Capsule Endoscope System

User's Manual

---------- Smart capsule

SCIE-OM-01

Contents

Smart capsule

Smart capsule is used for taking snap shots and transmitting color image information. The lens, sensor, battery and RF module are enclosed in a capsule shell made of medical polymer material, which cannot be dissolved in human body.

1 Elements and Specifications

The functional elements of Smart capsule are sealed in a polymer shell. They are LEDs, lens, image sensor, processor, battery and RF module. A permanent magnet in the holder may keep the capsule switch off in storage and transportation. Serial number and channel code can be read from the outer and inner package box. The appearance of smart capsule package is as below:

Specification:

Physical	Size	Diameter 13.0±0.4mm , Length 27.9±0.5mm
	Weight	≤6g
	Material	Medical polymer material
Optical	Illumination	Six white LED
	View angle (in air)	120±15°
	Depth of focus (in air)	0~35mm
	Resolution (in air)	0.05mm
Operating Spec.	Max. Sampling rate	2fps ± 10% (QVGA) 0.5fps ± 10% （VGA）
	Max. Continuous Working Time	8±1h (QVGA/2fps)

	Voltage	3V DC
	Current	15 mA
	Working temperature	0~40□
	RH (Working)	75%
	RH (Storage)	80%
	Storage Temp.	0~50□
	Atmosphere	100KPa
Other	Image format	320*240 (QVGA) And 640*480 (VGA)
	Color type	24-bit true color
	Sealing	IPX7

2 Working of smart capsule

Smart capsule is sealed in the package with a permanent magnet to keep it inactive. Once the capsule be pull out from the holder, it will be switched on automatically and read to take snap shot. Patient can swallow only activated capsule in order to start a diagnostic procedure. As the capsule moving along GI tract, it can send image data and received command to and from image recorder. The capsule will stop its work as soon as the battery exhausted. In normal case, it may be excreted within 10-71 hours.

From corresponding interface of software, the user may send command to change parameters of a working capsule:

Image Format: Image formats can be switch from QVGA to VGA.

Sampling Frequency: Under the image format of QVGA, there is three speeds of snapshot for choose: “Fast”, “Normal” and “Slow” corresponding to 2 fps, 1 fps and 0.5 fps. Under the format of VGA, the snap shot speed has only two choices as “Fast” and “Slow” corresponding to 0.5 fps and 0.25 fps.

Flash Intensity: Control the brightness of LED grading in 31 levels. The higher the brightness level is, the more the power consumption is, as well as the exposure time gets shorter, the ability to shoot dynamic image is much stronger.

Exposure Controlling: Can be selected by Auto or Manual. The function of automatic exposure is to control the average brightness of an image central area around the pre-set lumen value (0-255). When automatic exposure is selected, the user may set the Lumen Value, which can be varies from 1-31. If the brightness is too lower to achieve the set value of Lumen Value, the automatic exposure function will utilize the maximum exposure value.

Under the mode of Manual Exposure, the image Lumen Value is disabled. But Exposure Time can be set, namely set the speed of exposure, such as 1/18s (2.0), 1/18s (1.9).……

White Balance: Can be selected by Auto and Manual.

Automatic White Balance is to lead capsule to control the increment of R and B automatically. In these two equations as $R_{Average}=R_{rate}*G_{Average}$, $B_{Average}=B_{rate}*G_{Average}$, R_{rate} and B_{rate} are the color temperatures for adjusting image, which can be set by factory setting or the user.

Manual White Balance means the increments of R, G and B are completely controlled by the user.

Sleep/Wakeup: Capsule standby and stop/recover snap shot.

ⓘ: The higher flash intensity is set, the more power consumption of a working capsule and the shorter duration hours. We recommend that the level of the flash intensity shall not be set over 12 for a long time in real case.

3 Activate a capsule

The inner package of the capsule is equipped with a permanent magnet, which controls the power switch of the capsule. The capsule power circuit will be kept off while it is in the holder of inner package. Pull it out from the holder (no rotating); the capsule power is switched on automatically until the LEDs flash at a rate of 2 times per second. Then the capsule can work normally.

·The user should **t**urn on the image recorder before pull out a capsule. Download serial number and channel code are necessary by software or portable view.

·In case the user pull out capsule before turn on the image recorder, the capsule may flash at a rate of 3 times per second with low brightness.

·Do not activate two capsules with the same channel number at the same time. Otherwise, the capsule may interfere each other.

·If LEDs does not flash or flash with extremely low brightness when the capsule is pulled out, check the channel code first. Once the serial number and channel number are correct and the trouble remains, refer to chapter V for trouble-shooting.

·In case of multi-diagnosis performed at the same time, the capsules must be used with different channels.

: The capsule serial and channel number can be read from its ou5ter package

and inner package.

: If capsule fell to the ground accidentally, it is forbidden to ask the patient to swallow it.

: Under the ambient light, snap shots taken by the capsule may be insufficient with the brightness. This is normal.

4 Power-off of a capsule

Insert the capsule with its lens towards the holder. Make sure the mark on PCB of LED is aligning with the magnet in the holder. Push down the capsule with care until half of its body get into the rubber ring. Check the flash of LED from an observation hole from the bottom of the holder to make sure the capsule is power off. Otherwise the user may repeat above-mentioned procedure before close the transparency cover.

: The smart capsule should be swallowed immediately after uncover and activation. It is forbidden to use the capsule with crack or other damage on its shell. The uncovered capsule should be sterilized with alcohol before it has to be used again.

: Do not insert the capsule to its holder too deep nor insufficient. A proper insertion can lead a secure power-off the capsule a reliable close of its transparency cover.

5 Recycling of the capsule

: A Lithium battery is used in the smart capsule, which is still being left in the smart capsule after service. Please dispose them according to the local regulations to protect environment.

6 Environment conditions of the smart capsule

The smart capsule should be kept away from heave magnetic field to avoid interference.

Working temperature of the smart capsule: 0～40□.

Within a certain the distance, two smart capsules cannot be activated at the same time. Otherwise, they may interfere each other and result malfunction.

Insert the previous activated capsule properly into the package until it is power off before uncover a new capsule.

7 Maintenance of the smart capsule

(1) The Smart capsule shall be kept in a radiation-free environment around 0～50□ with the maximum humidity of 90%;
(2) Keep the Smart capsule away from magnetic field in a secured external package without any damage when storing;
(3) Keep the Smart capsule away from children;
(4) Prompt use is suggested when the capsule package is unsealed, if not, sterilization shall be made before the next use.
(5) The valid period of the smart capsule is 14 months and any use after the valid period shall be prohibited.

⚠***Warning:*** Environment of use Product is designed for indoor use. Operator must confirm that the environment of use meets the required operating environmental specifications before using.

⚠ ***Warning:*** Cold Environments If the Product is stored in an environment with a temperature below the operating temperature; the unit should be allowed to warm up to the needed operating temperature before using.

⚠***Warning:***

FCC WARNING STATEMENT：

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

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.