issue within the medical, animal health or dental market, as the case may be, in which purchaser intends to use the product.

# 13.4 exclusive remedy; consequential damages disclaimer

Beyes' obligation under this limited warranty is the repair or replacement of defective parts. Beyes shall not be liable for and hereby disclaims any direct, special, indirect, incidental, exemplary or consequential damages or delays, including, but not limited to, damages for loss of profits or income, loss of use, downtime, cover and employee or independent contractor wages, payments and benefits.

# 13.5 Warranty disclaimer

This limited warranty is beyes only warranty and is in lieu of all other warranties, express or implied. Beyes makes no implied warranties of any kind including any implied warranties of merchantability or fitness for a particular purpose. This warranty is limited to the repair or replacement of defective parts.

### 13.6 Statue of limitations

No actions wmay be brought against beyes for breach of this limited warranty, or implied warranty, if any, or for any other claims arising out of or relating to the products, more than ninety (90) days following expiration of the limited warranty period.





Federal law restricts this device to sale by or on the order of a dentist, physician, or any other practitioner licensed by the law of the states in which he or she practices to use or order the use of this device.

Beyes Dental Canada Inc. 23-595 Middlefield Road

Scarborough, ON M1V3S2 Canada Tel: 1-855-603-1888 Fax: 1-855-720-1228 Email: info@beyes.ca Web: www.beyes.ca



Lotus NL B.V. Koningin Julianaplein 10, le Verd, 2595AA, The Hague, Netherlands

**CE** 0197

Printed in Canada ENI042 Rev.3/12.10.24