Evaluation of cough assist devices by the Swiss Society of Pulmonology (SIG Ventilation & O2)

Cough Assist Device: **Nippy Clearway 2**

Reviewer / institution: SSP-summary of evaluation by Georg Volk and team, certified respiratory therapist (USZ)

Device overview	
Company	Breas Medical
Mechanical insufflator exsufflator	NIPPY Clearway 2
CE marking	2797
Product class	☒ Mechanical insufflator exsufflator ☒ other: IPPB, NIV (only for intermittent therapeutic ventilation, max. 15 minutes)
Device specifications	
Weight, size	Weight: 3.75 kg (without internal battery) Size/dimension: 285 x 285 x 195 mm
Display	Touchscreen: ☒ YES ☐ NO Size/dimension: 150 x 90 mm Option to dim ☐ YES ☒ NO
Real-time and retrospective monitoring on ventilator display	**Real-time monitoring** Curves: ☒ pressure-time ☐ volume-time ☐ flow-time Scales: ☒ pressure ☐ volume ☒ flow ☒ Tidal volume ☒ Pressure; specify: cmH2O, hPa ☒ CPF ☐ Te ☐ Rise time / ramp; specify: ☐ Other: ☒ Supplementary external parameters: ☐ CO2, if yes ☐ ETCO2 ☐ tcpCO2 ☒ SpO2 ☐ other: Adaptable time period for monitoring: ☐ YES ☒ NO if YES, time window: - Comment: In M-I/E mode, a volume is displayed during inspiration in L. Value difficult to evaluate. NIV mode: Setting corresponds to an APCV mode, only pressure curve can be displayed, pressure and flow additionally on a scale. No display of Vt possible. O2 administration at the expiratory adapter possible. **Retrospective monitoring (previous usage)**

	☒ YES ☐ NO if YES: ☒ Utilisation ☒ Profile ☒ PCF ☐ Other: ☐ Curves: ☐ Pressure/time ☐ Volume/time ☐ Flow/time ☐ Supplementary external parameters: ☐ CO2 ☐ SpO2 ☐ FiO2 ☐ other: Available time periods: 30 + 90 days
Connections	☒ Power adapter, voltage: 100-240V ☒ External battery: ☐ Oxygen inlet port ☐ Outlet port (for tube) ☒ Supplementary measurements/monitoring, e.g. SpO2, CO2, FiO2, p_{oes}): SpO2 ☒ Remote control ☐ Other: Comment: O2 can only be supplied via expiration valve with IPPB and NIV
Electrical rating and system interface	AC (alternating current): 100-240 VAC, max. 260 W Accu level indicator: ☒ YES ☐ NO
Service	Emergency service (24h/7d): ☒ YES ☐ NO Company: VitalAire Suppliers of disposable material: VitalAire and others
Ventilation modes and settings	
Permitted age groups	Adults ☒ YES ☐ NO Children ☒ YES ☐ NO (not tested in children by SGP)
Device modes	☒ M-I/E ☒ IPPB ☒ NIV ☐ Other:
Profiles	Number: 4
Pressure and flow range	M-I/E: Insufflation 3 - 70 cmH2O, Exsufflation -3 - -70 cmH2O IPPB: Max. Insp. P 3 – 60 cmH2O, Flow: 20 – 120 L/min NIV: IPAP 3 – 50 cmH2O Maximum air flow: 120 L/min
Trigger	Inspiratory trigger: ☐ scale ☒ absolute value - Type: ☒ flow trigger ☐ pressure trigger - Range: 0 - 10 - Clarity of the scale: ☐ arbitrary ☒ clear/distinct Comment: No expiratory trigger
Pressure rise	Type: ☒ scale ☐ time Range: 1 - 10 Clarity of the scale: ☐ arbitrary ☒ clear/distinct
Inspiratory and expiratory time	T insp.: NIV 0.5-3.0 s, M-I/E 0.5 – 5.0 s

	T exp: M-I/E 0.5 – 5.0 s Pause: Off / 0.1 – 9.0 s (depends on mode)
Oszillation	Insuff.: frequency 0 – 20 Hz, amplitude 0 – 10 cmH2O Exsuff: frequency 0 – 20 Hz, amplitude 0 – 10 cmH2O
Oxygen	Direct O2 connection on the ventilator: ☐ YES ☒ NO
Alarms	Pressure high/low ☒ YES ☐ NO ☐ Range: 120% > 2 s Device in battery mode ☐ YES ☐ NO Other: No exhalation valve detected, Internal temperature high, Battery level low, Leakage low, Device error, NIV treatment about to end, NIV treatment finished, Power failure, Pressure measurement error, Pressure sensor error, SpO2 sensor disconnected, Treatment too long (to be stored inTreatRepeat), Treatment finished. Option to deactivate all alarms ☐ YES ☒ NO
Safety	Expert area enabling: YES Battery capacity shown ☒ YES ☐ NO If yes: scale: in %
Additions	
Filter	Filter class: Reusable filter (grey), disposable filter (white)
Relevant accessories	Pedestal/Carrier ☐ YES ☒ NO External battery ☒ YES ☐ NO SpO2 sensor ☒ YES ☐ NO Other: Remote control, foot pedal
Software	
Connections / network	☒ USB ☒ SD Card, memory size: ☐ Other:
Software / statistics	Comment: not tested
Handbook	
Manual	Practicability: good Completeness: given
Validation studies	
Validation studies	Not available

Patient report	
Pros / advantages	<u>M-I/E:</u> Test performed on clients with Muscular Dystrophy Type Duchenne both experienced and inexperienced in cough assist use. All reported comfortable use. The therapy was comparable to the experience with other cough assist devices. The operation via the remote control could be carried out independently by patients after brief instruction, despite very limited finger motor skills. Patients found this feature very pleasant. <u>IPPB:</u> Subjectively, the patient succeeds in achieving complete distribution. The therapy was not perceived as unpleasant with adjusted settings. The patients were motivated to perform the therapy independently after instruction. From a therapeutic point of view, the device proved to be efficient in recruitment and mobilisation of secretions.
Cons / drawbacks	

Summary	
Pros / advantages	M-I/E: Easy and clear operation. The application proves to be equivalent overall compared to other devices. In the test of the application via mask and tracheostoma, the Nippy fulfilled the expectations. The patients did not express any undesirable side effects that could not have been remedied by changing the settings. Remote control very practical, can possibly also be operated by the patient himself. TreatRepeat function facilitates the adjustment of the M-I/E IPPB: Simple and clear operation. The "plateau function" in particular allows great therapeutic flexibility. The Nippy also proves easy to use for the patient. In the test of use via mask and tracheostoma, the Nippy fulfilled the expectations from a therapeutic point of view.
Cons / drawbacks	NIV mode: Setting corresponds to an APCV mode, only pressure curve can be displayed, pressure and flow additionally on one scale. No display of the Vt possible. O2 administration at the expiratory adapter possible. Tube change necessary to switch from M-I/E to NIV. During the test phase, the patient selection did not indicate the use of the additional NIV mode. M-I/E: there is no possibility to have each insufflation triggered by the patient. Pat. can only trigger the first breath in basic auto mode. A Vin is measured, which is given in L and is difficult to evaluate. According to the manual, the estimated lung volume during insufflation is given in ml. Despite the set language German in the Compliance Overview and Alarm Log menu, the display is partially in English.
Recommended setting and patient groups	According to manufacturer: M-I/W: muscular dystrophy, amyotrophic lateral sclerosis (ALS) or motor neurone disease (MND), myasthenia gravis, poliomyelitis, other neurological disorders, spinal cord injury. IPPB: Cystic fibrosis, bronchiecatsia, emphysema, post-operative patients (without contraindications).

Recommendation of the SIG ventilation & O2 of the Swiss Society of Pulmonology

Based on the above evaluation, we recommend the availability of this device on the Swiss market.

Comment: IPPB and NIV mode more suitable in clinical than in out-of-hospital settings

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On behalf of the SIG Ventilation and O2