SmartMirror

User's Guide

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1. Introduction

This document is the official User Guide for SmartMirror, a device designed and manufactured by Dental SmartMirror, Inc. This manual is maintained by Dental SmartMirror, Inc., you can find the latest version at <u>www.smartmirror.dental</u>.



Read this instruction manual carefully before use of the device.

1.1 Conventions

The following special messages emphasize important information or indicate potential risk to the operator or other persons and equipment:



WARNING: Warns you to avoid injury to yourself or others by following the safety instructions precisely.



Caution: Alerts you to a condition that might cause serious damage.



Note: Emphasizes important information.

1.2 Intended Use

SmartMirror is a dental mirror with an intraoral imaging system designed for use by dental professionals to educate patients as to their dental treatment needs. SmartMirror, paired with an iOS device, allows the dental professional to closely examine treatments as they are being performed, and to capture both snapshot images and short videos.

2. Precautions

2.1 Compliant Use

 \triangle The user shall:

- Only use non-defective products.
- Protect patients, third parties, other operators, assistants, and themselves from all unintended use of the product.
- Always perform reprocessing steps between patients.
- Check the safety of operation and the condition of the device before each use.
- Verify that the product is operational at all times and kept in good working condition.

2.2 Disposal

Please dispose of the equipment at the end of its life cycle according to local regulations.

2.3 Safety Instructions

igtarrow Do not use this product if there are any signs of damage to any of the components of the product.

If there are signs of damage, you must contact Dental SmartMirror, Inc. All repairs must be performed only by trained technicians of Dental SmartMirror or an authorized service representative.

- Do not use SmartMirror if there is any damage to the mirror surface or any other part of the device.
- Always use the original charging cable or Edge system for charging your SmartMirror.
- Do not immerse the SmartMirror Streamer in any liquid.
- Do not expose any part of SmartMirror to a direct or indirect heat source.
- For patient and operator safety, always go through the reprocessing steps between patients.
- Do not allow unauthorized or unsupervised use of SmartMirror.
- Do not attempt to change or modify any of the components of SmartMirror.
- Do not drop SmartMirror.
- Immediately stop using SmartMirror if there are signs of an allergic reaction by the patient or user.
- Do not attempt to remove or service any part of SmartMirror. Doing so may damage the device and will void the warranty.
- If there is a liquid leak from the device, a faulty battery may be to blame. In this event, immediately discontinue use of the device and contact Dental SmartMirror, Inc. or your authorized sales representative.

2.4 Electromagnetic Interferences

Declaration – electromagnetic emissions			
Emissions test	Compliance	Electromagnetic environment – guidance	
RF emissions CISPR 11	Group1 Class A	The SmartMirror 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.	
Harmonic emissions IEC 61000-3-2	Class A	The SmartMirror is suitable for use in all establishments. Warning: This equipment/system is intended for use by	
Voltage Fluctuations and Flicker IEC 61000-3-3:2013	Complies	healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the SmartMirror or shielding the location.	

Declaration – electromagnetic immunity				
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance	
Electrostatic discharge (ESD) IEC 61000-4-2	8 kV contact 2, 4, 8, 15kV air	8 kV contact 2, 4, 8, 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.	
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/output lines	2 kV for power supply lines 1 kV for input/output lines	The mains power quality should be that of a typical commercial or hospital environment.	
Surge IEC 61000-4-5	1 kV line(s) to line(s) 2 kV line(s) to earth 2 kV Signal input/output) to earth	1 kV line(s) to line(s) 2 kV line(s) to earth 2 kV Signal input/output) to earth	The mains power quality should be that of a typical commercial or hospital environment.	
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% UT; 0.5cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315° 0% UT; 1cycle and 70% UT; 25/30 cycles Single-phase at 0° 0% UT; 250/300 cycle	0% UT; 0.5cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315° 0% UT; 1cycle and 70% UT; 25/30 cycles	SmartMirror is supplied by a DC battery and therefore no voltage faults should apply.	

	Single-phase at 0° 0% UT;	
	250/300 cycle	

Declaration – electromagnetic immunity			
Immunity test	IEC 60601 TEST	, Compliance	Electromagnetic environment –
	LEVEL	level	guidance
Conducted RF IEC 61000-4-6	3V, 6V	3Vrms, 6V	Portable and mobile RF communications equipment should be used no closer to any part of the SmartMirror, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	3V/m	3V/m	$d = \left[\frac{12}{V_2}\right]\sqrt{P}$ $d = \left[\frac{12}{E_1}\right]\sqrt{P} \text{80 MHz to 800 MHz}$
	3V/m from 0.15 to 80MHz; 6V/m from 0.15 to 80MHz and 80% AM at 1kHz 10V/m from 80MHz	3V/m from 0.15 to 80MHz; 6V/m from 0.15 to 80MHz and 80% AM at 1kHz 10V/m from 80MHz	$d = \left[\frac{23}{E_1}\right]\sqrt{P}$ 800 MHz to 2,5 GHz 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.
	to 2.7GHz	to 2.7GHz	D Interference may occur in the vicinity of equipment marked with the following symbol:

1		
		(t_{ℓ}, y)
		(((•)))

Recommended separation distances between				
portable and mobil	e RF communications	s equipment and the	SmartMirror produ	ct.
Rated maximum	Separation distance according to the frequency of the transmitter			
output	М			
power of transmitter	150 kHz to 80 MHz	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
W	outside ISM	in ISM bands		22
	bands $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$	$d = [\frac{12}{V_2}]\sqrt{P}$	$d = [\frac{12}{E_1}]\sqrt{P}$	$d = \left[\frac{23}{E_1}\right]\sqrt{P}$
0.01	0.12	0.2	0.4	1
0.1	0.37	0.64	1.3	2.6
1	1.17	2	4	8
10	3.7	6.4	13	26
100	11.7	20	40	80

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, all pieces of equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of said equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of SmartMirror, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

2.4.1 Electrical Connection

Use only the original SmartMirror Female USB-C charging cable or the SmartMirror Edge device for charging your Streamer.

2.4.2 Environment

 Δ SmartMirror is intended for use in the dental operatory or dental patient treatment area.

- Avoid direct exposure to sunlight.
- Do not expose SmartMirror to extreme heat or cold.

2.4.3 Storage Conditions

Store SmartMirror in a cool, dry environment.

The SmartMirror Streamer may be left connected to the charging unit.

2.5 Malfunction

In case of malfunction:

- Immediately stop using the device.
- Try to identify or eliminate the cause using the instructions in this manual (Troubleshooting chapter 9).
- If it is not possible to identify or eliminate the cause using the provided instructions, contact Dental SmartMirror, Inc. or its licensed sales representative.

3. System Overview

SmartMirror includes the following components:

Head – Includes the Mirror, Camera, LEDs and the autoclavable body.



Streamer – Includes the computing processor, Wi-Fi components and battery.



4. Package Contents

SmartMirror Head package includes:

- SmartMirror Head
- Sterilization cap

SmartMirror Streamer package includes:

- SmartMirror Streamer
- Original SmartMirror USB charging cable

5. Instructions for Initial Use

5.1 Charge Your SmartMirror Streamer

Before first using SmartMirror, make sure to fully charge the Streamer. It is recommended to allow it to charge for at least 6 hours before its first operation.

5.2 Sterilize Your SmartMirror Head

Follow the reprocessing procedure described in this manual before using your SmartMirror for dental practice. (Reprocessing Instructions – chapter 8)

5.3 Download the SmartMirror Direct App and Install It on an iOS Device (iPad/iPhone)

You can download the SmartMirror Direct App for iOS using the following QR code:



You can also use this <u>link</u> or search "SmartMirror Direct" in the App Store.

6. Instruction of Use

6.1 Turning Your SmartMirror On

To turn your SmartMirror on, simply insert the SmartMirror Streamer into the SmartMirror Head. The orientation of the streamer is important for proper connection; please see the correct orientation in the illustration below.



6.2 Turning Your SmartMirror Off

To turn your SmartMirror off simply pull the SmartMirror Streamer out of the SmartMirror Head; the device will shut off automatically.

6.3 Pairing Your SmartMirror to an iOS Device

To pair your SmartMirror to an iOS device follow the steps below:

- Turn your SmartMirror on all LEDs will flash once, followed by slowly flashing LEDs at the top of the mirror , your SmartMirror is now ready to pair.
- Open the SmartMirror App on your iOS device.
- Press Settings then Scan QR . Using the rear facing camera on your iOS device scan the QR code located on the bottom of the Streamer.
- Once pairing is complete, a live video stream from SmartMirror will be displayed on the App.

6.4 SmartMirror App Overview



After a successful connection has been made between the iOS device and SmartMirror, the main page is displayed.

6.4.1 Saving Media

Save snapshots (still images) or recorded videos to the iOS device by using the relevant buttons as described above. Images and videos will be saved in dedicated folders on the iOS device (SmartMirror Images, SmartMirror Videos).

6.4.2 Changing the Lights Intensity

Control the LED light intensity by using the Brightness slider. Note: lower light levels will result in a lower quality of video stream and will increase image noise.

6.5 SmartMirror Connection Methods

6.5.1 Hotspot

In this communication method the iOS device connects directly to SmartMirror.

When SmartMirror is paired to an iOS device using the QR code, SmartMirror acts as a Wi-Fi hotspot and the iOS device is connected to that hotspot.

- This method allows solid communication with less interference (latency, low image quality, low frame rate) from other devices.
- It allows you to connect to SmartMirror when no other communication method is available (weak signal from your office router, using SmartMirror outside of your office, etc.).
- It will most likely require you to pair SmartMirror with the iOS device each time you turn SmartMirror on/off. In order to avoid this you will need to disable auto connect or forget all other Wi-Fi networks on your device.
- Your iOS device will not have access to the internet while connected to SmartMirror. Live sharing of your video stream or media will not be available.

In order to connect SmartMirror as a Hotspot, see section 6.3.



6.5.2 External Wi-Fi Router

In this communication method the iOS device and SmartMirror are connected through an external Wi-Fi router network.

- This method allows the iOS device to have access to the internet while connected to SmartMirror (only if the router is connected to the internet).
- It allows for a quicker pairing process between SmartMirror and the iOS device. As long as the iOS device is connected to the same Wi-Fi network, each time SmartMirror is turned on a stream will begin seamlessly, allowing for better workflow.
- If multiple iOS devices using the SmartMirror Direct app are found on the network, SmartMirror will stream to the last iOS device it was paired to.
- This method can be used when a strong Wi-Fi signal is available in the operatory and when the network is not loaded with traffic from other devices.

In order to connect SmartMirror through an external Wi-Fi router, see section 6.6.



6.6 Connecting SmartMirror to an External Router

To connect your SmartMirror to a Wi-Fi network, please follow the steps below:

- Pair your SmartMirror with your iOS device (see section 6.3).
- Press Settings then Mirror WiFi setup
 SmartMirror to a WiFi Network" then press Proceed
- A list of all available networks will be presented, choose the network you want to connect with, enter the network password if needed and press "Connect".
- A popup will appear as your SmartMirror attempts to connect to the network, once a successful connection is complete, the iOS device will change its network connection to the one of choice and the video stream will begin.
- SmartMirror will automatically attempt to connect to the last known network each time it is turned on.

6.7 Charging SmartMirror

To charge your SmartMirror, use the original USB-C charging cable included with the device, or by using the SmartMirror Edge docking station.

Plug the charging cable into any USB port and connect the USB-C female end to the SmartMirror Streamer.

7. Reprocessing Instructions

To protect your patients and staff always use a single-use protective barrier on your hands when operating or reprocessing SmartMirror.

Instruments must be reprocessed only in the rooms/areas designated for this.

7.1 Reprocessing of the SmartMirror Head

• Preparation:

Before each reprocessing of the SmartMirror Head make sure to follow these steps: 1) Lubricate the Sterilization Cap O-rings using NSF approved O-ring grease or other nontoxic lubrication (such as Vaseline).

2) Fully insert the Sterilization Cap into the SmartMirror Head.

Observe the standard instructions for instruments in your practice.

• Disinfecting:

The SmartMirror Head can be disinfected using an approved dental mirror disinfectant according to their written instructions; or the aids recommended therein. However, do not use any mechanical/abrasive aids in order to prevent damage to the unit surface. On completion of disinfection, rinse with fully demineralized (desalinated, deionized) water, to avoid calciferous residues on the instrument, which leave behind watermarks.

• Cleaning:

Use cleaning aids such as soft brushes and treatment chemicals.

All cleaning solutions recommended for use on mouth mirrors in their written instructions are considered safe for use. Clean the SmartMirror Head in accordance with the instructions for use by the selected treatment chemical. On completion of cleaning, rinse with fully demineralized (desalinated, deionized) water, to avoid calciferous residues on the instrument, which leave behind watermarks.

• Sterilization:

Use Steam sterilizer (Autoclave).

Steam sterilization at 121° C in a device in accordance with EN 13060: Observe EN 17665 for moist heat sterilization. To prevent staining and corrosion, the steam must be free of particles. When several instruments are sterilized, the maximum capacity of the sterilizer must not be exceeded. Follow the device manufacturer instructions for correct use of the steam sterilizer.

7.2 Reprocessing of the SmartMirror Streamer

Do not immerse the SmartMirror **Streamer** in any liquid.

Do not steam sterilize the SmartMirror **Streamer**.

• Cleaning:

The SmartMirror **Streamer** can be cleaned using disinfectant wipes. Wipe all surfaces of the device and dispose of the wipes afterward. Do not wipe the USB-C connector.

8. Maintenance

Aside from charging and reprocessing, there is no need for any user maintenance of the SmartMirror system. All software updates and routine system checks are performed remotely by Dental SmartMirror.

9. Troubleshooting

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This section is intended to help users, should a problem occur.

Never try to repair this device alone.

In the event of abnormal operation, immediately stop using the device and consult the Troubleshooting Section.

If it is not possible to locate or eliminate the problem using this section, or if the malfunction is still present, switch off the device and contact Dental SmartMirror, Inc. support department info@smartmirror.dental.

Malfunction	Possible cause	Solution
SmartMirror does not turn on	Streamer battery is discharged	Charge the SmartMirror Streamer
SmartMirror does not turn on	The SmartMirror Streamer is not fully or not properly inserted into the SmartMirror Head	Try reinserting the Streamer
SmartMirror does not turn on	Malfunction in the Head or the Streamer device	Contact support
Connection to Streamer using QR code has failed	SmartMirror is not ON	Make sure that the SmartMirror is turned on and ready to pair (top LEDs flash).
SmartMirror App could not scan the Streamer QR code	iOS device autofocus is struggling to focus on the QR code	Try to position your device QR reader at different angles or positions, sometimes when there is a very bright background QR reading becomes harder for the device.

It is hard to insert the Sterilization Cap into the SmartMirror Head	Dry cap O-rings	Lubricate the cap O-rings using approved NSF O-ring lubricant or Vaseline
Illumination is off while the SmartMirror is streaming	Illumination slider is on 0%	Slide the illumination slider to the desired level
Streamer is not charging	Wrong connection	Make sure that you use only the original SmartMirror charging cable Make sure the connectors are properly connected Make sure the USB port that is used for charging is not defected