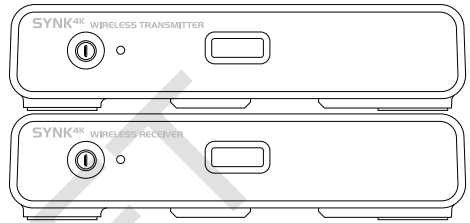


## SYNK® 4K Wireless System

### User Guide

REF	0240031065
REF	0240031061
REF	0240031075



DRAFT

# Table of Contents

Warnings and Cautions .....	3
Warnings .....	3
Cautions .....	4
Product Description .....	6
Intended Use .....	6
Contraindications .....	6
SYNK® 4K Wireless Transmitter .....	6
SYNK® 4K Wireless Receiver .....	7
System Features .....	8
SYNK® 4K Wireless Transmitter Front Panel .....	8
SYNK® 4K Wireless Transmitter Rear Panel .....	9
SYNK® 4K Wireless Receiver Front Panel .....	10
SYNK® 4K Wireless Receiver Rear Panel .....	11
Standby Mode .....	11
Setup .....	12
Device Compatibility .....	12
Maximum Number of Active Transmitters .....	12
Mounting the Receiver on a Display .....	13
Connecting Power from the AC/DC Power Adapter .....	15
Connecting Power to the Receiver from a Display .....	16
Setting up the SYNK® 4K Wireless System .....	16
Generic Video Source Direct to Display .....	17
Generic Remote Port Routing .....	17
Wireless Configuration .....	19
Using the Region Token (Orange) - International Only .....	19
Using the Bandwidth Toggle Token (Gray) .....	20
Using the Channel Configuration Token .....	20
Operation .....	21
Pairing the Devices Using a Temporary Token (Blue) .....	21
Pairing the Devices Using a Permanent Token (Red) .....	21
Breaking a Temporary Link .....	21
Breaking a Permanent Link .....	22
Powering off the Devices .....	22
Troubleshooting .....	23
Cleaning .....	25
Cleaning and Disinfecting the Transmitter, Receiver, and Tokens .....	25
Materials and Equipment .....	25
Maintenance .....	27
Inspecting the Transmitter and Receiver .....	27
Storage .....	27
Periodic Maintenance Schedule .....	27
Service Life .....	27
Adverse Event Reporting .....	28
Disposal and Recycling Information .....	29
Disposal .....	29
Recycling Information .....	29
Technical Specifications .....	31
Electromagnetic Compatibility .....	33
Symbols and Definitions .....	40

DRAFT

# Warnings and Cautions

In this manual, the terms and definitions below apply.

- **Warning:** Possible injury to the patient or user.
- **Caution:** Possible damage to the equipment.
- **Note:** More information to clarify the instructions.

## Warnings

To avoid potential serious injury to the user and the patient and/or damage to this device, please note the following warnings.

1. Read this manual thoroughly and know its contents prior to using the device.
2. This system is not suitable for use in the presence of flammable anesthetic gases.
3. The device is for indoor use only.
4. This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20 cm (7.9 inches) between the radiator and your body.
5. Install this system in an operating room that complies with all applicable IEC, CEC, and NEC requirements for safety of electrical devices. Any installation or connection with other devices shall be evaluated for electrical safety according to the IEC 60601-1.
6. This product is non-sterile and therefore should not be placed in the sterile field.
7. Although the device was fully tested at the factory before shipment, the user should always test it for proper function prior to a surgical procedure.
8. To achieve grounding reliability, connect the product to an AC/DC power adapter that is connected to a hospital-grade power cord, and ensure the power cord is plugged into a grounded power outlet. Do not use extension power cords.
9. To avoid risk of electric shock, use only the hospital-grade power cord furnished with the receiver and/or transmitter. Disconnect the receiver and/or transmitter from the power supply to make connections or to inspect the equipment.
10. Use Stryker HDMI cable only provided with the product. Use of third-party HDMI cables with the camera console is not recommended due to potential problems with secure connections or electromagnetic compatibility. Use the provided HDMI high speed cable (or other Stryker-approved HDMI cable) with the SYNK® 4K Wireless System.
11. Only connect items that have been specified as part of the SYNK® 4K Wireless System or that have been specified as being compatible with the system.
12. To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
13. Do not place any heavy object on the power cord. Damage to the power cord can cause fire or electric shock.
14. Do not put any liquid or solid object into the device. If this occurs, unplug the device and have it checked by qualified personnel before operating it any further.
15. Use appropriate caution to prevent contact with fluids if the receiver or transmitter is being used with a power supply in patient environments.
16. To avoid electric shock, do not open the receiver or transmitter housings.

17. Do not modify this equipment without authorization of the manufacturer.
18. Attempt no internal repairs or adjustments not specifically detailed in this operating manual. Refer any adjustments, modifications, and/or repairs to Stryker Endoscopy or its authorized representatives.
19. Do not touch the device and a patient simultaneously, as there is a risk of electric shock.
20. Do not touch the patient with signal input or output connectors. Equipment with SIP/SOP connectors should either comply with IEC 60601-1 harmonized national standard or the combination should be evaluated for safety.
21. For optimal operation of the SYNK® 4K Wireless System, leave a minimum of 1 m (3.3 ft) between any part of the System and portable RF communications equipment.
22. To prevent tampering with the SYNK® 4K Wireless System device settings, setup, or information, ensure only authorized personnel have access to the device or physically secure the devices when they are not in use.
23. Any serious incident that has occurred in relation to the devices should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

## Cautions

To avoid potential damage to this device, please note the following cautions.

1. Carefully unpack the system and check if any damage occurred during shipment. If damage is detected, refer to the warranty.
2. Do not install the devices near sunlight, excessive dust, mechanical vibration, or shock.
3. Keep the devices away from equipment that uses strong magnets (i.e., large loudspeakers).
4. To ensure electromagnetic compatibility, refer to the "Electromagnetic Compatibility" section of this manual. The devices must be installed and operated according to the EMC information provided in this manual.
5. Do not position the devices so that it is difficult to disconnect the power cords from the supply mains.
6. Connect the devices to a hospital grade receptacle to achieve grounding reliability.
7. To connect to an international power supply, use an attachment plug appropriate for the power outlet.
8. Remove the power cord when transporting the devices.
9. Never operate the devices immediately after transportation from a cold location to a warm location.
10. Power off the devices when they are not in use.
11. Unplug the receiver and transmitter if they are not to be used for an extended period of time.
12. Pay close attention to the care and cleaning instructions in this manual. A deviation may cause damage.
13. Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the devices.

**Note** - This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

The user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiver.
- Increase the separation distance between the transmitter and receiver.
- Connect the transmitter to an outlet on a circuit different from that to which the receiver(s) are connected.
- Consult the manufacturer or field service technician for help. The warranty is void if any of these warnings or cautions are disregarded. These products contain electrical waste or electronic equipment. They must not be disposed of as unsorted municipal waste and must be collected separately.

**Note** - This device complies with RSS-247 of the Industry Canada Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. This device is only for indoor use.

DRAFT

# Product Description

The SYNK® 4K Wireless System wirelessly transfers video data from a transmitter to up to two linked receivers. The transmitter provides an HDMI input that supports 1080p and 4K video formats, and the receiver provides an HDMI output supporting the same formats. Once the devices are linked, the transmitter wirelessly transfers high-definition video to the receiver for output on a secondary display.

At least one transmitter, one receiver, and a pairing token are required for full functionality of the system. A link between the transmitter and the receiver(s) is established by manually inserting a token in the transmitter and then in the receiver(s). Encrypted network data is written onto the token from the transmitter, and the data is decrypted in the receiver to establish a private and secure connection. A token is a small memory device that is programmed with frequencies allowed to establish a link.

The receiver can optionally be mounted to the back of the 32" 4K Surgical Display (0240031050), and it comes with the necessary mounting hardware. A dedicated power supply is included with the transmitter and the receiver to provide power. Alternatively, a Y-cable is provided with the receiver so it can share the 32" 4K Surgical Display's power supply (use when the receiver is mounted to the back of that display).

The system transfers video data without controlling or altering the functions or parameters of any connected devices.

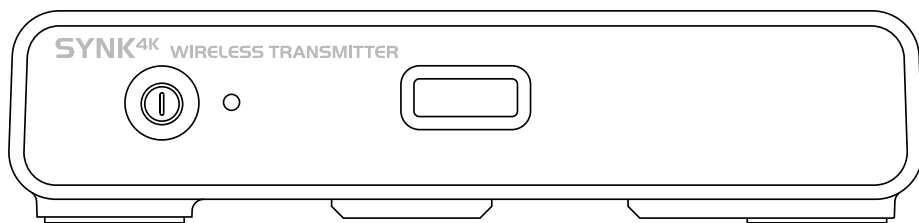
## Intended Use

The SYNK® 4K Wireless System is intended for wireless transmission of high definition video data to secondary displays in a professional healthcare setting. The system is a non-sterile reusable device not intended for use in the sterile field. The system is intended for use by qualified physicians and qualified OR personnel having complete knowledge of surgical procedures in the operating room.

## Contraindications

There are no contraindications for these devices.

## SYNK® 4K Wireless Transmitter



REF: 0240031065 (U.S.), 0240031061 (International)

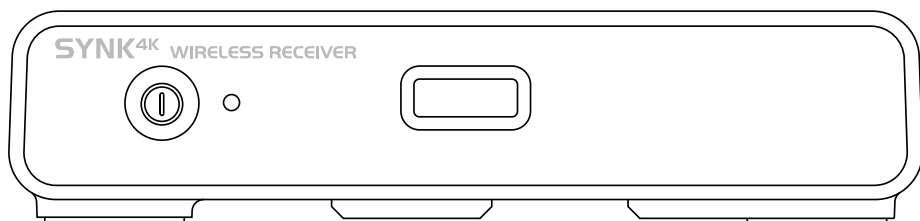
### Package Contents

- (1) SYNK® 4K Wireless Transmitter (0240031065)
- (1) Hospital-grade power cord (0105033001)



- (1) HDMI high speed cable, 2M (P39077)
- (2) Remote cables (0105206758)
- (1) Power supply (P27315)
- (2) Temporary tokens (blue) (0105208884)

## **SYNK® 4K Wireless Receiver**



REF: 0240031075

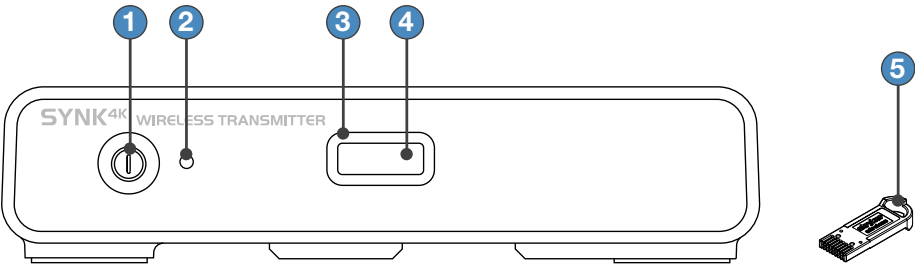
### **Package Contents**

- (1) Receiver (0240031075)
- (1) Hospital-grade power cord (0105033001)
- (1) Power supply (P27315)
- (2) Shoulder bolts (P44094)
- (1) Y cable (P43614)
- (1) HDMI high speed cable, 2M (P39077)

# System Features

This section outlines the features of the SYNK® 4K Wireless Transmitter and Receiver.

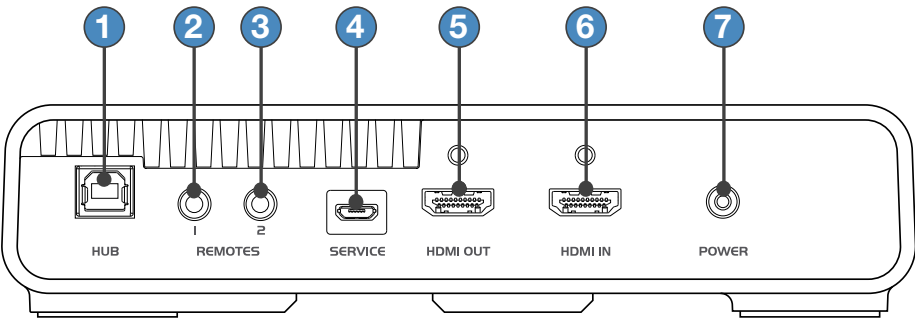
## SYNK® 4K Wireless Transmitter Front Panel



1. Power switch (hard)	Powers transmitter ON and OFF
2. Power Indicator	Steady Green - Power is ON
3. Token Status Indicator	Blinking White - Waiting for normal token Green - Ready for pairing or Wireless link is established Blue - Standby mode, see Standby Mode section Amber - Warning, see Troubleshooting section Red - Error, contact service representative
4. Token Slot	Token insertion site used to establish a wireless connection
5. Token	Initializes a wireless connection after insertion into the transmitter and receiver

**Note** - The transmitter emits a pairing sound when a wireless link is established. The transmitter emits a link drop sound when one or both receiver links have been dropped.

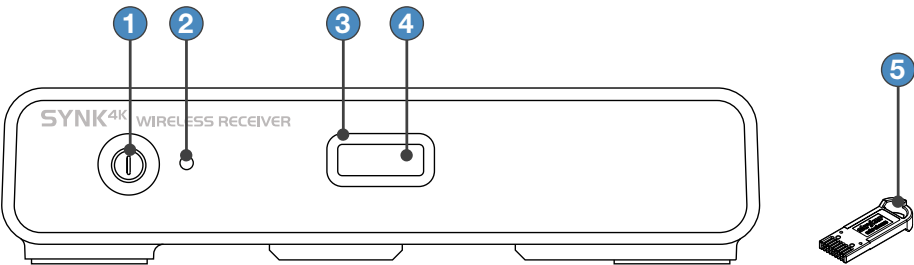
# SYNK® 4K Wireless Transmitter Rear Panel



1. HUB Port	Maintenance port (Stryker use only)
2. Remote 1*	Connects to video source remote output 1
3. Remote 2*	Connects to video source remote output 2
4. Micro USB Port	Maintenance port (Stryker use only)
5. HDMI Out	Connects to a primary display
6. HDMI In	Connects to a digital input source
7. DC Power Inlet	Connects to AC/DC power adapter

**Note** - \*Remote ports are only used when the Camera Control Unit (CCU) and the capture device are set up at different locations (e.g., CCU on a boom and Connected OR Hub at a nurse station). See the Generic Remote Port Routing section for more details.

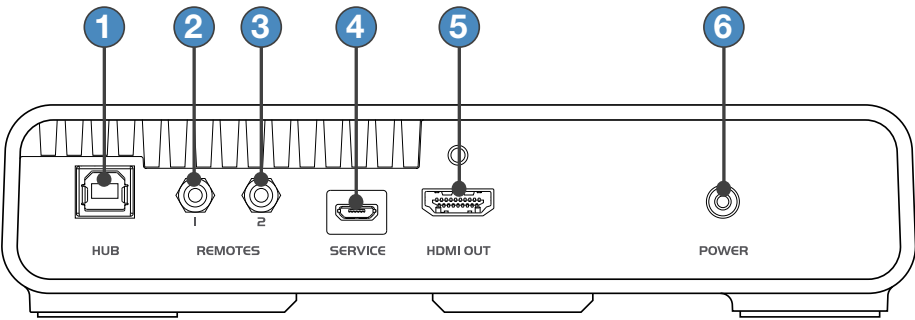
# SYNK® 4K Wireless Receiver Front Panel



1. Power switch (hard)	Powers receiver ON and OFF
2. Power Indicator	Steady Green - Power is ON
3. Token Status Indicator	Blinking White - Waiting for normal token Blinking Green - Attempting to pair Green - Wireless link is established Blue - Standby mode, see Standby Mode section Amber - Warning, see Troubleshooting section Red - Error, contact service representative
4. Token Slot	Token insertion site used to establish a wireless connection
5. Token	Initializes a wireless connection after insertion into the transmitter and receiver

**Note** - The transmitter emits a pairing sound when a wireless link is established. The transmitter emits a link drop sound when one or both receiver links have been dropped.

# SYNK® 4K Wireless Receiver Rear Panel



1. HUB Port	Maintenance port (Stryker use only)
2. Remote 1*	Connects to Connected OR Hub Remote 1
3. Remote 2*	Connects to Connected OR Hub Remote 2
4. Micro USB Port	Maintenance port (Stryker use only)
5. HDMI Out	Connects to a primary display
6. DC Power Inlet	Connects to AC/DC power adapter

**Note** - \*Remote ports are only used when the Camera Control Unit (CCU) and the capture device are set up at different locations (e.g., CCU on a boom and Connected OR Hub at a nurse station). See the Generic Remote Port Routing section for more details.

## Standby Mode

If the transmitter does not receive an active video signal from the video source for more than five minutes (e.g., HDMI input is unplugged or video source is turned off ), the system will enter Standby Mode. The transmitter and receiver token status indicators will turn blue (see Note). The transmitter will temporarily stop transferring video to the receiver(s).

When an active video signal to the transmitter resumes (e.g., HDMI input is inserted or video source is turned back on), the transmitter token status indicator will turn green and the transmitter will automatically attempt to relink with the receivers. After the links are re-established, the receiver(s) token status indicator will turn green.

**Note** - In the initial launch version of the SYNK® 4K Wireless System, the token status indicators will remain green during Standby Mode. You can enable the blue LED by updating the system with a software upgrade token. Please contact a Stryker representative for assistance.

# Setup

## WARNING

- When the SYNK® 4K Wireless System is interconnected with other electrical devices, leakage currents may be additive, resulting in electromagnetic emissions that can interfere with the normal function of electronic medical equipment. To properly control electromagnetic emissions and avoid potential harm to the patient or user, ensure all electrical devices are installed and interconnected according to the requirements of IEC 60601-1.
- RF and other mobile communications equipment may affect the normal function of the SYNK® 4K Wireless System. When placing the SYNK® 4K Wireless System, follow the instructions located in the “Electromagnetic Compatibility” section of this manual.

## Device Compatibility

**WARNING** - Only connect items that have been specified as part of the SYNK® 4K Wireless System or that have been specified as being compatible with the system.

For optimal use, the SYNK® 4K Wireless System is designed to work with the 1688 Camera Control Unit (1688010000), the Connected OR Hub (0240200100) with software version 1.2.3 or higher, the 32" 4K Surgical Display (0240031050), the VPI (PC9001), the SDC3 HD information management system (0240060100), and the 1588 AIM Camera Control Unit (1588010000).

All features and instructions described in this user manual apply to this system unless otherwise noted.

The following table lists alternate video sources that are compatible with the SYNK® 4K Wireless System. Please contact a Stryker representative for assistance.

## Maximum Number of Active Transmitters

The SYNK® 4K Wireless System supports a maximum number of transmitters operating at the same time in close proximity (same floor and operating room area) based on wireless channels available in each region.

The following table lists the maximum number of active transmitters in close proximity per region. Please contact your Stryker sales representative for assistance if more transmitters are needed to operate at the same time.

Region	Maximum Number of Active Transmitters
US	4 Transmitters
Canada	3 Transmitters
EU	2 Transmitters
Australia and New Zealand	2 Transmitters

## Mounting the Receiver on a Display

The receiver can be mounted on the back of a 32" 4K Surgical Display (0240031050), on a roll stand or cart.

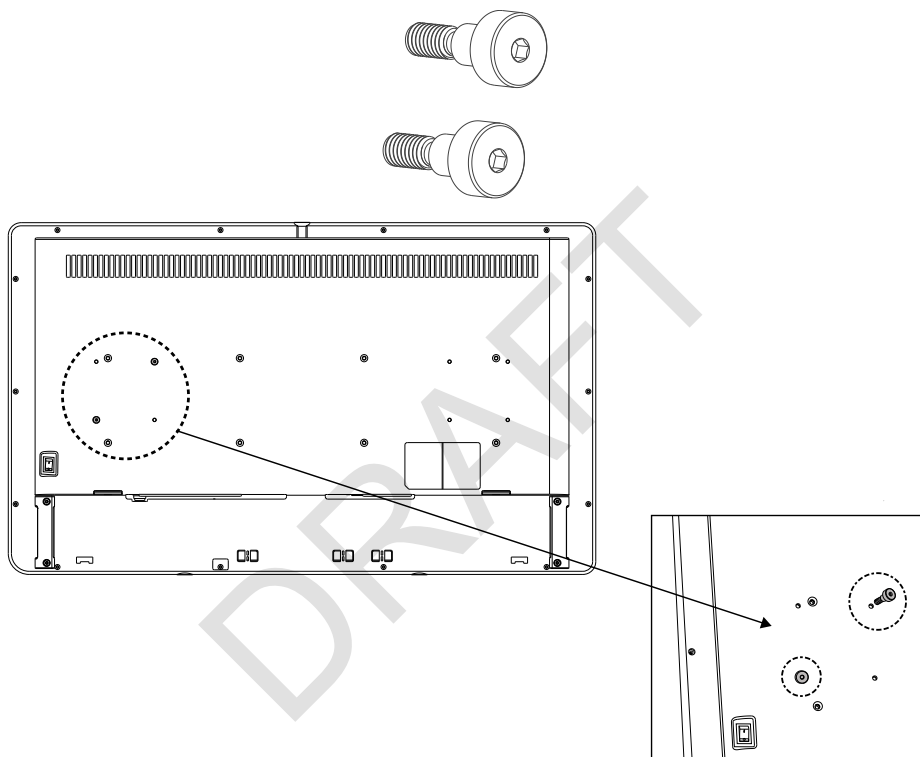
---

**CAUTION** - Power off and unplug the receiver and display from the electrical outlets before mounting.

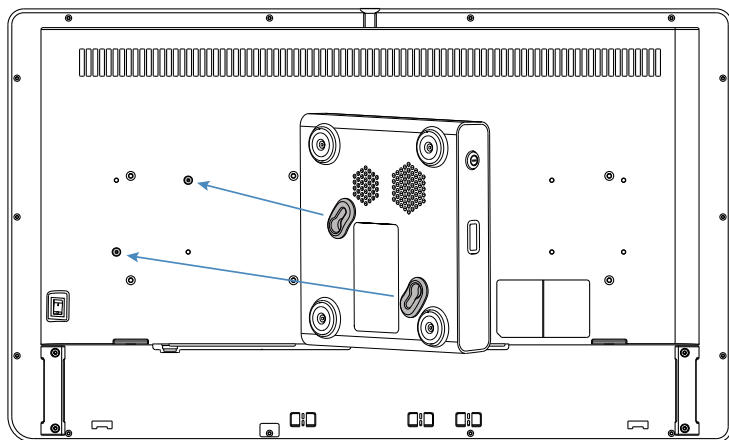
---

1. Insert the provided shoulder bolts into the back of the display.

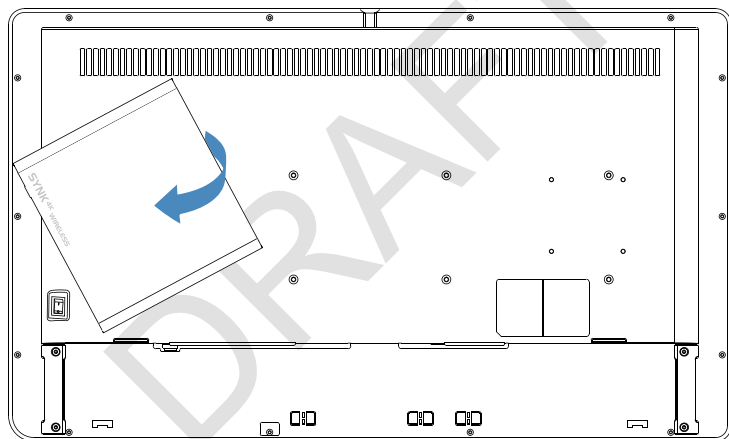
**Note** - (2) Shoulder bolts (P44094) are included in the receiver package.



2. Ensure the shoulder bolts are secured before proceeding.

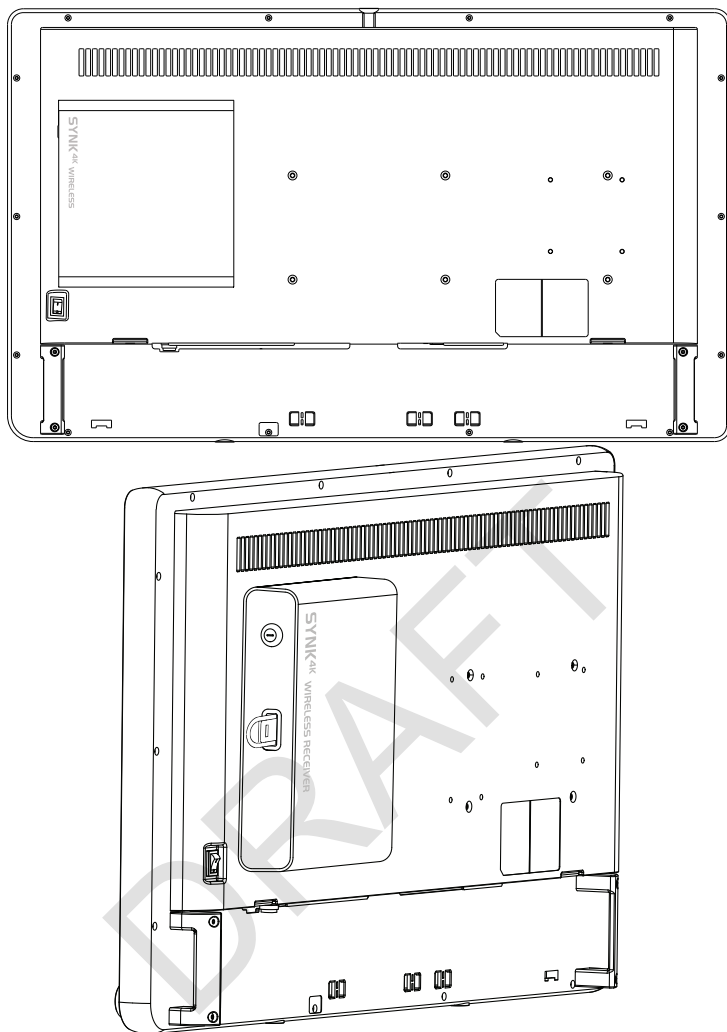


3. Align the key holes on the bottom of the receiver with the shoulder bolts on the display.
4. Push the receiver forward, then rotate it clockwise until you hear two clicks that indicate both bolts were locked firmly into place.



5. Ensure the receiver is positioned perpendicular to the display, with token slot positioned to the left (shown in the two images below).





## Connecting Power from the AC/DC Power Adapter

The transmitter must be powered by the AC/DC power adapter provided in its packaging. The receiver may be powered by the AC/DC power adapter provided in its packaging or by using the provided Y-cable to draw power from the 32" 4K surgical display. To power the receiver from the display, see the next section.

Follow these instructions to connect power to the transmitter and receiver from the AC/DC power adapter.

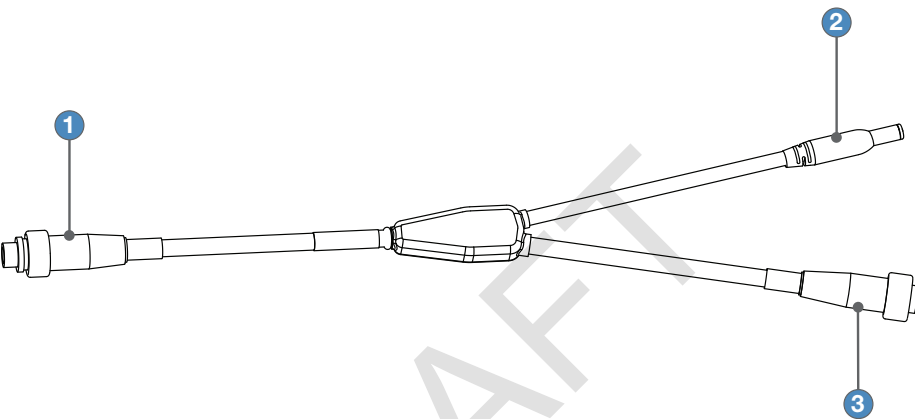
1. Using the provided power cord, connect the AC/DC power adapter to a hospital-grade outlet.
2. Insert the AC/DC power adapter's outlet plug into the transmitter's or receiver's DC power inlet.

# Connecting Power to the Receiver from a Display

**WARNING** - Periodically check the display's power supply for usability. Replace the power supply if needed.

Follow these instructions to connect power to a receiver that is mounted on the back of a 32" 4K Surgical Display.

- 1. Disconnect the display's power supply from the 24 V input on the display.
- 2. Using the provided Y cable (P43614), connect the display's power supply to the 24 V input on the display.



1. Plugs into monitor power supply
2. Plugs into SYNK 4K receiver
3. Plugs into monitor

- 3. Insert the Y cable outlet plug into the receiver's DC power inlet.

## Setting up the SYNK® 4K Wireless System

**WARNING** - Before connecting any device to the SYNK® 4K Wireless System, all devices must be installed according to their respective instructions, and the combination of devices must meet the electrical safety requirements of IEC 60601-1.

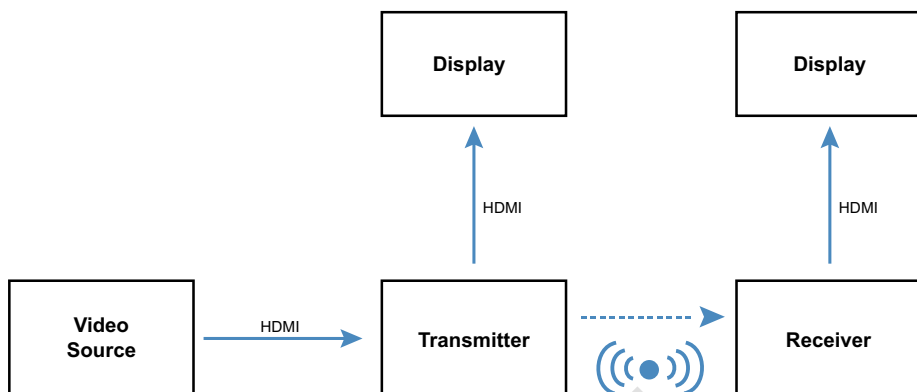
The SYNK® 4K Wireless System can be set up in a number of different ways, depending upon which video sources and other visualization equipment are available. This section describes two generic configurations.

**Note** - When the Connected OR Hub and two camera control units are used, you can switch between Channels 1 and 2. Review the Connected OR Hub Instructions for Use (P35947) for more information.

Please contact a Stryker representative for assistance.

## Generic Video Source Direct to Display

Refer to the following instructions and wiring diagram for a typical wireless configuration.



1. Using the provided HDMI cable, connect the HDMI OUT on the video source to the HDMI IN on the transmitter.

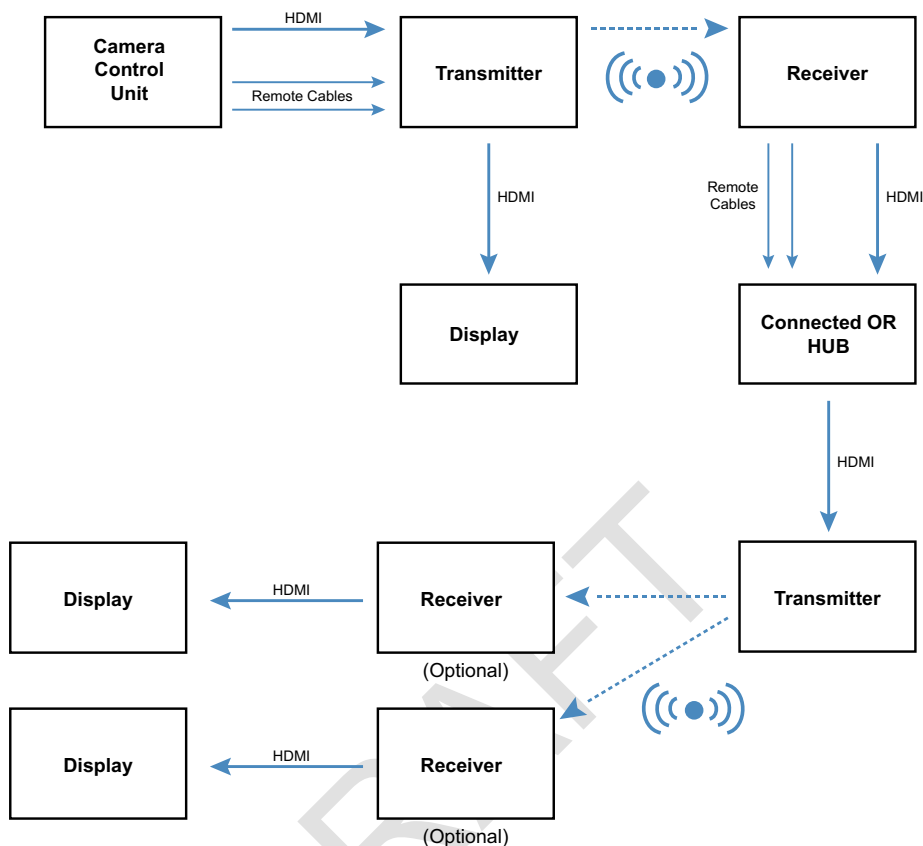
**Note** - The HDMI OUT on the transmitter can be connected to the HDMI IN on a secondary display.

2. Using the provided HDMI cable, connect the HDMI OUT on the receiver to the HDMI IN on the primary display.
3. (Optional) Repeat Step 2 for a second receiver.
4. Link the receiver to the transmitter with the token. (If using a temporary token, linking is required each time the receiver or transmitter is powered on.)
5. (Optional) Link a second receiver.

## Generic Remote Port Routing

Refer to the following instructions and wiring diagram for a wireless configuration where the camera control unit is located separately from the Connected OR Hub.

**Note** - Obtain a second set of remote cables from another Stryker visualization system before proceeding.



**CAUTION** - Ensure the remote cables are connected as described in the instructions.

1. Using the provided HDMI cable, connect the HDMI OUT on the camera control unit to the HDMI IN on the transmitter.
- Note** - The HDMI OUT on the transmitter can be connected to the HDMI IN on a secondary display.
2. Using a provided remote cable, connect the Remote Out 1 on the camera control unit to the Remote 1 on the transmitter.
  3. Using a provided remote cable, connect the Remote Out 2 on the camera control unit to the Remote 2 on the transmitter.
  4. Using the provided HDMI cable, connect the HDMI OUT on the receiver to the HDMI IN 1 (4K) on the Connected OR Hub.
  5. Using a remote cable, connect the Remote 1 on the receiver to the Remote 1 on the Connected OR Hub.
  6. Using a remote cable, connect the Remote 2 on the receiver to the Remote 2 on the Connected OR Hub.
  7. Link the receiver to the transmitter with the token. (If using a temporary token, linking is required each time the receiver or transmitter is powered on.)

# Wireless Configuration

The SYNK® 4K Wireless System uses a radio-frequency (RF) link to deliver high-definition video signals in real time. Each system uses a portion of the RF spectrum commonly referred to as a “channel” to broadcast its signal. The list of allowed channels is regulated and varies by region.

The SYNK® 4K Wireless System uses 40 MHz channels in the 5.170-5.850 GHz spectrum. The 5.170-5.850 GHz spectrum is also used by 802.11a/n/ac devices as well as 5.8 GHz cordless phones. The System uses an automatic frequency selection (AFS) mechanism in combination with a passive scanning capability to maintain compatibility with these devices and identify unoccupied channels for use.

Each linked SYNK® 4K Wireless System requires two 40 MHz channels to properly operate. The System is designed to transmit video on a single 40 MHz channel and allocate an additional 40 MHz channel as a backup in case of co-channel interference. Systems that are separated by a large distance may use the same channel.

**Note** - The SYNK® 4K Wireless System uses a proprietary transmission method, which cannot connect to or be accessed by 802.11 devices or 5.8 GHz cordless phones.

In order to make sure that there are enough free channels for each SYNK® 4K Wireless System, follow the steps outlined below:

1. Contact your IT administrator to determine if 802.11a or 802.11n WiFi is in use at your facility. If so, note which channels are in use in or near each SYNK® 4K Wireless System installation location.
2. Determine if any 5.8 GHz cordless phones are in use at your facility. If so, note their locations.
3. For each SYNK® 4K Wireless System installation location, ensure that there are two unused 40 MHz channels per SYNK® 4K Transmitter installed. If a 5.8 GHz cordless phone is used in the vicinity, assume that channels 149-165 are occupied.

Contact your Stryker sales representative for more details.

## Using the Region Token (Orange) - International Only

REF: P46267 (Canada), P25600 (EU), P25603 (Australia and New Zealand)

---

**WARNING** - In accordance with the European REACH Regulation and other environmental regulatory requirements, the orange region token contains 2-(2H-benzotriazol-2-yl)-4,6-diterpentyphenol (UV-328). This declaration is made in good faith and is either based upon a technical evaluation, supplier data and/or laboratory testing.

---

The orange region token configures wireless settings correctly for your region. This procedure only needs to be done once per transmitter by your Stryker sales representative. To configure wireless settings correctly:

1. Power on the transmitter.
2. Insert the orange region token into the transmitter.
3. Wait until the token LED changes from fast pulsing white to slow pulsing white.
4. Remove the token from the transmitter.
5. Power cycle the transmitter.

# Using the Bandwidth Toggle Token (Gray)

REF: 0240031095

The SYNK 4K bandwidth toggle token changes bandwidth modes on SYNK 4K transmitters from 20MHz to 40MHz, or from 40MHz to 20MHz.

Toggling to 20MHz saves wireless bandwidth and allows more systems to be set up simultaneously in the operating room. Toggling to 40MHz enables the use of 4K video resolution. The 20MHz bandwidth mode only supports 1080p video resolution.

The bandwidth mode is passed to a receiver when it is paired with the transmitter. Please contact your Stryker representative to perform this procedure.

# Using the Channel Configuration Token

The channel configuration token bans the use of specific wireless frequencies (see table below). This procedure only needs to be done once per transmitter by your Stryker sales representative. To ban wireless frequencies correctly:

- 1. Power on the transmitter.
- 2. Insert the channel configuration token into the transmitter.
- 3. Wait until the token LED changes from fast pulsing white to slow pulsing white.
- 4. Remove the token from the transmitter.
- 5. Power cycle the transmitter.

Token Part Number	Banned Frequency Ranges	Compatible Devices	Token Color
0240030976	All unbanned (as per region)	WiSe™, SYNK® 4K	Yellow
0240030975	UNII-1: 5170 – 5250 MHz UNII-3: 5710 – 5850 MHz	WiSe™, SYNK® 4K	Green
0240030978	UNII-1: 5170 – 5250 MHz UNII-2: 5250 – 5330 MHz UNII-3: 5710 – 5850 MHz	WiSe™, SYNK® 4K	Black

# Operation

Pairing is the act of creating a wireless link between a transmitter and a receiver. A token is used to create the link, by inserting it into the token slot of the transmitter to write discrete pairing data and then inserting the token into the token slot of the receiver to read the pairing data. A transmitter can pair with up to two (2) receivers. The same token may be used to create each pair, or a different token may be used for each pair.

Once paired, a transmitter can wirelessly transmit video data to a receiver, which can send the video data from its HDMI OUT port to a display. The transmitter can also wirelessly transmit data to a receiver, which can send the data from its remotes ports to a digital capture device.

## Pairing the Devices Using a Temporary Token (Blue)

REF: 0105208884

To pair a transmitter with a receiver:

1. Power on the transmitter and receiver. The token LED remains off as the devices perform startup functions.
2. When the LED pulses white, insert the temporary token into the token slot on the transmitter.
3. When the token LED is green, remove the token from the transmitter.
4. Within 2 minutes and 30 seconds, insert the token into the token slot on the receiver.
5. Remove the token from the token slot on the receiver when the token LED flashes green.
  - An audible tone sounds from the transmitter.
  - The video feed appears on the display.
6. By repeating steps 4 and 5, you can link one additional receiver.

**Note** - Link a second receiver directly after linking the first receiver. Do not reconnect the token to the transmitter.
7. Store the token in the transmitter token slot when not in use.

## Pairing the Devices Using a Permanent Token (Red)

REF: 0240030977 (Sold separately)

A permanent link may be desirable in certain cases. Please contact your Stryker representative in order to permanently link the receiver(s) with a specific transmitter, as deemed appropriate. Once the transmitter/receiver set has been permanently linked, the set will automatically link when powered on. Keep transmitter/receiver sets that are in permanent link mode in the same operating room.

## Breaking a Temporary Link

To break a link between a receiver and transmitter, either power off the devices or disconnect the HDMI cable from the display for more than 5 minutes. An active link cannot be broken by inserting a token into either device.

## Breaking a Permanent Link

To return a receiver and transmitter to the default linking mode:

1. Turn on the devices.
2. Insert the temporary token into the transmitter and remove when the token LED turns green.
3. Power cycle the transmitter.
4. Insert the token into the receiver and remove the token when the token LED turns green.
5. Power cycle the receiver after removing the token.
6. Repeat Steps 4 and 5 for a second receiver.
7. The system is ready to be linked as described in the temporary linking mode procedure.

## Powering off the Devices

---

**CAUTION** - Unplug the receiver and transmitter if they are not to be used for an extended period of time.

---

To power off the receiver or transmitter:

1. Press and hold the power switch on the device.
2. Release the power switch.

**Note** - The Power LED on the device turns off when the device is powered off.



# Troubleshooting

Before returning your receiver or transmitter for service, consult the troubleshooting list below:

Problem	Current	Status Remedy
No video	Power LED off	Make sure that the power cord is properly connected to the device.
	Power LED on	Make sure the HDMI video cables are connected to the Transmitter and Receiver.
	Token LED pulsing white	Insert the token to link Transmitter and Receiver.
Blue screen on the display connected to Receiver		This indicates that the Receiver is not receiving any video from the Transmitter. Make sure the Transmitter and Receiver are paired and both have green LEDs.
Token LED blinking amber		Make sure the device is well ventilated and air vents are not blocked.
		Conditions are not sufficient for optimal wireless performance. Reorient or relocate the unit. Increase separation distance between units. Increase separation between other SYNK® 4K units, Connected OR Hub and other wireless capable devices in the room and adjacent rooms. Cycle the power switch on the device and re-link. If none of these remedies resolve the problem, switch to a wired video input on the display and contact your Stryker representative.
		Applies if using SYNK® 4K unit with the Connected OR Hub:  If the Connected OR Hub WiFi feature is not required for connection to any external systems or networks, please set the WiFi to the OFF position in the network settings for optimized compatibility.
		Transmitter is set to 20 MHz mode, but video source is 4K. Switch to a 1080p video source or use the bandwidth toggle token to set the bandwidth to 40 MHz.
Token LED solid red		Please contact your Stryker representative.

Problem	Current	Status Remedy
Wireless link established, but then drops within ten seconds		Transmitter is set to 20 MHz mode, but video source is 4K. Switch to a 1080p video source or use the bandwidth toggle token to set the bandwidth to 40 MHz.
Wireless link not established within 2.5 minutes		Cycle the power switch on the device. Re-orient or relocate the unit. Increase separation distance between units. Increase separation between other SYNK® 4K units, Connected OR Hub and other wireless capable devices in the room and adjacent rooms.
Wireless link established with some but not all Receivers		Cycle the power switch on the device. Ensure that the Receiver is within 10 meters of the Transmitter. Re-insert token into Receiver.

DRAFT

# Cleaning

The SYNK® 4K Transmitter and Receiver are not intended to come into contact with the patient or to be used in the sterile field. The devices may be cleaned and disinfected, but not sterilized. Follow the instructions below.

The temporary token or permanent token may also be cleaned and disinfected, if soiled. Follow the instructions below.

## Cleaning and Disinfecting the Transmitter, Receiver, and Tokens

Follow the warnings, cautions, and instructions below to clean and disinfect the SYNK® 4K Transmitter, SYNK® 4K Receiver, and tokens.

---

**WARNING** - To avoid electric shock and potentially fatal injury, unplug the transmitter from the electrical outlet before cleaning.

---

**CAUTION** - Observe the following cautions to avoid damaging the transmitter, receiver, or tokens and rendering them inoperable:

- Do not wipe the rear and bottom of the transmitter or receiver.
  - Do not wipe the connecting end of the tokens.
  - Do not spray cleaning liquid directly onto the devices. Spray cleaning liquid onto a cloth before wiping the devices. Do not saturate the cloth.
  - Do not allow liquid to collect on the devices.
  - Do not immerse the devices in any liquid.
  - Do not clean the devices with abrasive products or corrosive cleaning solutions.
  - Do not sterilize the devices.
- 

1. Clean and disinfect the device using a germicidal disposable wipe<sup>1</sup> (or equivalent combination or germicidal spray and sterile cloth) according to the manufacturer's instructions.
2. Visually inspect the external surface of the device for cleanliness, focusing on hard-to-reach areas. If visible soil remains, repeat cleaning and disinfection until all visible soil is removed.

<sup>1</sup>Cleaning and disinfection were validated using PDI® Super Sani-Cloth® Germicidal Disposable Wipes.

## Materials and Equipment

The user shall provide all materials and equipment required to clean and disinfect the SYNK® 4K Transmitter, SYNK® 4K Receiver, and tokens.

Item	Description
Gloves, eye protection, etc.	Wear protective equipment as required by the medical facility
Germicidal disposal wipes (or germicidal spray and sterile cloth)	To clean exterior of devices

DRAFT

# Maintenance

Follow the instructions in this section for proper care of the devices.

**Note** - Repairs and equipment modifications shall be performed only by Stryker-authorized personnel. Stryker Endoscopy assumes no product liability or warranty responsibility for devices repaired by or purchased from third-party service organizations.

## Inspecting the Transmitter and Receiver

Inspect the transmitter and receiver regularly for cleanliness. If the device appears dirty, repeat the cleaning procedure described in the previous section.

Inspect the transmitter and receiver before each use. If a problem listed below is observed or suspected, contact your Stryker representative or return the device to Stryker for service.

- Device does not power on
- Visible cuts or breaks in any cables
- Unacceptable deterioration such as (but not limited to) corrosion, discoloration, pitting, cracked seals, or abnormal noises

## Storage

Store the device in a dry, clean, and dust-free environment at room temperatures.

## Periodic Maintenance Schedule

---

**WARNING** - To ensure safe operation of the device, you should periodically perform the following procedure:

---

Every 12 months, check the earth leakage current to  $<500 \mu\text{A}$ .

**Note** - If you encounter operating difficulties not detailed in this manual, refer them to your Stryker representative.

## Service Life

The transmitter has an expected service life of 4 years.

The receiver has an expected service life of 4 years.

Expected service life is determined by the number of times the device can be expected to be reused and/or reprocessed before it may require repair. In addition, the device's service life is largely determined by wear, reprocessing methods, and any damage resulting from use. To extend the time between device servicing, always follow the care and handling instructions in this user manual.

Before each use, test the device functionality and inspect it for any sign of damage per the Inspection section. If the device does not properly function or appears to be damaged, return it to Stryker for evaluation and/or repair. Repair through Stryker, the equipment manufacturer, brings

the device back to manufacturer specifications. Clean all potentially contaminated devices before returning them to Stryker.

## **Adverse Event Reporting**

Any serious incident that has occurred in relation to this device should be reported to Stryker and, in the European Union, to the competent authority of the Member State in which the affected person resides.

DRAFT

# Disposal and Recycling Information

## Disposal

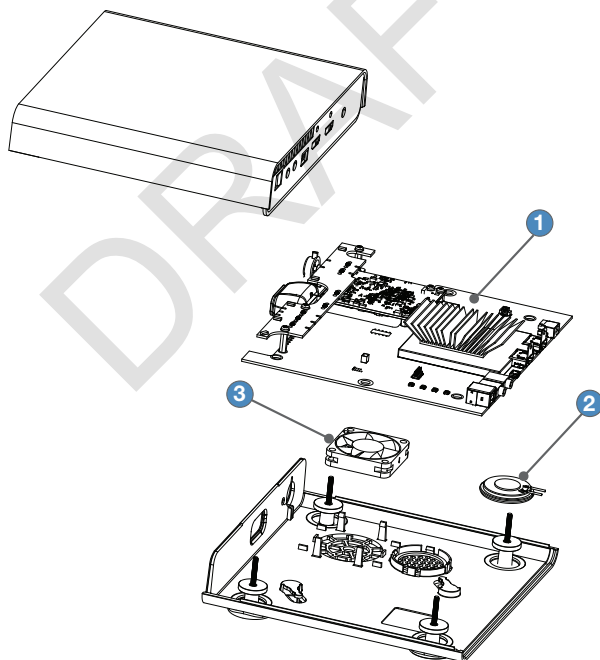


In accordance with the European Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE) as amended, the device(s) should be collected separately for recycling. Do not dispose of the device(s) as unsorted municipal waste. Contact your local distributor for disposal information. Ensure the device(s) is cleaned disinfected prior to recycling.

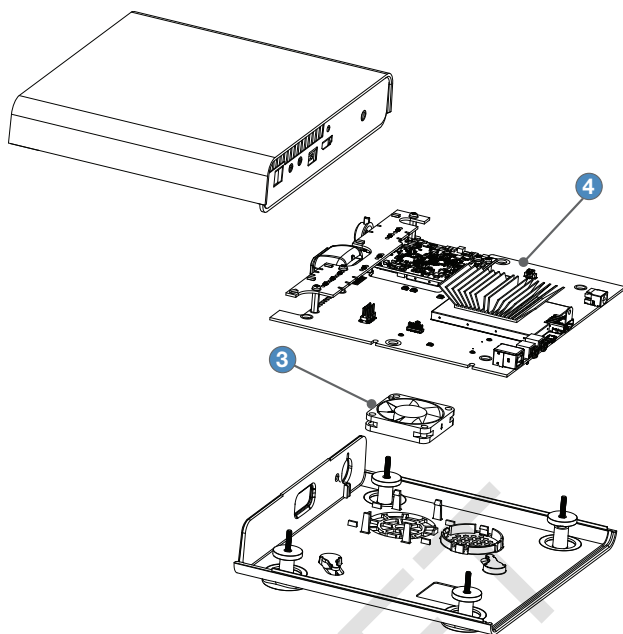
## Recycling Information

The graphics and table below show the parts to recycle as electrical waste.

Product Name: SYNK 4K Wireless Transmitter International  
Release Year: 2020  
Model Name: 0240031061



Product Name: SYNK 4K Wireless Receiver  
Release Year: 2020  
Model Name: 0240031075



Item	Description	Quantity	Type
1	Assembly, PCBA, Transmitter (P43576)	1	Circuit Board
2	Assembly, Speaker (P44039)	1	Speaker
3	Assembly, Fan (P43585)	2	Fan
4	Assembly, PCBA, Receiver (P43605)	1	Circuit Board

In addition to the items listed in the table, the following components and materials must also be recycled as electrical waste:

- (2) Hospital-grade power cord (0105033001)
- (2) Remote cables (0105206758)
- (2) Power supply (P27315)
- (1) Y cable (P43614)
- (2) HDMI high speed cable, 2M (P39077)
- (2) Temporary tokens (blue) (0105208884)
- (1) Region token (orange) (P46267, P25600, P25603)
- (1) Software upgrade token (black) (0240031085)
- (1) SYNK 4K bandwidth toggle token (20MHz / 40MHz) (0240031095)



# Technical Specifications

SYNK® 4K Transmitter	
Video Digital Input / Outputs	Input: One High-Definition Multimedia Interface (HDMI) Connector  Output: One High-Definition Multimedia Interface (HDMI) Connector
Video Formats	1080p: 1920 x 1080 @ 60 fps  4K: 3840 x 2160 @ 60 fps
Weight	1.4 lbs (0.6 kg)
Total Shipping Weight	3.8 lbs (1.7 kg)
Dimensions	7.7" W x 7.2" D x 1.8" H (19.6 cm W x 18.3 cm D x 4.5 cm H)

SYNK® 4K Receiver	
Video Digital Input / Outputs	Output: One High-Definition Multimedia Interface (HDMI) Connector
Video Formats	1080p: 1920 x 1080 @ 60 fps  4K: 3840 x 2160 @ 60 fps
Weight	1.4 lbs (0.6 kg)
Total Shipping Weight	4.5 lbs (2.0 kg)
Dimensions	7.7" W x 7.2" D x 1.8" H (19.6 cm W x 18.3 cm D x 4.5 cm H)

Wireless	
Frequencies of Operation	5.170 GHz to 5.850 GHz
Maximum Power Output	10 dBm (SYNK® 4K Wireless Transmitter)  12 dBm (SYNK® 4K Wireless Receiver)

Wireless	
Channel Bandwidth	40 MHz or 20 MHz
Channel Allocation	Automatic frequency selection with Wi-Fi avoidance
Encoding	Orthogonal Frequency Division Multiplexing with AES 128-bit encryption
Antenna	Contact us for more information

Electrical	
Electrical Input Ratings	Power Supply Input: 100 – 240 V ~ 50-60 Hz 1.1 A AC/DC Adapter Manufacturer: XP Power / Bridge Power Model: AFM30US12 / BPM150S24F11 12V $\overline{\text{---}}$ 2.5A / 24V $\overline{\text{---}}$ 2.0A

Operating Conditions	
Temperature Range	10 – 40°C (50 – 104°F)
Relative Humidity Range	25% to 75%
Atmospheric Pressure	700 to 1060 hPa

Transport and Storage Conditions	
Temperature Range	-18 – 60°C (-0.4 – 140°F)
Relative Humidity Range	15% to 90%
Atmospheric Pressure	500 to 1060 hPa

Classification and Approvals
Class I Medical Equipment  Medical equipment with respect to electric shock, fire, and mechanical hazards only in accordance with IEC 60601-1 and CAN/CSA C22.2 No. 60601-1  Continuous Operation  IPX0

Compliance	
FCC Regulations	<p>FCC Identifier (SYNK® 4K Wireless Transmitter): SSH-SYNK4KTX</p> <p>FCC Identifier (SYNK® 4K Wireless Receiver): SSH-SYNK4KRX</p>
IC Regulations	<p>IC (SYNK® 4K Wireless Transmitter): 4919C-SYNK4KTX</p> <p>IC (SYNK® 4K Wireless Receiver): 4919C-SYNK4KRX</p>
Radio Equipment Declaration of Conformity	<p>Hereby, Stryker Endoscopy declares that the radio equipment type SYNK® 4K Wireless System is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address: <a href="http://endoifu.stryker.com">endoifu.stryker.com</a>.</p>

# Electromagnetic Compatibility

## WARNING

- Do not use cables or accessories other than those provided with the devices, as this may result in increased electromagnetic emissions or decreased immunity to such emissions.
- If the devices are used adjacent to or stacked with other equipment, observe and verify normal operation of the device in the configuration which it will be used prior to a surgical procedure.
- Equipment which employs radio frequency (RF) communications may affect the normal function of the device.

All electrical medical equipment requires special precautions to ensure electromagnetic compatibility with other electrical medical devices. To ensure electromagnetic compatibility (EMC), the devices must be installed and operated according to the EMC information provided in this manual.

## Note

- The devices have been designed and tested to comply with IEC 60601-1-2 requirements for EMC with other devices.
- This equipment is for use in a professional healthcare environment. It is not for use in the radio frequency (RF) shielded room of a medical electrical system for magnetic resonance imaging, where the intensity of electromagnetic disturbances is high.
- The devices are unlikely to experience interference by being in close proximity to an active high-frequency (HF) surgical instrument. In the case that HF surgical interference is observed, adjust the separation distance of the equipment.


Guidance and Manufacturer's Declaration: Electromagnetic Emissions		
The devices are intended for use in the electromagnetic environment specified below. The customer or user of the devices should ensure that they are used in such an environment.		
Emissions test	Compliance	Electromagnetic Environment - guidance
RF emissions CISPR 11	Group 1 Class B	<p>The devices are suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:</p> <hr/> <p><b>WARNING</b> - This system is intended for use by health care professionals only. This system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the system or shielding the location.</p> <hr/>
Harmonic emissions  IEC61000-3-2	Class A	
Voltage Fluctuations/ flicker emissions  IEC61000-3-3	Complies	

## Guidance and Manufacturer's Declaration: Electromagnetic Immunity

The devices are intended for use in the electromagnetic environment specified below. The customer or user of the devices should ensure that they are used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment: Guidance
Electrostatic Discharge (ESD) IEC61000-4-2	±8kV contact ±15kV air	±8kV contact ±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 IEC61000-4-4	±2kV for power supply lines ±1kV for input/output lines (if applicable)	±2kV line to ground ±1kV for input/output lines (if applicable)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	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 IEC61000-4-11	0% Ut; 0.5 cycle 0% Ut; 1 cycle 70% Ut; 25 cycles 0% Ut; 5 seconds		Mains power quality should be that of a typical commercial or hospital environment. If the user of the devices requires continued operation during power mains interruptions, it is recommended that the devices be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power-frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

**Note** - Ut is the AC mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration: Electromagnetic Immunity			
The devices are intended for use in the electromagnetic environment specified below. The customer or user of the devices should ensure that they are used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment: Guidance
Conducted RF IEC 61000-4-6	6 Vrms  150 kHz to 80 MHz	6 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the devices, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended Separation Distance</p> $d = 2\sqrt{P}$ <p>80 MHz to 2.7 GHz</p> <p>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).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (a), should be less than the compliance level in each frequency range(b). Interference may occur in the vicinity of equipment marked with the following:</p> 
Radiated RF IEC 61000-4-3	3 V/m  80MHz to 2.7 GHz	3 V/m	

## Guidance and Manufacturer's Declaration: Electromagnetic Immunity

The devices are intended for use in the electromagnetic environment specified below. The customer or user of the devices should ensure that they are used in such an environment.

(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 due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the devices are used exceeds the applicable RF compliance level above, the devices should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the devices.

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

DRAFT

Tested Specifications for Immunity to RF Wireless Communications Equipment						
Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380–390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430–470	GMRS 460, FRS 460	FM $\pm$ 5 kHz deviation 1 kHz sine	2.0	0.3	28
710	704–787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800–960	GSM 800/ 900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2.0	0.3	28
870						
930						
1720	1700–1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2.0	0.3	28
1845						
1970						
2450	2400–2570	Bluetooth, WLAN, 802.11 b/ g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2.0	0.3	28
5240	5100–5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						



**Tested Specifications for Immunity to RF Wireless Communications Equipment**















5785




**Note** - 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 the devices, including cables specified by the manufacturer, otherwise the devices performance could degrade.

DRAFT

# Symbols and Definitions

The devices and labeling contain symbols that provide important information for the safe and proper use of the devices. These symbols are defined below.

Device/Package Labeling	
	Consult Instructions for Use
	Date of manufacture
	Legal manufacturer
	Catalog number
	Serial Number
	Quantity
	Made in the USA
	Denotes compliance to CAN/CSA C22.2 No 60601-1 and ANSI/AAMI 60601-1
	Medical device in the European Union
	The device meets European Union medical device requirements
	Radio Equipment Directive 2014/53/EU precaution: In all EU member states, operation of 5150-5350MHz is restricted to indoor use only
	Authorized representative in the European Community
	Complies with Australian regulatory requirements
	Power on/off (alternates when button is pushed)

User Manual	
	<p>This product contains electrical waste or electronic equipment. It must not be disposed of as unsorted municipal waste and must be collected separately</p>
	<p>Radiation emitting</p>
	<p>Direct current</p>

DRAFT

# Contact Information



Stryker EMEA Supply Chain Services B.V.

Frans Maasweg 2

Venlo 5928 SB, The Netherlands

DRAFT

DRAFT



Stryker Corporation or its divisions or other corporate affiliated entities own, use or have applied for the following trademarks or service marks: **SYNK, WiSe, CrossFlow, Formula, the Stryker logo**. All other trademarks are trademarks of their respective owners or holders.



**Manufactured By:**  
Stryker Endoscopy  
5900 Optical Court  
San Jose, CA 95138 USA  
1-800-624-4422