DoubleCHEK™

DC-1001 Device to assist placement confirmation of Naso / Oro gastric tube.

GENERAL DESCRIPTION

The DoubleCHEK is a hand-held, non-powered device consisting of a test chamber, sample reservoir, and integrated test papers so that results can be compared to a visual colour guide.
After connection to the feeding tube, aspirate is drawn into the device using a syringe; low pH indicates gastric placement and high CO_2 indicates respiratory placement.

INTENDED USE

The DoubleCHEK device is intended to aid in the placement of naso/oro gastric tubes and assist a user to assess whether a naso/oro gastric tube tip is in an acidic or CO_2 environment, prior to use.

INTENDED POPULATION

The intended population of this device is anyone who has a naso/oro gastric tube that requires assessment of placement.

INDICATIONS FOR USE

The DoubleCHEK device should be used when a naso/oro gastric tube is initially inserted/placed or where tube tip position needs to be assessed while in-situ.
The device is intended to be used by Health Care Professionals and suitably trained home users on all patients both within and outside a health care setting.
The device is intended to be used with a single patient for up to 24 hours.

WARNING: Not to be used in isolation to confirm position of naso/oro gastric tube.
Do not use immediately after or during use of the naso/oro gastric tube.
Not to be used to insufflate or administer substances to a patient.
Do not use past expiry date.

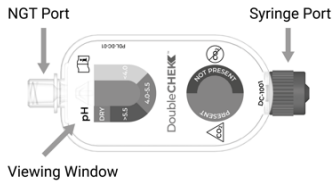
PRECAUTIONS: Appropriate PPE should be worn in line with local regulations and procedures.
Vacuum forces can cause patient injury, e.g., a tissue blocked tube.
Not to be used on patients with a respiratory condition which may affect CO_2 detection performance.

CONTRAINDICATIONS FOR USE: There are no contraindications for use.

REQUIRED EQUIPMENT

Reservoir with an internal diameter of 21.9mm.- two different volumes supplied
ENFit Syringe appropriately sized 5ml - 60ml.
ENFit Milk Straw

PRODUCT DIAGRAM



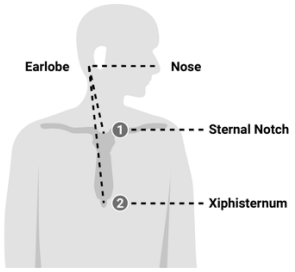
INSTRUCTION FOR USE

STEP 1 -SETUP

1.a Take two patient measurements:

- **1st CHEK Point** for initial placement; Nose-Ear-Sternal Notch (NESN).
- **2nd CHEK Point** for full placement; Nose-Ear-Xiphisternum, (NEX) or your Healthcare provider's preferred method.

1.b Record both measurements on the label on the back of the DoubleCHEK pouch
1.c Confirm the pH paper is Blue and CO_2 paper is purple. If this is not the case discard the device and select a new one.
1.d Attach the appropiate sized reservoir the underside of the DoubleCHEK device. Make sure the device is fully inserted into the reservoir.
1.e Connect an appropriately sized syringe to the syringe port.
1.f If applicable, confirm any potential transitional connectors are connected to an enteral port and not an IV set.
1.g Connect the DoubleCHEK to the NG/OG tube (leave the guidewire in place if present).



STEP 2 -INITIAL PLACEMENT

2.a Insert the NG/OG tube to the 1st CHEK Point measurement.
2.b If desired, secure to the face to reduce tube movement.
2.c Pull back the syringe plunger to 10 ml on the smaller reservior or 30ml on the larger reservior, release the plunger and wait for 5 seconds
2.d if plunger does not maintain the 10ml/30ml position, pull back again until it does.

ADVISORY: You can pump the syringe plunger in and out without putting air into the patient**.**
The tube may be occluded or kinked if unable to maintain the 10ml/30ml position.

2.e Observe the CO_2 window looking for colour change for an indication of CO_2.
2.f If there is a colour change from purple to pink, CO_2 present, the tube may be in the airway. Consider tube removal and reinsertion.
2.g If removal is advised, disconnect the device from the feeding tube, reset to purple per step 5, reconnect and repeat **Step 2**.

STEP - 3 FULL PLACEMENT

3.a Insert the tube to the 2nd CHEK Point (NEX).
3.b Secure to the face to reduce tube movement.
3.c Pump the syringe plunger in and out to draw up aspirate until the liquid reaches the viewing window of the pH chamber at the top of the device.
3.d If the pH paper remains blue, continue to pump the syringe until you observe stomach content, if the patient is being given fluid to ease the passage of the tube this may be drawn into the device before any stomach content.
3.e Check for a colour change of the pH indicator – see **Step 4** for colour interpretation
3.f Disconnect the device from the patient once aspirate has been collected.
3.g Record the device usage on the patient log on label on the back of the DoubleCHEK pouch.
3.h Reset the device according to **Step 5**

STEP 4 RESULTS INTERPRETATION

CO_2

Purple: CO_2 not present

Pink: CO_2 present

pH.

- Blue: pH of sample >5.5
- Green: pH of sample 4.0 – 5.5
- Yellow: pH of samples <4.0

WARNING: If results are ambiguous, seek additional healthcare professional advice.

STEP 5 FLUSH AND RESET THE DEVICE

CO_2 Chamber

5.a Disconnect the device from the ENFit Tubing.
5.b Pump air through the device until the CO_2 paper resets to purple.

WARNING: If the CO_2 paper doesn't return to purple, then dispose of the device.

pH Chamber

5.a Examine the device for signs of contamination. Gross contaminated devices should be disposed of.
5.b Use a ENfit milk straw to draw water through the device until pH paper returns to blue. Typically, 3-4 reservoirs of water for the large reservior . Take care not to over fill the reservoir.
5.c Remove, empty, and dry the reservoir.
5.d Gently wipe and dry the external surfaces.
5.e Record the device use and reset on the patient log on label on the back of the DoubleCHEK pouch.

5.f Place the device, ENfit milk straw, and reservoir in the foil pouch and seal to protect from light.

WARNING: If blood is drawn into the device, the device or the device cannot be reset, then dispose of the device.

USE ON PATIENT WITH IN-SITU NG/OG TUBING – USING PH INDICATOR ONLY

- Assemble the DoubleCHEK device as per step 1a-1c.
- Connect the DoubleCHEK device to the NG/OG tube.
- Follow the process from step 3C for using the device.

REPETITIVE USE ON A SINGLE PATIENT WITHIN 24 HRS & 14 CYCLES

- A cycle is defined a single use and reset flush of the device.
- Confirm the device is for the intended patient.
- Confirm the device has not been used for more than 24 hours or 14 cycles in a 24-hr period.
- Confirm the device has been flushed and reset.
- Confirm the pH indicator is showing > 5.5 (blue) and CO_2 is absent (purple).
- Repeat steps 1-5 **OR** follow the instructions for use on a patient with an in-situ tube.

WARNING: Product must be stored away from direct sunlight.
Device not to be used after 24hrs /14 cycles from first use.

DISPOSAL INSTRUCTIONS

The device should be removed from the patient after its final use and disposed of according to local authority regulations for clinical waste.

	Keep Dry		Do not use if package is damaged
	Temperature limits		Keep away from sunlight
	Prescription only (US Market)		Medical device
	CE Mark		Consult instructions for use
	UK Conformity Assessed		

SERIOUS INCIDENT

In the event of a serious incident please report to the manufacturer and the Competent Authority in the territory the incident occurred.

 Manufacturer

Enteral Access Technologies Ltd,
Liverpool Science Park, 131 Mount Pleasant, Liverpool, L3 5TF. www.enteralaccesstech.com
Tel: +44 151 705 3466

EC REP **Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta**